EUROPEAN CHEMICALS AGENCY

APPENDICES A and B

TO THE INVESTIGATION REPORT

ON

PVC AND PVC ADDITIVES

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LIST OF ACRONYMS AND ABBREVIATIONS

Acronym / abbreviation	Meaning
ACT	Activities coordination tool
ARN	Assessment of regulatory needs
ASR	Automotive shredder residue
BAT	Best available technique
BAT-AELs	BAT associated emissions levels
BOEL	Binding occupational exposure limit
BREFs	BAT reference documents
CfE	Call for Evidence
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic, or toxic for reproduction
CoRAP	Community rolling action plan
CPE	Chlorinated polyethylene
CWW	Common waste water
DWD	Drinking Water Directive
ECVM	European Council of Vinyl Manufacturers
ED	Endocrine disruptor
EDC	Ethylene dichloride (1,2-dichloroethane)
EoL	End-of-life
EQS	Environmental quality standards
ES	Exposure scenario
HBM4EU	Human biomonitoring for Europe
HCl	Hydrochloric acid
HDPE	High density polyethylene
IED	Industrial Emissions Directive

Acronym / abbreviation	**Meaning**
LDPE	Low density polyethylene
LVOC	Large volume organic chemicals
OC	Operational conditions
OEL	Occupational exposure limit
PBT	Persistent, bioaccumulative and toxic
vPvB	Very persistent and very bioaccumulative
PMT	Persistent, mobile and toxic
vPvM	Very persistent and very mobile
PCDDs	Polychlorinated dibenzodioxins
PCDFs	Polychlorinated dibenzofurans
PE	Polyethylene
PET	Polyethylene terephthalate
PEX	Crosslinked polyethylene
PLASI	Plastics additives initiative
PMT	Persistent, mobile and toxic
vPvM	Very persistent and very mobile
POP	Persistent organic pollutant
PP	Polypropylene
PS	Polystyrene
PUR	Polyurethane
PVC	Polyvinyl chloride
PVDC	Poly(vinylidene chloride)
QSAR	Quantitative structure-activity relationship
RAC	Risk assessment committee
REACH	Registration, evaluation, authorisation and restriction of chemicals

Acronym / abbreviation	**Meaning**
RMM	Risk management measures
RMOA	Risk management options analysis
RoHS	Restriction of (the use of certain) Hazardous Substances
RoI	Registry of intention
RRM	Regulatory risk management
SEAC	Socio-economic analysis committee
SEv	Substance evaluation
SIDS	Screening information dataset
SLF	Shredder light fraction
SVHC	Substance of very high concern
TPE	Thermoplastic elastomer
TWA	Time-weighted average
VCM	Vinyl chloride monomer
WEEE	Waste from electrical and electronic equipment
WFD	Waste framework Directive
WGC	Waste gas from chemicals

APPENDIX

A. PVC as a material

A.1. Manufacture, import and uses overview

Polyvinyl chloride or PVC is the third largest-selling commodity plastic in the world after polyethylene and polypropylene and followed by polystyrene. PVC is a very durable, oil/chemical resistant, fire retardant and long-lasting material which can be used in a variety of applications, either rigid or soft, at an affordable cost (Plastics Europe, 2023).

According to the information provided by VinylPlus, the total PVC production and conversion industry in Western Europe comprises more than 21 000 companies with more than 500 000 jobs and a turnover of more than 80 billion Euros. The industry can be divided into seven groups:

- PVC resin producers
- Stabiliser producers
- Plasticiser producers
- Other additive producers (flame retardants, lubricants, fillers, impact improvers etc)
- Compounders (formulating mixtures of PVC resin and additives)
- PVC converters (article manufacturers)
- Recyclers

The PVC resin industry, the PVC additive manufacturers and the PVC compounding and converting industry are closely associated with one another and they are often referred to as the ‘PVC industry’.

A.1.1. Manufacture and import

PVC is produced by polymerisation of vinyl chloride monomer (VCM). VCM is almost exclusively produced by cracking 1,2-dichloroethane (EDC) and EDC is manufactured from the chlorination/oxychlorination of ethylene.

Manufacture of EDC

EDC can be produced by direct chlorination or by oxychlorination of ethylene.

Direct chlorination of ethylene uses ethylene produced by cracking of natural gas or petroleum and chlorine generated by the chlor-alkali industry in the production of sodium hydroxide. Approximately 30 % of the chlorine generated seems to be used for the production of EDC/PVC.

Hydrochloric acid (HCl) is generated during the production of EDC via direct chlorination. The HCl is recovered by distillation during the purification of EDC and subsequently reused in the oxychlorination of ethylene in the presence of oxygen to produce more EDC. The

HCl produced and recovered during the production of VCM (Figure 1) is also used in this process.

Thus, both direct chlorination and oxychlorination of ethylene are part of an integrated process. When all the HCl generated is reused as above and no EDC or HCl is imported or exported, the EDC/VCM plant is called a 'balanced unit'. Most EDC/VCM plants in Europe operate in this manner (CfE2, #1601).

EDC is manufactured under strictly controlled conditions in VCM plants as an 'isolated intermediate' as defined by REACH. It is mainly used on-site but a small fraction may also be delivered to other VCM plants (transported isolated intermediate). In any case, the majority of the manufactured and/or imported EDC is used as an intermediate in the production of VCM for use in the manufacture of PVC.

Manufacture of VCM

VCM is produced by thermal cracking (a gas free radical chain reaction at high temperature) of EDC which also generates HCl. According to the REACH registrations VCM is then highly purified by distillation before being polymerised into PVC, recovering as well HCl and EDC. The recovered HCl is used in the oxychlorination production of EDC and the recovered EDC is used in the production of more VCM.

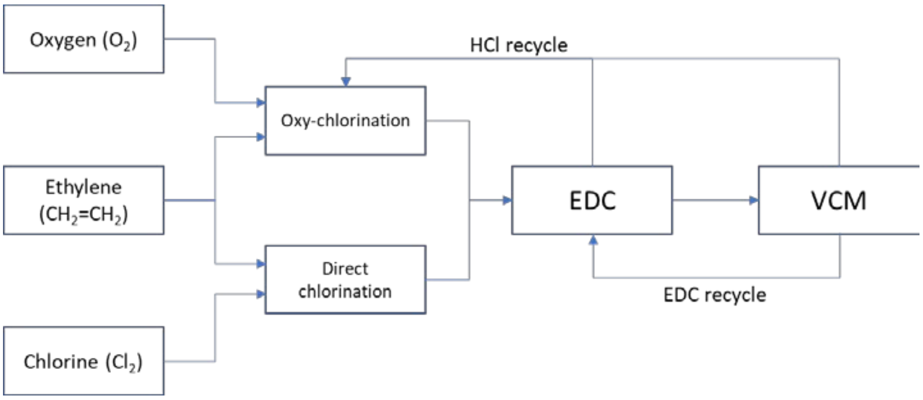

Figure 1. EDC/VCM production process

Manufacture of PVC resin

PVC is produced by polymerisation of VCM and is frequently carried at the same premises where EDC and VCM are manufactured (CfE2, #1601). This polymerisation is done using three main polymerisation processes (Saeki and Emura, 2002, Schiller, 2022):

- Suspension (S-PVC): in this batch process, droplets of VCM are suspended in water by intensive stirring in presence of suspending agents (to prevent agglomeration) and radical initiators (e.g. azobisisobutyronitrile). This process occurs under pressure and at a temperature ranging 40 to 60 °C. The particle size of the PVC produced by this method ranges from 50 to 200 µm and it is used in rigid and flexible applications. If emulsifiers are used in addition to suspending agents, the resulting particle size is much lower (5-10 µm). This method accounts for around 85% of the PVC produced in Europe.

- Emulsion (E-PVC): it can be run as a continuous or batch process and it involves the use of emulsifiers and initiators like e.g. peroxides that are soluble in water in similar pressure and temperature ranges as above. The particle size of the PVC produced by this method ranges 0.1-3 µm. This method accounts for around 12% of the PVC produced.

- Bulk (mass) (M-PVC): in this process no water is used in the polymerisation and an initiator is dissolved in the VCM. Articles made with this PVC appear more transparent and more brilliant than those made with PVC produced by suspension or emulsion. This method only accounts for around 3% of the PVC produced and it is used in transparent and special applications.

The slurry/latex discharged from polymerisation reactor is stripped of residual monomer, dehydrated, dried and particle size is controlled by screening to yield PVC in the form of a white powder that is then stored.

The unreacted VCM is recovered in the stripping process and after purification it is recycled as raw material for further production of PVC.

In general, companies will produce different grades of the polymer, with variations in molecular weight, particle size and morphology and other aspects dependent on the end use requirements. Depending on the polymerisation technology employed and the end use requirements of the polymer, some particle size reduction may take place before storage.

PVC compounding

As described above, PVC resin is actually in powder form and it is not used alone. Before PVC can be made into articles, it requires the incorporation of additives that will provide the properties required for the use of the articles.

A combination of PVC resin with additives, which are intimately mixed together, is called a ‘PVC compound’. Different PVC compounds are developed to meet application requirements or processing constrains. Thus, the PVC resin without additives can be also referred to as ‘uncompounded PVC’ and a formulation of PVC with a set of additives can be referred to as ‘compounded PVC’.

There are many types of PVC additives, such as heat stabilisers, plasticisers, lubricants, flame retardants, UV stabilisers, impact modifiers, fillers, blowing agents, smoke suppressants, biocides, processing aids, and pigments.

The choice of additives is driven by the cost/performance requirements of the use and the composition can vary largely in both the type and quantity of additives incorporated into PVC. Nevertheless, PVC compounds can be generally differentiated into ‘rigid’ (not containing a plasticiser) and ‘soft’ (containing plasticiser, also called flexible PVC).

The ‘compounded PVC’ is then pelletised, stored, and sold to the manufacturers of articles. Some article manufacturers may, however, buy the polymer and additives directly from the primary manufacturers. In the case of certain grades of PVC, often made via the emulsion route, compounding is made in the form of a plastisol, which is a liquid dispersion of PVC resins in a plasticiser.

A.1.2. Uses overview and volumes

The main sectors using PVC are building and construction (pipes and pipe fittings, cables, flooring, window frames, wallpaper, roofing, other rigid profiles), electrical and electronic equipment (cables), health services (medical applications), plastic products (packaging, toys), textiles, leather and fur (clothing) and vehicles (automotive interiors and cables).

Volume data has been obtained via ECHA market survey (CfE2) and it is presented as the sales volume of compounded PVC in tonnes per year (tpa), including both virgin and recycled material. Compounded PVC includes both the PVC resin and additives. When the original volume estimate has been provided as uncompounded PVC, compounded volume has been calculated by adding the typical average share of additives in the use to the volume of PVC resin. Exact volume estimates are in many cases known but confidential, and so they have been replaced by volume ranges.

The annual sales volume of uncompounded PVC totalled 5.2 million tonnes in the EU in 2021 (Eurostat, 2023b). Approximately 60-70 % of that volume goes to rigid applications and 30-40 % to flexible applications (ECVM, 2023). That volume corresponds to approximately 6.8 million tonnes of compounded PVC considering the typical average compounding in rigid and soft PVC. In addition, 0.5 million tonnes of uncompounded PVC are imported annually to the EU and 1.2 million tonnes exported outside of EU (Eurostat 2023).

More information about the volume data can be found in Appendix C. Table 1 shows the estimated volumes of compounded PVC per sector and use.

Table 1. Overview of uses and compounded volumes of PVC

Sector	Use	Sub-use	Type of PVC	PVC compounded volume (tonnes/year)	Share of the total volume (%)	Average PVC compounded volume (tonnes/year)[1]	Average share of the total vlume (%)
Building and construction	Pipes and fittings	Water mains; water service lines; water piping systems	Rigid	254 000	3.3–7.9	3 799 960	69.7
		Rain water; sewage	Rigid	682 000	8.9–21.2		
		Irrigation	Rigid	37 000	0.5–1.2		
		Natural gas; industrial processes	Rigid	40 000	0.5–1.2		
		Flexible tubes	Soft	35 000–44 000	0.6–1.1		
	Cables[2]	-	Soft	466 000	6.1–14.5		
	Flooring		Soft	772 710	10.1–24.0		
	Roofing	-	Soft	88 000–526 000	2.7–6.8		
	Wallpaper	-	Soft	15 000–92 000	0.5–1.2		
	Window frames	-	Rigid	274 000–1 900 000	8.5–24.7		
	Other profiles and sheets	-	Rigid	17 500–105 000	0.5–1.4		
Medical applications	Blood and infusion bags, medical devices, gloves and medical tubing	-	Both	28 000–170 000	0.9–2.2	99 000	1.8
Plastic products	Packaging	Rigid food and non-food packaging	Rigid	41 000–244 000	1.3–3.2	230 500	4.2
		Flexible food and non-food packaging	Soft	88 000	1.1–2.7		
		Blister packs	Rigid	47 000–284 000	1.5–3.7	165 500	3.0
	Toys	-	Both	6 000–36 000	0.2–0.5	21 000	0.4
Textiles, leather and fur	Clothing	Artificial leather (not car) / Bags, luggage	Soft	47 000–281 000	1.5–3.7	164 000	3.0
Vehicles	Automotive (interior)	Artificial leather, foamed films	Soft	21 000–127 000	0.7–1.7	131 500	2.4
	Automotive (exterior)	Tarpaulins etc.		9 000–53 000	0.3–0.7		
	Automotive	Dashboards, sheets, profiles		8 000–45 000	0.2–0.6		
Other	Miscellaneous consumer articles	-	Rigid	54 000–323 000	1.7–4.2	840 000	15.4
	Miscellaneous consumer articles	-	Soft	186 000–1 117 000	5.8–14.5		
Total				3 216 210–7 686 710		-	-

[1] Average from the range

[2] Figures for cables comprise several sectors: building and construction, electrical and electronic equipment and vehicles

A.1.3. Waste management

Directive 2008/98/EC (Waste Framework Directive, WFD) amended by Directive (EU) 2018/851 defines waste as 'any substance or object which the holder discards or intends or is required to discard'.

Several major applications of PVC are for products with long service lifetimes. As the widespread production of many of these long-lived products already began several decades ago, increasing amounts of PVC waste will enter the waste management system over the coming decades. It is estimated that 2.9 million tonnes of PVC waste are generated annually in Europe (VinylPlus, 2017, Conversio Market & Strategy GmbH, 2021) (CfE2, #1601).

There are two main sources of PVC wastes: pre-consumer and post-consumer waste. Pre-consumer waste consists of waste generated during the production of final and intermediate products in which the materials are normally homogeneous, and the additives are known. Pre-consumer waste can be recycled within the manufacturing facility and thus it might not even enter the external waste stream. Post-consumer waste consists of waste produced by end consumers or commerce in which materials are likely not homogeneous and the additives are less known.

The main source of PVC waste is of post-consumer origin (around 83 % or 2.4 million tonnes per year). Post-consumer waste consists of products that have been discarded at the end of their life and rigid PVC accounts for 63 % of the total. Further, from the total post-consumer waste the majority comes from the building and construction industry (44 %), packaging (20 %), electric and electronic equipment (8 %), automotive industry (4 %) and the rest from other several sectors. However, waste composition is affected by the lifetime of the articles (CfE2, #1601). Thus, for articles with a relatively short lifetime (e.g. packaging), most of the PVC consumed enters the waste stream within one year from production, and waste production is closely coupled with consumption. For other products with longer lifetimes the situation is different.

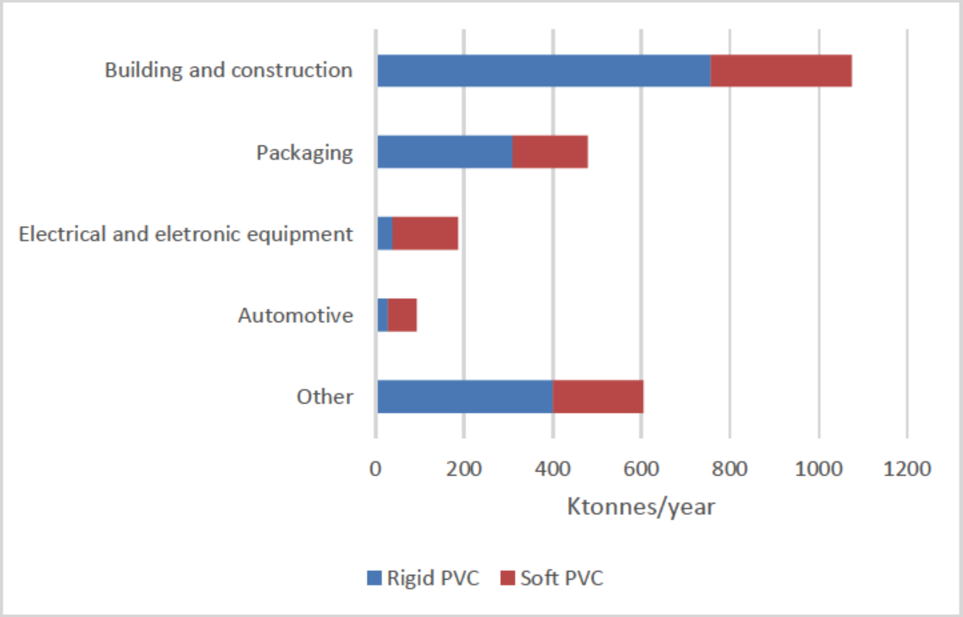

Figure 2. PVC post-consumer waste per sector

At present the vast majority of PVC pre-consumer waste is recycled (>90 %). Incineration accounts for <8.0 % and landfilling for <2 % (CfE2, #1601).

Within the EU, post-consumer waste is mostly incinerated (51 %). Landfilling accounts for 29 % and recycling for 20 % of the total post-consumer waste (CfE2, #1601).

Incineration

According to data provided in CfE2 (#1601) approximately 1 330 kilotonnes of PVC waste is incinerated.

Several hazardous substances are generated upon incineration, such as polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) or hydrochloric acid.

Nevertheless, there is evidence that the production of PCDD/Fs in incineration processes is strongly linked to furnace types, their operating conditions and the type and efficiency of air-pollution control systems (Altwicker, 1996, Huang, 1994, McKay, 2002). For instance, high temperatures and long residence time in the furnace which lead to complete combustion, fast cooling of combustion products, which minimise the time flue gases spent at a temperature range leading to PCDD/Fs formation (300-400 ºC), and the right abatement systems lead to low emissions of PCDD/Fs regardless of the chlorine input from PVC and other chlorine sources. This enables the incineration plants to meet the emission limits set in Europe (see section A.2.3). Further, the formation of PCDD/Fs might strongly depend on the concentration of precursor molecules. Thus, PCDD/Fs might be formed via precursor pathways and their formation is related to the catalytic nature of fly ashes, concentration of precursors and the incinerator operating conditions but not directly related to the concentration of chlorine in the incinerator feedstock (Milligan and Altwicker, 1995).

Nevertheless, even at the right conditions, during the combustion of PVC or salty food waste, chlorine is released and transformed into hydrogen chloride (exit gases should be treated using HCl absorbers) which may cause corrosion of boilers in the incineration plant and thus increasing the need for maintenance. This is a very important issue, since it is the main factor considered by incineration plants to accept waste containing a high amount of PVC (communication with CEWEP). Generally, PVC content in waste that is incinerated cannot be higher than ~2 %. PVC waste is estimated to grow and based on an interview with an industry expert, the additional waste would not be a problem in terms of actual capacity for incineration in the EU. However, there seems to be an unequal geographical distribution of the capacity in the EU (higher capacity in the north compared to the south).

As the formation of hazardous transformation products depends on the conditions of incineration, it is not possible to quantify to which extent these products are formed in standard waste incinerators in the EU in practice and the share that would correspond to PVC waste. From a regulatory point of view, the Industrial Emission Directive imposes limits (BAT-AELs) on the emission of all harmful pollutants (e.g. chlorine, PCDD/Fs, EDC, VCM) from waste incineration plants (Commission Implementing Decision (EU) 2019/2010) As commented in section A.2.3.1, permitting authorities must set maximum allowed emissions in line with, or below these BAT-AELs. Derogations may be granted in exceptional cases, under strict conditions (Article 15 & 4 of the IED). Further, changes in BAT-AELs resulting from a BREF revision must be transposed in permits within at most 4 years (Art. 1 & 21 of the Industrial Emission Directive).

It is important to note that all waste that is incinerated go mostly to energy recovery (ca. 85 million tonnes/year) or to co-incineration in cement plants (ca. 6 million tonnes/year) (communication with CEWEP).

Landfill

According to data provided in CfE2 (#1601) approximately 550 kilotonnes of PVC waste is landfilled.

A landfill is defined as ‘a waste disposal site for the deposit of the waste onto or into land (i.e. underground)’. Under the WFD and in accordance with the waste hierarchy, landfilling is the least preferable option for waste management and should be limited to the necessary minimum. The Landfill Directive (Council Directive 1999/31/EC, amended by Directive (EU) 2018/850) introduces targets to reduce landfilling. Some Member States (Germany, Austria, the Netherlands, Sweden, Denmark, Luxembourg, Belgium and Finland) have adopted landfill restrictions for plastic waste. Landfills receiving more than 10 tonnes of waste per day or with a total capacity exceeding 25 000 tonnes, excluding landfills of inert waste, are included in Annex I of Directive 2010/75/EU on industrial emissions (IED)[1] and are subject to provisions set out in Articles 10 to 27, including implementing Best Available Techniques.

Due to the targets under the Landfill Directive to reduce landfilling, it is expected that the relative tonnage landfilled instead of incinerated or recycled will decrease over time; however, this cannot be quantified.

Although PVC polymer is generally regarded as being resistant under soil-buried and landfill conditions, there is nevertheless a potential for thermal- and photodegradation of the polymer affecting the polymer integrity and resulting on the release of PVC microparticles. However, this potential cannot be quantified at this moment (EU, 2000).

In addition, losses of additives, in particular plasticisers from soft PVC are widely recognised. Risks associated with PVC additives are described in section B.6.

Accidental or illegal landfill fires can contribute to the formation of dioxins and furans but will not be considered in the scope of this report.

Recycling

According to VinylPlus, approximately 813 000 tonnes of PVC waste was recycled in 2022 (VinylPlus, 2023). This figure includes pre-consumer waste (508 000 tonnes) and post-consumer waste (305 000 tonnes). The rate of recycling is much higher for pre-consumer waste (> 90 %) than for post-consumer waste (~20 %). This is mainly due to the fact that in the pre-consumer waste, the materials are normally homogeneous and the additives in the PVC compound are known, which facilitates the recycling.

Figure 3 shows that the volume of recycled PVC in from pre-consumer waste is always higher than the volume of recycled PVC in from post-consumer waste, with the notable exception of cables for which the volume of recycled PVC in from post-consumer waste far exceeds the volume of recycled PVC in from pre-consumer waste. It can also be seen that window frames are the main source of the total PVC (rigid and soft) that is recycled, both from pre-consumer (47 % of the total) and post-consumer (56 % of the total) waste.

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[1] DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast) (Text with EEA relevance) (OJ L 334, 17.12.2010, p. 17).

The economic incentives and technical needs for collection, sorting and processing make recycling more difficult in some waste stream than others. An example of non-recovery post-consumer waste is PVC water pipes that remain in the ground after replacement. Another example in the opposite direction is in cables, where the economic incentive to recover the metal seems to drive the recycling of PVC.

If economic profitability cannot be achieved, recycling of PVC will not take place, unless there are legal obligations or voluntary measures to enforce or promote the recycling of PVC.

In terms of the type of PVC, recycled rigid PVC accounts for 60 % of the total recycled PVC both from pre-consumers and post-consumer waste (VinylPlus, 2023).

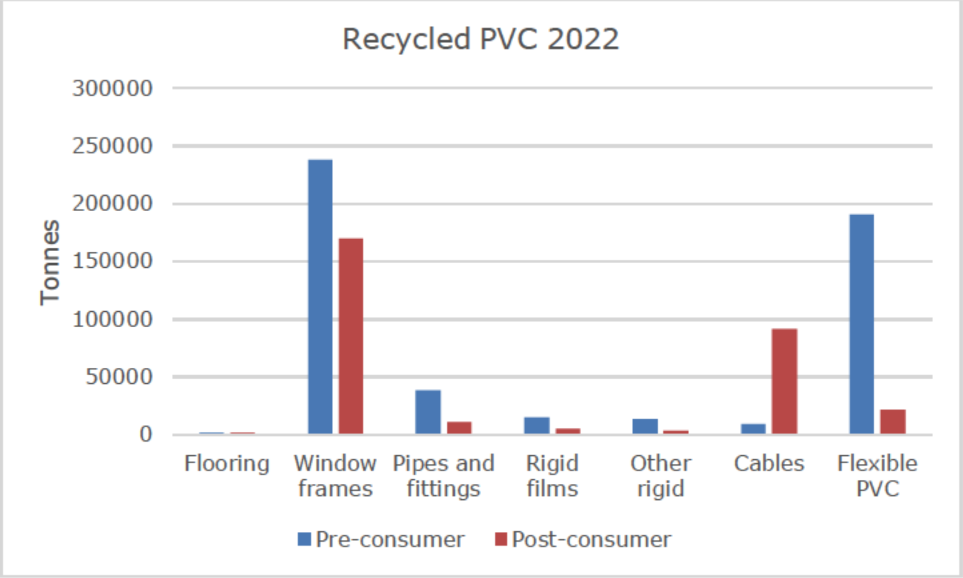

Figure 3. Recycled PVC in 2022 (VinylPlus Progress Report 2023)

Today, PVC waste is recycled mainly by mechanical recycling which is more successful when the provenance of PVC waste is known, i.e. with a cleaner PVC waste with known composition and previous history available to the recyclers. However, those waste sources are limited.

New technologies for chemical (feedstock) recycling of mixed PVC wastes are still under development (Sadat-Shojai and Bakhshandeh, 2011). And even though the recycling rates have increased in general they are still not optimal for several uses.

For PVC itself there is a potential for release of PVC dust that might be formed during handling, conveying and/or processing of PVC and PVC articles. One of the most common means of generation is via abrasion but also when articles are cut or shredded, which are activities in the recycling processes. However, this potential cannot be quantified at this moment.

A.1.3.1. Waste management per waste type

Further consideration can be given to the main waste categories relevant to PVC articles.

Building and construction waste

Building and construction waste is regulated under the WFD. This category includes all waste produced by the construction and demolition of buildings and infrastructure, as well as road planning and maintenance. Recycling and material recovery is highly variable depending on the Member State (EU, 2023b). The Directive sets objectives to increase recycling and promote safe handling of hazardous substances through selective demolition measures and the establishment of sorting systems for different construction and demolition waste fractions.

When it comes to rigid PVC, waste is generated during construction, renovations and demolition activities. Collection systems in place for those activities have resulted in a significant recycling industry (CfE2, #1552), in particular for rigid applications. As mentioned before, window frames are the main source of recycled PVC accounting for 78 % of the total rigid PVC recycled pre-consumer and 89 % of the total rigid PVC recycled post-consumer. This recycled rigid PVC is mostly used for the same application but also in other rigid applications (VinylPlus, 2023).

Pipe and pipe fittings are the second source for recycled rigid PVC accounting for 13 % of the recycled pre-consumer rigid PVC but only 6 % of the recycled post-consumer rigid PVC. In this case, according to TEPFFA (CfE2,#1596), for below ground pipes 95 % of below ground pipes are left in the ground and only ca. 2.5 % is recycled and the rest incinerated. For above ground pipes, 80 % is landfilled, 15 % is incinerated and only 5 % is recycled.

With regard to soft PVC in building and construction, the main post-consumer waste volumes are obtained from cables. Cables are recovered mainly for their metal (primarily copper) content that has a high economic value. Cable strippers and choppers recover the metal and the cable sheeting (containing flexible PVC as well as other materials like cross-linked PE, PUR, rubber, textile, aluminium plastic composite films, residual copper and residual aluminium) is collected.

According to Plastic Recyclers Europe, a large fraction of the cable sheeting material is not further sorted. Instead, it is used in a plastics conversion process called compression moulding to manufacture articles such as artificial lumber or blocks of weight that are used to keep fences upright or place road furniture. This would reduce the total substance emitting surface by >99 % (CfE2, #1552). Another use of that recycled material is in agricultural use like e.g. geomembranes or greenhouse foils.

Nevertheless, there are also specialised recyclers who are able to process further the cable sheeting fraction to a good purity PVC by e.g. dissolution or by cryogenic micronization and sieving. Similar quality could be achieved using other techniques or combination of techniques (e.g. eddy current separation, grinding and several steps of electrostatic separation). Still, ca. 50% of this cable sheeting is not being recycled and is sent to landfill or incineration.

Another source of soft PVC in building and construction is flooring, for which recycling rates are still low (less than 5%) according to the data provided by VinylPlus (VinylPlus, 2023).

Overall, the majority of PVC waste from building and construction is incinerated (46 %) and landfilled (29 %). Recycling accounts for 25 % (VinylPlus, 2023).

Electrical and electronic equipment

When it comes to electrical and electronic equipment, the main source of PVC waste is coming from cables.

According to the information provided by Plastic Recyclers Europe, electric and electronic equipment have separate collection systems that directs the different qualities of waste to specialized treatment centres. In these centres, after applying actions according to the procedures required by the WEEE directive, the material is shred. The shredded material is then sorted into material streams (e.g. ferrous vs non-ferrous metals) with regular sorting techniques (e.g. magnetic separation, eddy current separators) and plastics accumulate in the so-called shredder light fraction (SLF). This fraction is then directed to specialized plastic recyclers.

In those specialised plastic recyclers users, density is used to recover polyolefins (<1.0 g/cm^3) and styrenics (>1 to <1.1 g/cm^3). According to the plastic recyclers industry (CfE2, #1552) any material with a density greater than 1.1 g/cm^3 ends up in the 'heavy' SLF. This is where PVC ends up together with polyolefins and styrenics containing functional working levels of brominated flame retardants. Since a great fraction of those contain PBDEs, the 'heavy' SLF is considered hazardous waste and needs to be destroyed through incineration.

However, according to VinylPlus, the majority of PVC waste from PVC cables from electric and electronic equipment is recycled (61 %) and a still significant fraction is incinerated (25 %) and landfilled (14 %). This seems to contradict the information above and may suggest that cables from different sectors might have different recycling rate.

Automotive waste

In the automotive sector, PVC is used in underbody coatings, sealants and floor modules, wire harnesses (e.g. cable insulation and grommets), passenger compartment parts (e.g. dashboard and door panels seating and arm rests), artificial leather (seat upholstery) and exterior parts (e.g. body side protection strips, weather strips and window sealing profiles).

Directive 2000/53/EC on end-of life vehicles establishes that waste from vehicles has to be collected and transferred to authorised treatment facilities. In these facilities spare parts are recovered and (limited) depollution takes place (e.g. removal and collection of fluids). According to the information provided by Plastic Recyclers Europe, husks are subsequently sent to shredders and the shred is sorted in a similar fashion to the WEEE shred. The only difference is that the plastics accumulates in what is called the automotive shredder residue (ASR). ASR is more complex that the shredder light fraction (SLF) since it contains more materials and while there are specialized recyclers that take both SLF and ASR, the majority focus on SLF. The majority of ASR is directed to incineration, particularly in locations where gate fees for incineration are low.

According to VinylPlus, the majority of PVC waste from the automotive sector is incinerated (50 %) and landfilled (32 %). The rate of recycling is 18 %.

Packaging

Packaging waste is generated not only by households but also in distribution channels and commercial usage. Packaging other than from households is normally cleaner mono-material and may be recycled.

Household packaging waste can be collected together with all other waste (co-mingled) or separately. Plastics can be separated from co-mingled collection systems in material recovery facilities. The household plastics normally go to plastics waste sorting facilities where object-based sorting technologies are used to create bales of plastics waste. This gives rise to bales of packaging plastics such as blue PET bottles, polyolefin films, HDPE 'hollow bodies', PP trays, etc. For every type of bale generated, a separate processing step is added. Very small items and materials that only occur in low amounts are normally collected in a residual waste fraction. The volume of PVC packaging is overall low and consequently seems to be not sorted into a separate bale because there is no economic incentive.

Blister packs from medical applications end up mainly in mixed consumer waste.

According to VinylPlus, the majority of PVC waste from packaging is incinerated (67 %) and landfilled (19 %). The rate of recycling for packaging is just over 14 %.

<u>Other</u>

No specific information was provided for the other uses of PVC during the calls for evidence. They have been rather aggregated into miscellaneous consumer and institutional articles.

For those uses separate collection is limited and, as such, recycling rates are rather low with an average of 13 %. Most of the waste is then incinerated (62 %) or landfilled (25 %) (CfE2,#1601). This is likely due to the small size of the individual uses and in some cases related to the complexity of the articles. For example, a piece of artificial leather will likely have a textile base on which a PVC plastisol is applied. A composite material like this is difficult to recycle since the textile and PVC will be difficult to separate.

This could be different for medical applications where separation could occur. However, healthcare waste is likely either collected separately as hazardous waste (and then disposed accordingly) or enters mixed waste streams. In both cases, this PVC will end up being incinerated (Nordic Council of ministers, 2019).

A.2. Risk assessment

This section focuses on the risks from the uncompounded PVC resin, i.e. PVC itself, not considering the additives. Risk from the additives will be covered in the Appendix B.

Considering the processes involved in the production of PVC, this section covers the starting materials EDC and PVC, as well as the potential production of PCDDs/PCDFs and PVC dust. PVC is thermally stable below 225 ºC and therefore significant thermal degradation products are not expected during the life cycle of PVC (see further discussion in sections A.2.2 and A.2.3).

A.2.1. Classification and labelling

The starting materials in the production of PVC, i.e. EDC and VCM, have a harmonised classification (Table 2 below).

Table 2. Harmonised classification for EDC and VCM according to the CLP regulation 1272/2008

EC	CAS	Substance name	Index No.	Harmonised classification
203-458-1	107-06-2	1,2-dichloroethane (EDC)	602-012-00-7	Flam. Liq. 2 (H225) Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)

				STOT SE 3 (H335) Carc. 1B (H350)
200-831-0	75-01-4	Chloroethylene (VCM)	602-023-00-7	Press. Gas Flam. Gas 1 (H220) Carc. 1A (H350)

EDC (EC 203-458-1, CAS 107-06-2) was identified as a substance of very high concern (SVHC) in accordance with Article 57(a) of the REACH Regulation since it is classified as carcinogen, Carc. 1B (H350: “May cause cancer”). Consequently, it was included in the Candidate List for authorisation on 19 December 2011 and finally included in the Authorisation List on 14 August 2014 (EU, 2014).

PVC itself does not have a harmonised classification. Conventional warnings related to generic dust properties are used also for PVC dust based on several safety data sheets available publicly.

A.2.2. Hazard assessment

In addition to the hazard properties of the PVC precursors EDC and VCM covered by CLP hazard classes, it is important to note that PCDDs and PCDFs are families of organic compounds that are known persistent organic pollutants (POP) listed in the Stockholm Convention on Persistent Organic Pollutants. PCDD/Fs can be generated during the oxychlorination of ethylene as well as during the thermal oxidation of chlorinated production residues.

PVC itself as a halogenated polymer can be considered to have a very low degradation rate in nature (Tang et al., 2018, Veronelli et al., 1999). The resistance to biodegradation would also apply to fine particle forms, although the degradation is influenced by, among other things, particle form, size (surface area to volume ratio), temperature and other environmental conditions. Data on the very high persistence of PVC was not further compiled, but it is considered as a fact for the risk screening. The Background Document of the ECHA’s restriction proposal on microplastics discussed the degradation of polymer microparticles. In the opinion, and RAC concluded on the extreme persistence of microplastics generally. In this investigation report, releases of PVC as microparticles (particle size < 5mm or finer) form to the environment have been in focussed (see rationale and definitions in section A.2.3.4). A very high persistence is assumed for the PVC microparticles, in line with the above opinion. A more specific assessment of persistence of PVC microparticles would need to be compiled for the purpose of a potential restriction dossier (ECHA, 2020b).

In the Background Document (ECHA, 2020) it was also assumed that microplastics are not degradable in wastewater treatment plants. Accordingly, this the same assumption can be made for the PVC microparticles in wastewater treatment plants (ECHA, 2020b).

Although PVC is more prone to thermal degradation than other plastics (Varma et al., 1999, Xu et al., 2005), thermal degradation is not relevant for the assessment of persistence in the environment and the WWTP. In addition, PVC is stabilised prior to its use. Even for specific environmental conditions such as landfills the half-life of the thermal degradation of stabilised PVC can be expected to be much longer than the vP criteria. Also importantly, the stabilised PVC polymer is not degradable under landfill conditions (EU, 2022, Mersiowsky, 2002).

The environmental monitoring data and fate of PVC microparticles is discussed in section A.2.3.

In relation to the uptake, translocation and potential bioaccumulation (including trophic transfer) of PVC microparticles in the environment and their potential ecotoxic effects, reference is made to ECHA (2020). No systematic data review was carried out specifically to PVC microparticles. It is noted that ecotoxic effects of PVC may be also at least partially attributed to the additives migrating and leaching from PVC microparticles in the environment (Zhang et al., 2020).

PVC resin is not classified as a possible carcinogen and it is considered a polymer of low concern by the OECD (OECD, 2009a). Nevertheless, some epidemiology data in PVC baggers suggest that long-term exposure to high levels of PVC dust might promote pulmonary carcinogenesis through persistent alveolar inflammation, alveolar macrophage activation, and release of growth factors (Girardi et al., 2022, Mastrangelo et al., 2003). That could be similar to what was already reported for other non-genotoxic non-soluble dusts with low toxicity (e.g. carbon black, toner, talc) (Soutar et al., 1997). Inhaled PVC dust (in particular with an aerodynamic diameter of less than 5 µm) may remain in the pulmonary interstitium for a long time (Waxweiler et al., 1981). PVC dust is also associated with pneumoconiosis or interstitial fibrosis (Studnicka et al., 1995).

It should be noted that the measured PVC dust concentrations in those studies were often over 10 mg/m^3 which indicates that it cannot be clearly differentiated whether the cause of the effects has been the substance in particulate form or dust itself. Also, the effect of the size of the PVC dust particles needs evaluation. A data gap can be indicated for a closer evaluation and literature review for epidemiological and toxicological data on the specific effects of PVC via inhalation.

It is noted that, for this investigation report, no systematic data search on specific effects of PVC microparticles was carried out. Reference with regard to environmental effects is made to the final RAC and SEAC opinion on microplastics (ECHA, 2020d). Same effect types can be assumed to apply to PVC microparticles generally. Analogously, in combination with the very high persistence, the environmental hazards from PVC microparticles should be considered as non-threshold, type similarly to PBT/vPvB substances. Differences between PVC microparticles and other plastic microparticles were not elaborated in this investigation report. Due to some differences, e.g., in relation to the further deformation/degradation, PVC microparticles can be expected to elicit have a somewhat different fate compared to other microparticles. Specific data on effects of PVC is a data gap but it may not be the highest priority to explore further considering the overall conclusions.

A.2.3. Release and exposure assessment

A.2.3.1. Regulatory context

National or regional authorities are obliged to issue and regularly renew operating permits for plants conducting activities under the scope of the Industrial Emissions Directive with conditions based on the use of Best Available Techniques (BAT), which are developed, agreed and documented in BAT Reference documents (BREFs). EU Member States' permitting authorities must use these as the reference when setting permit conditions. BAT Associated Emissions Levels (BAT-AEL) are especially relevant because permitting authorities must set maximum allowed emissions in line with, or below these BAT-AELs. Derogations may be granted in exceptional cases, under strict conditions (Article 15 & 4 of the IED). Changes in BAT-AELs resulting from a BREF revision must be transposed in permits within at most 4 years (Art. 1 & 21 of the Industrial Emission Directive).

With regard to the release and exposure assessment, it is important to understand the regulatory context in governing the production of PVC.

Three sectoral BREFs are relevant for the EDC/VCM/PVC manufacturing chain:

- The Large Volume Organic Chemicals (LVOC) BREF published in 2017, for emissions from EDC and VCM manufacturing into air and water (Falcke et al., 2017);

- The Polymers BREF (issued under Directive 2008/1/EC concerning Integrated Pollution Prevention and Control), which will be superseded with respect to air emissions by the Waste Gas from Chemicals (WGC) BREF (EC, 2007); and

- The Waste Gas from Chemicals (WGC) BREF (published in January 2023)

In addition, the EDC/VCM/PVC manufacturing chain is also regulated by BREFs covering all industry like e.g. the Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector (CWW) BREF (Brinkmann et al., 2016).

These BREFs set forth BAT-AELs for, among others, EDC, VCM, dioxins to both air and water, as well as HCl and dust emitted to air.

BREF is also available for Waste Treatment (Pinasseau et al., 2018). No specific document for plastic waste recycling exists.

With regard to the incineration of waste the Waste Incineration BREF also sets forth BAT-AELs for, among others, PCDD/Fs and HCl (Neuwahl et al., 2019).

A.2.3.2. Voluntary industry commitments

Voluntary industry commitments to reduce the health and environmental impacts of VCM and PVC manufacturing activities have been in place for some time (CfE2, #1601). They encompass emission limits, commitments to apply Best Available Techniques and to undergo verifications by an independent third party.

The first one covered VCM and S-PVC and was signed by the members of the European Council of Vinyl Manufacturers (ECVM) in 1995. The second was for E-PVC and was signed in 1998. The Charters' criteria were clarified, and compliance was third-party verified several times during the last 20 years.

In 2018, it was agreed to merge both Charters into a single comprehensive Charter, revising the emission limits in line with technical progress, and to add a limit for workers' exposure to VCM in line with the regulatory limits already being complied with. This revised Charter was published in 2019 (ECVM, 2019) and verified by auditing company DEKRA in 2022, based on the performance of the EDC/VCM and PVC production plants in 2021.

In addition to the verification of the Charters' criteria, ECVM has been collecting emission data from its members' plants on a yearly basis since 1998 and the monitored emissions include VCM, EDC, dioxins, PVC dust, as well as Chemical Oxygen Demand of wastewater and hazardous waste arising from production activities (mainly oxychlorination catalyst potentially polluted with dioxins with such waste being subject to stringent disposal requirements, i.e. either incineration in incinerators especially designed to handle hazardous waste, or landfilled in sites dedicated to the safe disposal of hazardous waste.

Regarding workers' exposure to VCM and EDC, ECVM collected data from its members' plants in 2007 and in two recent periods, namely 2013-2015/6 and 2017/8-2021. The consolidated data is shown in section A.2.3.3.

In addition, the production and environmental, health and safety (EHS) managers of ECVM members' plants attend a yearly 2-days seminar to exchange information and best practice about manufacturing safety, health and environmental protection.

A.2.3.3. Exposure and releases of PCDD/F, EDC and VCM from compounding and PVC raw materials

Workers

Exposure to EDC and VCM is predominantly occupational and there are Binding Occupational Exposure Limits (BOEL) for workers in the PVC industry: 2 ppm or 8.2 mg/m3 (8h TWA) for EDC and 1 ppm or 2.6 mg/m3 (8h TWA) for VCM.

Both EDC and VCM are produced in closed systems that are highly automated. Fugitive emissions are minimized using leak-tight connections and seals. Monitoring is conducted to assess the effectiveness of the connections and seals. Transportation within plants or into shipping tankers is done through pipelines. During storage in tanks, inert blanketing substances such as nitrogen are used to prevent venting of 1,2-dichloroethane (Cherrie et al., 2011b). The highest exposure levels are during maintenance activities.

According to a dataset of VCM (Cherrie et al., 2011a) exposure at 36 VCM and PVC manufacturing plants across the UE in 2008 provided by the ECVM, representing 85 % of the PVC resin manufactured in the EU, in most cases 90th percentile exposures for all plants were already below 1 ppm even though at that time the OEL was set to 3 ppm. Exposures were generally higher in PVC production compared to VCM production.

According to ECVM, monitoring campaigns are regularly performed at manufacturing plants with personal and static measurements. In addition, as part of their obligations, medical surveillance of workers exposed to VCM is performed. ECVM members agreed in 2001 a set of guidelines for the medical surveillance of workers who could have potential exposure to VCM, both at the pre-employment stage in VCM and PVC production, periodically during employment entailing VCM and PVC production and post-employment in VCM and PVC production. These guidelines were updated in 2015.

The data collected in two recent periods, namely 2013-2015/6 and 2017/8-2021 shows measurements below the EU BOELs as it can be seen in Figure 4, Figure 5 and Figure 6.

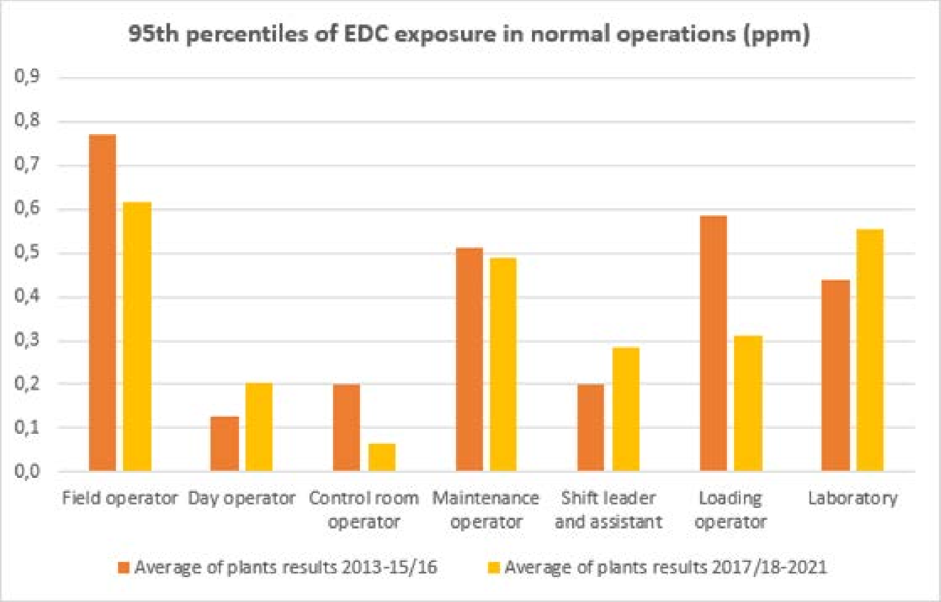

Figure 4. EDC exposure measurements in European plants

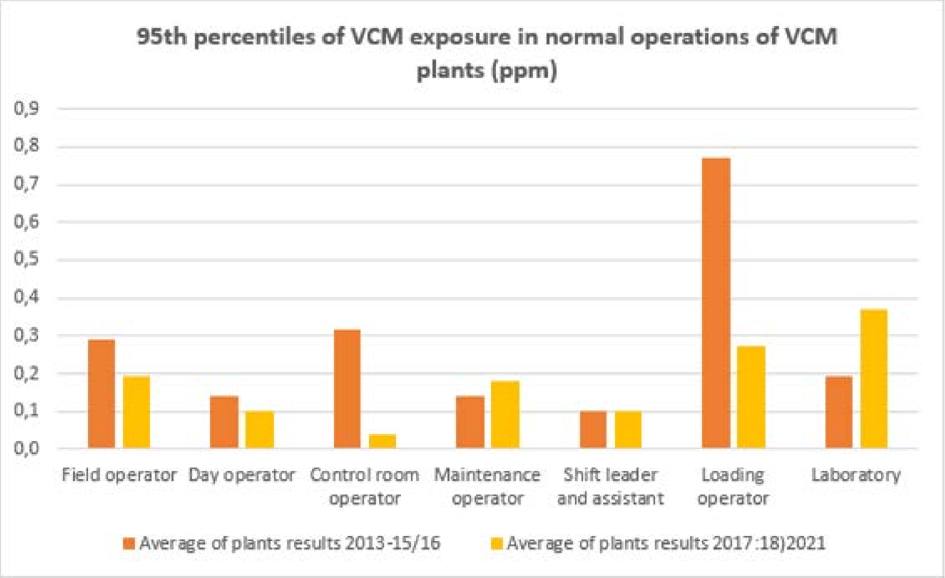

Figure 5. VCM exposure measurements in VCM plants

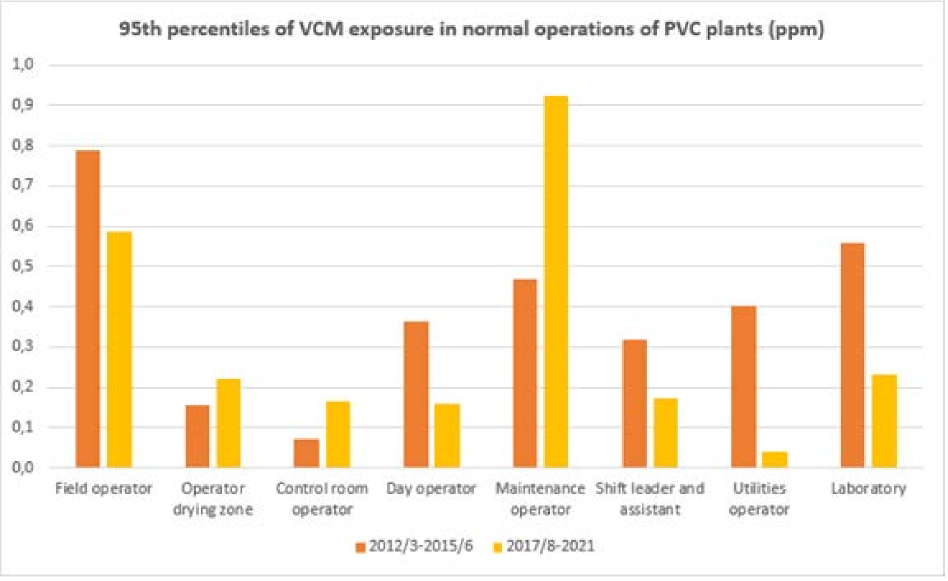

Figure 6. VCM exposure measurements in PVC plants

The Medical Committee of ECVM has been maintaining a registry of cases of angiosarcoma of the liver, a rare type of cancer associated with repeated exposure to VCM. According to VinylPlus, no angiosarcoma case has ever been reported in persons having started working in the VCM/PVC industry after implementation of the measures to stringently reduce VCM exposure. This seems to indicate that the limits seem to be adequate in controlling the risk.

Further, the improvements over the years in PVC production have resulted in lower monomer content in the polymer and consequently highly reduced residues of VCM to the ppb levels (Svensson, 1994).

Environment

Releases from EDC manufacturing plants, as well as plants using EDC to manufacture VCM are already low because most of these European plants have to comply with several BAT-AEL limits.

Table 3. BAT-AELs for emissions to air (LVOC BREF)

Substance	Limit value
EDC + VCM	< 1 mg/Nm^3
PCDD/F	0.025-0.08 ng I-TEQ/Nm^3
HCl	2-10 mg/ Nm^3
Cl_2	< 1-4 mg/Nm^3

Table 4. BAT-AELs for direct emissions to a receiving water body at the outlet of the final treatment (LVOC BREF)

Substance	Limit value
EDC	0.01-0.05 g/ton EDC purified
PCDD/F	0.1-0.3 µg TEQ per ton of EDC produced by oxychlorination

In the Green Paper regarding the environmental issues of PVC it is acknowledged that, as in other sectors of the chemical industry, continuous improvements in the production processes have taken place over the years (EU, 2000). BATs for the production of VCM and PVC have been established which led to the adoption of a number of relevant emission limits by the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) decision 98/5 (S-PVC) and recommendations 99/1 and 2000/3 (E-PVC) together with a voluntary commitment signed by ECVM listing the BAT-AELs. Compliance with all the standards is also verified by an independent audit.

Overall compliance with Charter emission and exposure limits is now 90 %. Many of the 10 % non-or partially complying criteria resulted from failures to respect guidelines (e.g. monitoring frequency) rather than excessive emissions or exposure (CfE2, #1601).

The yearly monitoring by ECVM cited above shows that reduction of aggregated emissions to air and water from 2000 until 2021 has achieved a reduction ofdecreased by 65 % for VCM, a reduction of 22 % for dioxins and 67 % for EDC between 2000 and 2021. VCM and PVC manufacturing currently contributes currently only about 0.01 % of the total of dioxins emitted by human activities in the EU (CfE2, #1601). The 2021 dioxin emissions production-weighted average of ECVM VCM plants was 58 ng TEQ per ton of VCM to air and 312 ng/ton to water, which represents a 40% reduction when compared to the total of 600 ng/ton in 1998-2000.

The information provided in the call for evidence seems to correlate with the data from the national emissions reported to the Convention on Long-range Transboundary Air Pollution obtained from the European Environment Agency (EEA, 2023). The data shows that the emissions of PCDD/Fs have been declining over the years (not possible to determine the fraction corresponding to the PVC industry).

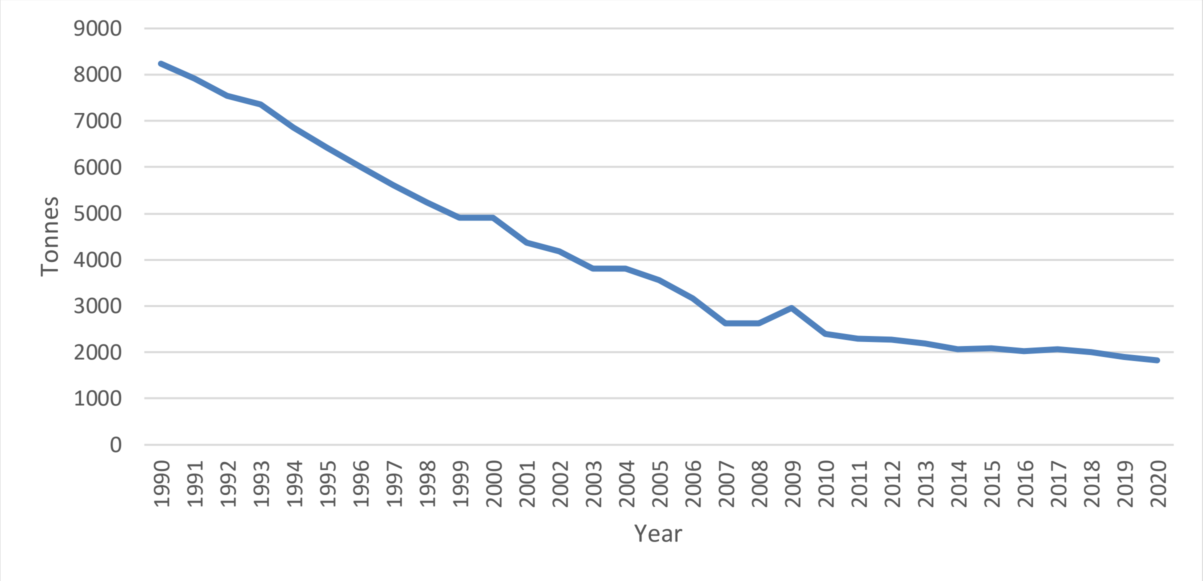

Figure 7. Evolution of the total emissions of PCDD/Fs (in grams) in Europe

With regard to releases of PCDD/Fs and HCl from incineration plants, those are also minimized due to the current BAT-AELs (Neuwahl et al., 2019) set forth in the waste incineration BREF (Table 5 and Table 6).

Table 5. BAT-AELs for emissions to air (waste incineration BREF)

Substance	Limit value
PCDD/F	0.01-0.04 ng I-TEQ/Nm3 (average over the sample period) <0.01-0.06 ng I-TEQ/Nm3

	(long-term sampling period)
HCl	<2-6 mg/Nm^3

Table 6. BAT-AELs for direct emissions to a receiving water body (waste incineration BREF)

Substance	Limit value
PCDD/F	0.01-0.05 ng I-TEQ/l

Information reported in the OECD Screening information data set (SIDS) for vinyl chloride reports that vinyl chloride has a vapour pressure of 3 330 hPa at 20ºC, a water solubility value of 1.1 g/l at 20 ºC and a log Pow of 1.58 at 22 ºC. In a soil and water microorganism study, vinyl chloride was biodegraded at 30 % after 40 days and 99 % after 108 days and has a low bioaccumulation potential. Environmental releases of vinyl chloride are almost exclusively to the air compartment. Fugacity modelling indicated that of the vinyl chloride released >99 % will remain in the air compartment. The dominant removal process in the atmosphere is photoxidation with a calculated half-life of 2.2 – 2.7 days. The 96 hour LC50 ranges from 210 to > 1000mg/l for fish (from four studies). The estimated (QSAR30) value for algae EC50 (96hr) is 118 mg/L and the LC50 (48 hr) for Daphnia is 196 mg/L. Toxic concentrations of vinyl chloride are not expected to be reached in aquatic systems based on low emissions, low bioaccumulation potential and high volatility.

The improved manufacturing practices over the years in the PVC industry have considerably reduced the residual content of VCM in PVC products. In some cases, such as PVC used for food packaging and PVC used for medical applications the levels permitted are set by the specific regulations (below 1 ppm in the finished article). For other cases, voluntary initiatives of the PVC industry have set a limit below 1 ppm as well and PVC producers are required a minimum of one sample per week in those cases (ECVM, 2019).

As already mentioned above, a third-party verification of compliance with the criteria set on the ECVM charter showed an overall compliance of ca. 90 %. In addition, measured data indicates very low residual content of EDC and VCM in articles manufactured with PVC (Borrelli et al., 2005, Svensson, 1994).

A.2.3.4. PVC microparticles

Definitions

The European Commission (EC, 2023a) definition of microparticles:

‘……

Synthetic polymer microparticles: polymers that are solid and which fulfil both of the following conditions:

(a) are contained in particles and constitute at least 1 % by weight of those particles; or build a continuous surface coating on particles;

(b) at least 1 % by weight of the particles referred to in point (a) fulfil either of the following conditions:

> *(i) all dimensions of the particles are equal to or less than 5 mm;*
>
> *(ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3*

....'

The 'microplastic' definition of ECHA (2020) for the restriction proposed by ECHA has been clarified by the European Commission by the above definition.

Releases of PVC itself take place during the PVC lifecycle. Generally these can be described as:

- Primary release in dust/solid form directly released as a result of abrasion during the mechanical activites such as cutting, extruding, filtering, grinding. Abrasion can occur in any life-cycle stages either intentionally or unintentionally. The released dust fulfils the criteria for microparticles (see below). Term PVC microparticle is applied in this report.
- Primary release of larger particles than microparticles (e.g., large PVC pellets directly ending up in the environment), microparticle sized pellets and parts or whole PVC products such as plastic bags (commonly named as plastics debris)
- Secondary release taking place in the environment as a result of abrasion of the above two forms of release.

Following existing definitions of the European Parliament (2018) and ECHA are also relevant:

Primary microplastics releases
- Directly released into the environment as small particles
    - From intentionally added microplastics (see (ECHA, 2020a))
    - By abrasion, shear, cutting, grinding and other physical activities taking place in the various plastics uses and end-of-life handling

Secondary microplastics releases
- Originate from degradation of larger plastic objects, such as plastic bags, bottles or fishing nets

In this section the focus is on the PVC particle form unintentional releases which occur during normal industrial, professional, consumer and end-of-life activities.

This project did not consider the releases of PVC waste/discarded articles or their parts which normally would be subject of industrial and professional waste handling obligations and/or public waste collection schemes but end up in the environment as 'debris'. Risks of plastic pellets were not targeted in this investigation but are covered by the Commission impact assessment (EC, 2023b) and proposal for a regulation on preventing plastic pellet losses to reduce microplastic pollution (EC, 2023d). This project does neither cover releases from the use of intentionally added 'microplastics' (intentionally added synthetic polymer microparticles) (ECHA, 2020b).

Releases and sources of microplastics from any plastic polymer have been estimated in UNEP (2018). EU level estimates of microplastic releases have been provided by ECHA (2020b) and, most recently, in a EC (2023c) brochure. The unintentional microplastic releases in the EU were reported to be between 0.7 and 1.8 million tonnes per year. The main sources were reported as pains, tyres, pellets, textiles, geotextiles and detergent capsules.

The term 'PVC microparticles' or 'microparticles' is applied further on in this report to denote the analysis of unintentional releases of PVC microparticles other than pellets. No information was received in the various calls of evidence during this investigation project on the size distribution of the PVC particles released. Some information is available on the size and form of the manufactured (uncompounded) PVC pellets (section A.1.1) and the recycled PVC (EC, 2022) but that information does not give indication to the size distribution of the PVC microparticle releases. It is not known whether also larger particles than those fulfilling the synthetic polymer microparticle definition above but smaller than normal debris (plastic product or product part size) are released to the environment. It is assumed that larger particles of PVC resulting from industrial and professional physical activities such as grinding, cutting and shredding are collected as waste or raw material and handled accordingly (pre-consumer recycling or other waste management).

Due to the data gap of the size distribution of the released PVC particles (with one exception for a recycling plant), this project cannot define a size limit to the PVC particle releases. However, as the hazards and fate of microparticle sized PVC are already covered to a sufficient extent by ECHA (2020), and on the other hand, potential measures targeted to reduce releases of microparticle polymer size also can be expected tobe at least partially effective to larger particles, we focus the following analysis on unintentional PVC microparticle releases.

Analytical methods on polymer microparticles (described, e.g., in ECHA (2020b) and EC (2023b)) are not able to differentiate between manufactured pellets and other plastic particles of the same size. Therefore, there may be some overlap in the estimations of unintentional releases of microparticles from pellet handling as provided by EC (2023b) and other sources when the estimates are based on measured data.

PVC microparticle releases are expected to be formed based on ECHA Guidance (ECHA, 2016b) when PVC (and other solid material) are handled in physical activities such as cutting, shredding, grinding, polishing, etc. ECHA Guidance mainly addresses this form of release for the processing and use of articles. It should be noted that OECD emission scenario document on plastic additives does not provide whether the releases take place in particle or in vapour/dissolved form (OECD, 2009b). For mechanical recycling activities ECHA Guidance (ECHA, 2016b) assumes all releases to be in particle form. It is plausible to assume based on the properties of PVC (not volatile, not water soluble) and based on the uses, that releases of PVC itself take essentially place in solid/particle form. For selection of release factors and operational conditions, it could be considere d that for some (industrial) uses the releases can be expected to correspond to releases from processing and handling of pulver/dust form substance. For many of the industrial uses and potentially majority of professional and consumer uses of PVC the conditions of use may be considered analogous or actual to exposure scenarios on article uses (regardless of whether the PVC object processed/handled can be legally defined as an article). In these uses compounded PVC is handled in solid form, well defined pieces of PVC at different stages of finalisation. The ECHA Guidance provides for such activities environmental emission factors between 2.5 to 20 % depending on the energy intensity of the process and whether the activity area is closed or open, based on OECD Emission Scenario Document on plastic additives (OECD, 2023). For comparison, (UNEP) (2018, table 17) reported that a fraction of 1 % of the produced PVC volume is released as microplastics to the environment (no further specification provided as justification in the report).

Microparticle emissions can be expected to occur practically at all PVC life-cycle stages. Subsequent environmental releases take place (after site release reduction measures, where applicable) following the principles of ECHA Guidance (ECHA, 2016b) on exposure assessment as fugitive PVC microparticle releases to air, wastewater (and soil).

ECHA requested information on microparticle releases during the CfE2 (see Appendix E) but no information was received.

The microparticle releases of PVC were not quantified with one exception for recycling plants in this project. The is no explicit consensus approach available to estimate unintentional plastics releases. If the ECHA Guidance and OECD emission scenario document would be directly applied for PVC material (and other polymers), or, as presented on a preliminary basis in the previous paragraph considering the PVC uses as uses of pulver/dust form substance and articles, the PVC microparticle releases to the environment could be expected to be at least at the same level of magnitude or higher than the releases of the prioritised additives as estimated in Appendix B.

In relation to the Commission proposal for the regulation on plastic pellets (EC, 2023d), differences and potential overlaps can be roughly identified. (1) Professional and consumer uses of PVC do not take place at 'installations' neither are a 'transport' activity, hence are not covered by the regulation proposal. (2) Professional and consumer uses as identified in section A.1.2 are not uses where handling of pellets take place. Furthermore, part of the industrial PVC uses do not handle pellets but rather semi-finalised articles. Also those are not hence covered by the proposal and the related impact assessment.

The potential overlap at recycling sites is discussed further below. Further differentiation and impact of the proposed regulation on plastic pellets for unintentional releases of PVC microparticles is discussed in the main report.

Regulatory limits on PVC dust

PVC dust does not have currently an EU BOEL. However, there are occupational limits for PVC dust in place in several countries in Europe that range from 0.3 mg/m^3 (8h TWA) in Germany for the respirable fraction to 5 mg/m^3 (8h TWA) in Austria with a median of 1 mg/m^3 (Gestis database). Further, nearly all countries in the EU have binding occupational limit values in place for general dust which is normally equal of or below 5 mg/m^3 (Gestis database).

The ECVM members do regular measurements for the most exposed activities (drying area, bagging area, truck loading area) on the respirable fraction. According to the data provided by VinylPlus, most results are either at a level of the detection limit (0.1 mg/m^3) or below.

Regarding PVC particle releases, there seems to be no specific emission or discharge limit in place, except the ranges of BAT-AELs for PVC dust in the EU BREFs (table):

Table 7. BAT-AELs for PVC dust in EU BREFs

BREF	S-PVC	E-PVC
Polymers	10-40 g/ton	50-200 g/ton
Waste Gas from Chemicals (WGC)	<1-5 mg/Nm^3	<1-10 mg/Nm^3

Releases from professional and consumer uses

Contribution of professional uses and service-life of PVC products can be expected to follow same proportions of the overall releases as the estimated additive releases as provided in section B.6. This is because the additive releases are expected to be in form of particle releases from these life-cycle steps. The main PVC microparticle releases can be expected to occur where cutting, shredding and abrasion is taking place. As professional uses and consumer uses are wide dispersive uses, active containment of the releases can be expected to be low compared to industrial life-cycle steps, which are mainly subject to the IED -Directive.

Releases from recycling

Additives used in PVC, and more generally additives considered in the development of the ECHA Guidance and the related OECD Emission Scenario Document on plastic additives, are normally not volatile. This is also the case for the prioritised PVC additives (see section 0. to B.5). Furthermore, the priority additives have a low migration and leaching potential (see section B.6.2.1) but their releases can be expected to occur as incorporated in particles and thus, PVC is the carrier of the additive releases. On qualitative level it may be inferred that the PVC (and other plastic) particle release factors would, in absence of a plastic release estimation approach, need to correspond to such release amount which is able to be the carrier of the releases estimated for the additives with the available ECHA and OECD approaches.

It can be noted that ECHA Guidance Chapter R.18 assumes that releases of substances from recycling take place into air with the release factor of 10 % (see section B.6, Table 52). Considering that shredding and cutting takes place at recycling sites, it can also be assumed that PVC particle releases to air occur at relevant rates.

Based on the available scarce studies summarised below it can also be concluded that relevant releases of microparticles to waste water occur from recycling plants. The findings can be, in absence of specific release information from EU recycling sites (no information received during the CfE2), directly applied to the releases of PVC particles to waste water from recycling in the EU, although release of PVC particles compared to other plastic particles may differ slightly due to the density of PVC.

Releases of plastic microparticles from a mixed plastic recycling plant in the United Kingdom have been measured recently by Brown et al. (2023). The authors focused on releases to waste water and found out that in the current situation, where filters were used at several points of the process, 5% of the plastic waste imported to the facility were released to waste water. A high removal efficiency of >40 µm particles was observed, the majority of the 5 to 40 µm -size particles was removed, whereas particles in size of <5 µm were generally not removed by filtering but were discharged. The authors estimated the release amount, calculated from the measured concentrations, to be with application of all available filter stations 59-1184 tonnes microparticles potentially discharged per year. The authors commented that the facility was a ‘state-of-the-art’ recycling facility. Two other similar publications exist (Guo et al., 2022, Suzuki et al., 2022). Brown et al. (2023) concluded that the findings from all the three available studies were coherent when taking into account the different analytical methods applied to measure the amount of microparticles in process and effluent waters of the recycling plants.

According to the progress report from VinylPlus (2023) the amount of recycled post-consumer waste was (in their membership area, hence Europe) around 310 000 tonnes in 2022, with 120 000 tonnes being soft and 190 000 tonnes rigid PVC waste. These can be considered as the post -consumer PVC waste input to plastic recycling plants. The total amount of post-consumer waste of PVC was in 2022 around 2 500 000 tonnes per year, and thus around 12 % is recycled. When applying the release factor obtained from the study of Browna et al. (2023) (5 % of input plastic released as very small microparticles), a significant amount of release from recycling plants to waste water results (from the VinylPlus -covered recycling plants to wastewater in 2022 would be ca. 15,500 tonnes per year). In addition to this, releases of microparticles to air can be expected but there is currently no release factor available (cf. RF of 10 % for additives). The pre-consumer waste can be recycled within the manufacturing facility and thus it might not even enter the external waste stream. Hence, the corresponding releases cannot be estimated. Although the representativeness of the Browna et al. (2023) outcome for all EU recycling plants would need further scrutiny, it can be assumed that the obtained releases and release factor from the study would apply for best available technology sites of similar sizes based on the description of the authors.

There are over 730 recycling facilities belonging to Plastic Recyclers Europe (PRE), which cover the recycled post-consumer recycled waste tonnage of VinylPlus provided above. Although the size and level of technology of the facilities can be expected vary (no information received on sites, this is a data gap), it can be concluded that the PVC microparticle releases to waste water from recycling plants are relevant at local, regional and the EU level. Assuming that the recycling plants are connected to municipal waste water treatment plants, 50 % of the microparticle releases to waste water enter the environment (see further details in the next subsection), the amount finally released to the environment due to the waste water releases from recycling plants would be ca 7,750 tonnes per year (air emissions not estimated).

Technical release reduction at recycling sites may be an effective measure to reduce the releases of PVC particle releases from recycling. Based on the Browna et al (2025 (study), however, even with multiple filters the microparticle releases are significant. Hence, in order to prevent microparticle -sized releases sequential filters in process waters with a capacity to filter out particles smaller than 5 µm of length would be needed. Feasibility to apply filters or other measures to remove microparticles from fugitive releases was not explored in this project (data and assessment gap). The microparticle formation potential of various recycling types (mechanical, chemical, etc.) and differences between the material (rigid vs soft PVC, other plastics) were not investigated. EC (2022) points out some differences in the recycling techniques of rigid vs soft PVC but it was not possible to infer from the provided information differences in the potential to form microparticle releases (data gap). Overall, further information on the releases of microparticles to air and waste water from recycling plants would be necessary to complement the release estimation at least for air and to propose targeted risk management measures for the recycling sites.

Municipal waste water treatment plant efficiency in removing PVC particles

ECHA (2020b) summarised extensively studies relevant for estimation of the municipal waste water treatment plant removal efficiency and releases of microparticles to the environment. The overall release factor for microparticles discarded to waste water, representative for, i.a., the EU waste water treatment plants and the sludge handling practices, was 50 %. Although ECHA (2020) took into account in the estimation also other down-the-drain routes than waste water connected to a treatment plant, those were found to contribute to the overall release factor only in an insignificant manner (Table 10 in ECHA, 2020). Of the 50 % overall release factor 43% was found to be distributed to agricultural soil via application of biosolids, 7% to surface water via WWTP effluent.

ECHA (2020) did not specify differences in the release factors between different plastic rawmaterials. The results described above are applied in the absence of PVC specific information as EU wide release factors also for the releases of PVC particles entering municipal WWTPs.

Fate of PVC microparticles in the environment

Main fate studies of plastic microparticles were summarised by ECHA (2020b). A lack of fate modelling of plastic microparticles and more specifically of PVC microparticles released to the environment can be highlighted as an information gap. The conclusions of ECHA (2020b) on the very high persistence can be also applied on PVC. The very high persistence of the released PVC microparticles causes an accumulation of PVC microparticles in the environment.

Transport and distribution of PVC microparticles released to the environment can be generally assumed to be analogous to the fate of any plastic particles of the same size and form. Several environmental parameters influence the fate of PVC microparticles in the environment. As PVC has generally a higher density than other plastics, PVC microparticles can be expected to be depositing faster than other plastics of the same size from air to soil and water and in water to sediment and hence to be not distributed as widely as other polymer microparticles.

ECHA (2020) concluded that for intentionally added microparticles the net mass flow after the release from the terrestrial compartment (including run-off from agricultural soils amended with biosolids) is, via freshwater, to the marine compartment, including ocean sediments (Geyer et al., 2017, Kooi et al., 2018, Rochman, 2018). Microparticles disposed to land could remain in the soil, run-off to water or be dispersed by wind (Duis and Coors, 2016). It is likely that very similar outcome would also apply to the plastic microparticle releases from the PVC life-cycle but for slightly different reasons. Analogous to the releases estimated for PVC additives (see section B), the main primary receiving compartment can be expected to be air, followed by soil (via sludge) and water. PVC microparticles could due to their higher density compared to other plastic microparticles of the same size also be expected to be deposited faster from air to soil and water and in water to sediment than other polymer microparticles but other parameters also play a role and make the comparison more uncertain. Further reports containing description of fate of microplastics are, i.a., UNEP (2023), EC (2023b) and UNEP (2018).

Very recently, information on fate and especially long-range transport potential of microplastics and particle-associated substances have been reviewed by UNEP’s Persistent Organic Pollutants Review Committee (UNEP, 2023). The report summarises diverse parameters influencing the long-range transport potential of particles, such as form, size and density, whereas for microplastics additionally, inter alia, the polymer substance, mechanical and (bio)chemical degradability, aggregation and source of the microplastic (e.g., tyre abrasion, textiles) seem to play a role in the distribution and environmental transport mechanisms and measured environmental data. The report also acknowledges uncertainties related to the analytical methods on microplastics.

ECHA (2020b) summarises the observations from many of the monitoring studies that contamination with plastic microparticles will continue to increase into the foreseeable future with the result that exposure of organisms is therefore largely unavoidable and likely to increase in magnitude in the future. It is noted that the data reviewed by ECHA does not highlight specific environmental monitoring findings on PVC but the findings and conclusions are generic to any microplastics.

A recent Canadian review by Hamilton et al. (2022) particularly highlights the uncertainty of knowledge of the origin of plastic additives found in the Arctic. They discuss that on the one hand there are studies indicating that additives may enter the different compartments and biota directly from distant releases of the substances respectively, or they may enter the compartments by leaching from microparticles and that currently it is not possible to identify the origin by a fingerprint the same way as is the case for, e.g., dioxins and furans. The figure below from the authors indicate the findings in Arctic measured data. The review does not discuss PVC specifically. The conclusion which can be drawn from this review and from the studies above for the purpose of this investigation is that measured data and studies to explore the contribution of PVC to the findings on micro- and nanosized plastic particles in the Arctic are only emerging today and that model estimations and measured data on PVC particle fate are needed to understand their contribution to the concentrations of additives found in remote areas (data gap).

PVC has been found in the environment including the Arctic. According to a review of Mishra et al. (2021) PVC has been found in the Arctic in eight studies but also other studies report PVC microparticles in the environment. Further studies (e.g. (Dekiff et al., 2014, Fabbri et al., 2000)) provide evidence of releases of PVC. Although PVC is the third most demanded polymer in Europe, the presence of PVC in marine ecosystems is mainly reported in low percentages in the literature where PE, PP and PS are the major contributors. A recent publication suggests that the presence of PVC might have been underestimated due to analytical challenges but this still remains unclear (Fernández-González et al., 2022).

For this investigation report, no systematic review of measured data of PVC microparticles accumulation in the receiving environments was carried out, and this can be denoted as an analysis gap. Analogous to the conclusion of ECHA (2020b) that microparticles releases cause an accumulation of microparticles in the environment, it can be assumed that PVC microparticles released accumulate in the environment, more specifically in sediment and soil. This has also consequences to the accumulation of the additives contained in the PVC particulates in these compartments (see also further discussion in Appendix B).

ECHA (2020) and EU (2022) did not review environmental measured data of PVC microparticles. Measured evidence on the distribution and environmental concentrations of PVC microparticles should be reviewed in the next steps and can hence be denoted as a data gap (and/or: assessment gap). Further, measured evidence is also recommended to prove a direct link between the use of PVC and the additives found in especially the remote environments. Need for such monitoring data has been requested, e.g., by Hamilton et al. (2022).

Conclusions

At this stage it can be concluded that PVC microparticles can be expected to be released as a result of the various PVC uses in roughly similar or higher quantities in the EU as the total releases of the additives as reported in Appendix B. The releases were not quantified in this project with the exception of releases from recycling sites. Considering the information screened in this project, it can be concluded on a preliminary basis that the EU releases of PVC microparticles are significant. PVC microparticles have been also found in the environment. Even though PVC is the third largest polymer used in Europe, the most abundant microparticles found in the marine environment are PE, PP and PS (Erni-Cassola et al., 2019, Fernández-González et al., 2022). Reasons for this may be various, e.g., PVC may be distributed faster to sediments and soil than other plastics due to its higher density. On the other hand, a recent study suggests also that analytical challenges might have lead to an underestimation of PVC microparticles in environmental samples (Fernández-González et al., 2022). The recent research appears to further support the opinion of ECHA (2020c), that conventional approaches for modelling exposure and long-range transport, which would normally be applied in chemical risk assessment in the absence of information on measured concentrations, are not applicable to microplastics. This applies also to PVC microparticles. Finally, it is noted that PVC microparticles generally contain more additives than other plastics (see section B for further details) and therefore would warrant further studies generating measured data on the levels of PVC microparticles in various environments and on the understanding of PVC microparticles as a carrier of additives (data gap).

A.2.4. Risks from PVC itself

For PVC itself, i.e. without considering the additives, the main sources of potential risk are:

- the starting materials, EDC and VCM, which are released during the production of PVC;

- the generation of PCDD/Fs during the production and during the incineration of PVC waste;
- exposure of workers to PVC dust;
- direct PVC microparticle releases to the environment;
- formation of PVC microparticles in the environment from PVC debris (secondary releases). This element was not covered in the project.

With regard to EDC and VCM, there are BOELs set to protect workers and emission limits set by several BREFs to minimise releases. For PCDD/Fs that might be generated during the production and incineration of waste there are also limits set by several BREFs to minimise releases to the environment. Therefore, it can be concluded that the limit values currently set serve to control the risk from those sources.

The risks from the starting materials and the PCDD/Fs formation, even if controlled, are unique to PVC when compared to the main polymeric alternatives like PE or PP. The manufacturing processes of PE and PP do not involve such hazardous substances nor have an influence in the generation of PCDD/Fs.

With regard to uncompounded PVC dust, there is currently no BOEL available in the EU. Nevertheless, several countries in the EU (Austria, Belgium, Finland, Germany, Hungary, Ireland, Latvia, Spain and Sweden) have set an occupational limit value that ranges from 0.3 mg/m^3 (8h TWA) in Germany for the respirable fraction to 5 mg/m^3 (8h TWA) in Austria with a median of 1 mg/m^3 (Gestis database). This median value is five times lower than the average value for general dust that nearly all countries in the EU have in place. Therefore, some consideration about setting a BOEL for PVC dust might be needed considering the hazardous effects observed (section A.2.2). Nevertheless, it remains unclear whether the effects seen (non-genotoxic pulmonary carcinogenesis) (Girardi et al., 2022, Mastrangelo et al., 2003) are due to PVC in particulate form or from dust itself and a closer evaluation and literature review on the specific effects of PVC via inhalation is needed. Further, it should be noted that it is expected a difference between exposure to uncompounded PVC resin dust and compounded PVC dust due to the micgration and leaching of additives from the PVC microparticles (Zhang et al., 2020).

Risk from microparticles formation is a common issue for all plastics including PVC.PVC microparticle releases can be expected from practically all PVC life-cycle steps and uses. Nevertheless, considering the higher density of PVC, it is expected that PVC microparticles will behave somewhat differently in the environment when compared to other polymeric alternatives, such as PE and PP (Erni-Cassola et al., 2019). Due to the extreme persistence and the analogous/same concerns as described in (ECHA, 2020b), releases of PVC microparticles should be considered as a proxy for risk. It is noted that the PVC microparticle releases have not been fully quantified for the EU. Releases to aquatic environment from recycling plants via municipal waste water treatment plants were estimated based on experimental data and can be considered significant. Overall, the releases of PVC microparticles can be expected to be similar or higher as the total releases of PVC additives (see section B). PVC microparticles have been found in environmental studies which provides further evidence of the releases. Therefore, despite of lack of data and assessment of the total releases of PVC microparticles in the EU, it can nevertheless be concluded that PVC uses cause a risk to the environment due to PVC microparticle releases as one component of the microplastic releases. The risks related to these releases are essentially of non-threshold character in analogy with ECHA (2020b). It is, however, noted that the risks from environmental plastic microparticle exposures cannot be fully differentiated from risks of additives, as the microparticles, in particular PVC microparticles, generally carry additives and effects data on virgin plastic microparticles are rare. UNEP (2018) highlights PVC microplastic exposures as a specific pollution issue due to the generally higher additive load of PVC compared to other plastics.

To summarise, for the risk sources of starting materials, formation of PCDD/Fs and workplace risks of PVC dusts, the risks are under control and have a downward trend considering the exposure and emission limits in place and the current emission trends (for PCDD/Fs). For the microparticle emissions of PVC, the risks are evident and similar to the risks as described in ECHA (2020b). It should be noted that plastic microparticles pollution is already in focus in the Microplastics Initiative under the Plastics Strategy of the European Commission[2]. This initiative aims to address the presence in the environment of unintentionally released microplastics from, i.a., tyres, textiles and plastic pellets (see further details in section A.2.3.4 and in the main report). .

There is currently no possibility to compare whether the risks would be more severe from PVC microparticles than other polymer microparticles. Hence, we note that these risks are not specific to PVC with the current state of knowledge but rather generic to all plastics. This conclusion applies for the PVC itself, in isolation of the risks from the additives. A difference between effects of exposure to uncompounded PVC resin dust and compounded PVC dust can be expected due to the migration and leaching of additives from the PVC microparticles (Zhang et al., 2020). Furthermore, soft PVC needs higher concentrations of additives compared to alternative plastics. Contribution of soft PVC via microparticle releases in particular to the co-exposures of additives is proportionally higher than for alternative plastics and for rigid PVC. Analysis and data gaps are noted for understanding the differences of the weathering, distribution and effects of PVC and other polymer microparticles in and to the environment. The risks arising from the releases of additives in PVC (see Appendix B) have been a focus of more detailed risk screening.

A.2.5. Comparative analysis with alternative materials

The main alternative plastics to PVC across all uses are polypropylene (PP) and polyethylene (PE) (see Appendix C). The main sources of (potential) risk outlined above will be assessed in the context of the alternative plastics to PVC.

- Exposure/release of hazardous starting materials in the polymer production

  Polyethylene and polypropylene are produced by chain polymerisation from ethylene (EC 200-815-3) and propene (EC 204-062-1) respectively in the presence of a catalyst. Both substances are classified for physicochemical hazards, but they are not hazardous for human health or the environment (Table 8), unlike EDC and VCM which are used in the production of PVC.

Table 8. Harmonised classification for ethylene and propene according to the CLP regulation 1272/2008

EC	CAS	Substance name	Index No.	Harmonised classification
200-815-3	74-85-1	Ethylene	601-010-00-3	Press. Gas Flam. Gas 1 (H220) STOT SE 3 (H336)
204-062-1	115-07-1	Propene	601-011-00-9	Press. Gas Flam. Gas 1 (H220)

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[2] https://environment.ec.europa.eu/topics/plastics/microplastics_en

Other materials identified as alternatives in Appendix C may also have potential risks associated to the polymer production. For instance, the manufacturing of polystyrene requires the use of hydrocarbons such as styrene and benzene, in the manufacturing of polyurethane there is a risk of exposure to diisocyanates.

- Generation of PCDD/Fs during the production and during the incineration of polymer waste

  Considering the starting materials, it is highly unlikely that the production process of both polyolefins could generate PCDD/Fs. Since the presence of chlorine is necessary for the generation of PCDD/Fs, the incineration of polyolefins in the absence of a chlorine source will not render PCDD/Fs. However, an incomplete combustion of the polyolefins with other municipal solid wastes (which might contain chlorine) may produce PCDD/Fs (Yao et al., 2022). No other side products with similar hazards as PCDD/Fs are generated during production or incineration of polyolefins.

  In Appendix C chlorinated polyethylene was also identified as a potential alternative material. That material would share the risk of generation of PCDD/Fs.

- Exposure of workers to polymer dust

  As described in section A.2.2, some epidemiology data suggest that PVC dust might promote non-genotoxic pulmonary carcinogenesis although it cannot be clearly differentiated whether the cause of the effects has been PVC microparticles or dust itself. Also, effects from addtives in compounded PVC dust cannot be disregarded due to the migration and leaching of additives from the PVC microparticles. Conventional warnings related to generic dust properties are used also for PVC dust based on several safety data sheets available publicly.

  No indication of hazard was found in literature for polyethylene or polypropylene dust. In the safety data sheets for polyethylene and polypropylene it is only referred to minor irritation to the respiratory tract.

  In the case of polyurethane dust and polystyrene dust, which might be alternative materials in some uses, irritation of the respiratory tract has been identified.

- Releases of microparticles to the environment

  As mentioned in section A.2.4, risk from microparticles formation is a common issue for all plastics. Nevertheless, it is expected that PE and PP microparticles will behave somewhat differently in the environment when compared to PVC considering the higher density of the latter. However, the actual differences in fate are highly uncertain as diverse other factors also influence the fate of plastic microparticles (see section A.2.3.4). Although PVC is the third most demanded polymer in Europe, the presence of PVC in marine ecosystems is mainly reported in low percentages in the literature where PE, PP and PS are the major contributors. A recent publication suggests that the presence of PVC might have been underestimated due to analytical challenges (Fernández-González et al., 2022) but this still remains unclear. There is currently no possibility to compare whether these risks would be more severe from PVC microplastics than other polymer microparticles.

To conclude, only the risk due to microparticles releases is common to the alternative plastics to PVC, although the behaviour in the environment can be expected to be slightly different according to the current level of information.

A.3. Key uncertainties, assumptions and data gaps

Please, refer to section A.1.

B. Substances used as additives in PVC

B.1. Substances currently used as additives in PVC

The starting point to establish a list of substances that are currently used as additives in PVC was Annex 2.2 to the report "The use of PVC in the context of a non-toxic environment" (EC, 2022). In that annex, there is a list of ca. 370 substances that was compiled using the results for the Plastic Additives Initiative (PLASI) and the results from other studies and reports available to the contractor.

A targeted call for evidence was organised towards key PVC supply chain industry associations in July-September 2022 (see Appendix E for details) to verify and complement the list of additives. Several substances were identified as never used in PVC or phased out and several other substances were added to the list. After this exercise, ca. 470 substances were identified as additives currently used in PVC (ECHA, 2023a). The number of substances and their main functions can be seen in Figure 8.

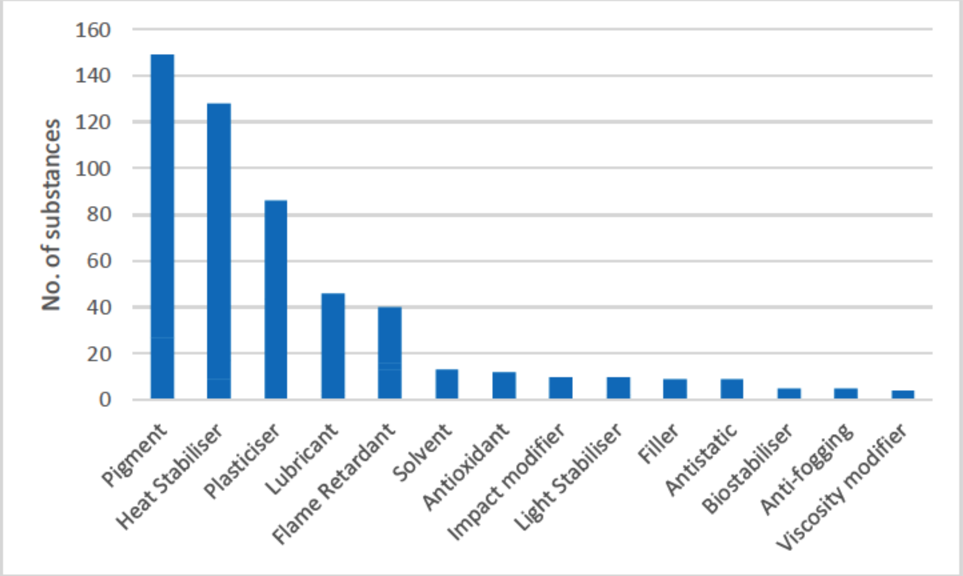

Figure 8. Main functions of substances currently used as PVC additives

A list of substances that are considered legacy substances was also compiled for further assessment of the situation and for estimating their implications in the recycling activities of PVC (see details in Appendix F).

Based on the information received in the targeted call for evidence and the data available in the PLASI project, it was possible to identify the use of the substances per function by type of PVC or in other polymers (Table 9).

Table 9. Use of PVC additives in types of PVC and alternative polymers

Function	Type of PVC	Used in other polymers
Pigment	Rigid and soft	Yes
Heat stabiliser	Rigid and soft	Mostly not
Plasticiser	Soft	Yes
Lubricant	Rigid and soft	Yes
Flame retardant	Soft	Yes
Solvent	Rigid and soft	No
Antioxidant	Rigid and soft	Yes
Impact modifier	Rigid and soft	Mostly not
Light stabiliser	Rigid and soft	Yes

Thus, plasticisers and flame retardants were mainly identified for the use in soft PVC and most of the substances/functions are also used in other polymers with the exception of heat stabilisers and impact modifiers.

B.2. Substance prioritisation

The substances that were confirmed to be currently in use in PVC were prioritised for further work in this investigation report considering the following aspects: hazard scoring and release potential. Several substances confirmed by the stakeholders to be currently in use were, however, excluded, because they were undergoing the final stages of regulatory decision process towards regulatory risk management.

B.2.1. Hazard scoring

A hazard scoring system was developed comprising of a hazard scoring criterion related to human health and environmental hazards and a scoring criterion related to the level of certainty of the hazard.

Criterion 1: hazards

For the purposes of the current prioritisation, we identified (a) hazard(s) for a substance when confirmed in a regulatory process or considered as potential hazard(s) as provided in at least one of the following sources:

- List of SVHC under REACH
- Harmonised classification under CLP
- Self-classification by any registrant
- CLP notification if the majority (≥50 %) of CLP notifiers proposed classification for the endpoint
- Assessments of regulatory needs (ARN)
- ROI intentions for CLH and SVHC
- On-going evaluation of a substance (RMOA, PBT, PMT, ED etc.) according to internal data and ACT database

The **human health** hazard properties and their scoring are as follows:

1. Score: **3 points** for each

- Carc. cat. 1A or 1B
- Muta. cat. 1A or 1B
- Repr. cat. 1A or 1B
- Resp. Sens. cat. 1 or 1A or 1B
- STOT RE cat. 1
- Endocrine disruptor (ED) for human health

2. Score: **2 points** for each
    - Carc. cat. 2
    - Muta. cat. 2
    - Repr. cat. 2
    - STOT RE cat. 2
3. Score: **1 point** for each
    - Skin Sens. cat. 1 or 1A or 1B

If a substance has one or more CMR cat. 1 then any CMR cat. 2 is ignored for the same substance, not only on the same endpoint, but for CMR in general. This is also applied even when CMR cat. 2 properties are of a higher certainty (e.g. CLH) than a potential CMR 1 property of lower certainty (e.g. self-classification). The maximum theoretical score for human health is 19 (6*3 + 1).

The **environmental** hazard properties and their scoring are as follows:

4. Score: **3 points** for each
    - Endocrine disruptor for the **environment**
    - PBT and/or vPvB substance
    - PMT and/or vPvM substance
5. Score: **1 point** for
    - Long term (chronic) aquatic hazard: category 1 (H410: Very toxic to aquatic life with long lasting effects)

A substance can only be either PBT/vPvB or PMT/vPvM for the purpose of the scoring. For the source RMOA inventory, the endpoint ‘aquatic toxicity’ for simplification was interpreted as hazard for aquatic chronic 1. The maximum score for environment is 7 (2*3+1).

The selected scoring method emphasizes human health hazards over environmental hazards, because for human health more hazard classes are included in the scoring system than environmental classes. This uneven weighing is reflected in the maximum possible score. This is more than two times higher for human health (19) than for environment (7). Therefore, to outweigh the potential bias, the environmental hazard score is multiplied by the factor 2. It is noted that this is a pragmatic approach and a total, well balanced equalisation is not pursued.

Criterion 2: Level of certainty of the hazard

Each individual hazard within the scope that was identified through the previously listed sources, receives an individual score based on the certainty that is attributed to the respective source that points out a hazard and the assessment status of the substance. The criterion 2 score is summed to the hazard score. The category definition and the scoring are provided in Table 10. The maximum possible score for this criterion is 3 points.

Table 10. Categories and their descriptions

Categories	Description
1. Sources / assessments with a very high level of certainty Score: **3 points**	A hazard was considered to have a very high level of certainty if it is included in any of the following: – The candidate list or formally proposed for SVHC identification. – Annex VI to CLP Regulation or adopted opinions on CLH by RAC for those not yet in the CLP Regulation. – Annex I, III, IV and V to Regulation (EC) 850/2004 or Annex A, B, C of the Stockholm convention.
2. Sources / assessments with a high level of certainty Score: **2 points**	A hazard was considered to have a high level of certainty if not listed under the category 1 above but it is included in any of the following: - Registry of intention (RoI) for SVHC or CLH. - List for confirmed ED or PBT/vPvB substances in the ACT database.
3. Sources / assessments with a medium level of certainty Score: **1 point**	A hazard was considered to have a medium level of certainty if not listed under the categories 1 and 2, if any of the following applies: - RMOA in progress or confirmed in the conclusion. - Potential hazard identified in an Assessment of Regulatory Needs (ARN). - Currently under PBT/vPvB or ED assessment according to the ACT database. - Submitted as self-classification by registrants.
4. Sources / assessments with a low level of certainty Score: **0 points**	A substance was considered to be of low certainty if not listed under the categories 1, 2 or 3.

The results obtained applying the scoring system described above were then aggregated by main function to identify the main functions with higher number of substances with high scores (Table 11). In Table 11 only the functions with the highest number of substances are shown.

Table 11. Number of substances per hazard score and main function

Main function	High score	Medium score	Low score
Plasticiser	28	18	29
Pigment	18	20	118
Flame retardant	10	6	16
Heat stabiliser	9	17	71

Lubricant	5	2	29
Antioxidant	3	3	6
Solvent	0	0	13
Impact modifier	0	0	9

High score: >11 points, Medium score: 5-11 points, Low score: <5 points

B.2.2. Release potential

The screening method developed in the plastic additives initiative (PLASI) was used for comparing the relative release potential (ECHA, 2023b). This screening method was developed between ECHA and Industry to enable the identification of plastic additives that should be prioritised for assessment in the light of available hazard data.

Qualitative considerations were applied in the comparison following the screening method developed in PLASI. Thus, for pigments having very low solubility in water and octanol, a low release potential is assumed by default. Also, additives where the release behaviour is uncertain, such as those with charged migrants, were also excluded from the comparison.

The results obtained applying the screening method for the substances with enough data to make the calculation and not excluded are shown in Table 12. In Table 12 functions with a low number of substances are not shown.

Table 12. Number of substances per release potential score per main function

Main function	High score	Medium score	Low score
Plasticiser	26	33	2
Heat stabiliser	9	26	25
Solvent	4	3	0
Flame retardant	1	6	1
Light stabiliser	1	2	5
Lubricant	0	3	15
Antifogging	0	3	0
Antioxidant	0	0	8

It should be noted, that the release potential scoring is not a direct quantitative surrogate on how long a certain fraction (e.g., 50 % w/w) of the additive remains in the plastic.

B.2.3. Prioritised functions and groups of substances

The functions to further focus the work were selected by considering the functions containing the higher number of substances with higher hazard and release potential scores. They include plasticisers, heat stabilisers and flame retardants.

The substances belonging to those functions with high and medium scores where further assessed and a subset of substances was selected considering if a (potential) hazard as CMR 1A or 1B, STOT RE 1, ED and/or PBT/vPvB was identified. Nevertheless, an extension to the selection criteria was made with the aim of considering the additives in the context of groups of structurally related substances an extension to the selection criteria was made. For those substances with high and medium scores, groups of substances were identified (e.g. terephthalates). Substances belonging to those groups were also considered even if not scoring high or medium (e.g. DOTP).

This resulted in a total of 63 substances covered under Appendices 0, B.4 and B.5.

The rest of the substances belonging to heat stabilisers, plasticisers and flame retardants identified as currently being used in PVC (Section B.1) are considered of low concern at the time of writing.

It is noted that with regard to the hazard assessment of the prioritised substances a meta-analysis was performed using the results from previous assessments including the assessment of regulatory needs (ARN) for groups of substances and, at this point, it is considered sufficient. Further hazard assessment including all endpoints may be done if further regulatory work is needed.

B.3. Heat stabilisers: information on properties and hazard

Heat stabilisers are substances that are added to polymers to inhibit or retard their thermal degradation. These are mostly used for PVC since it is particularly sensitive to thermal degradation because of its structure (Yu et al., 2016). Consequently, the onset temperature of PVC decomposition is much lower than for other plastics as it can be seen in Figure 9 below.

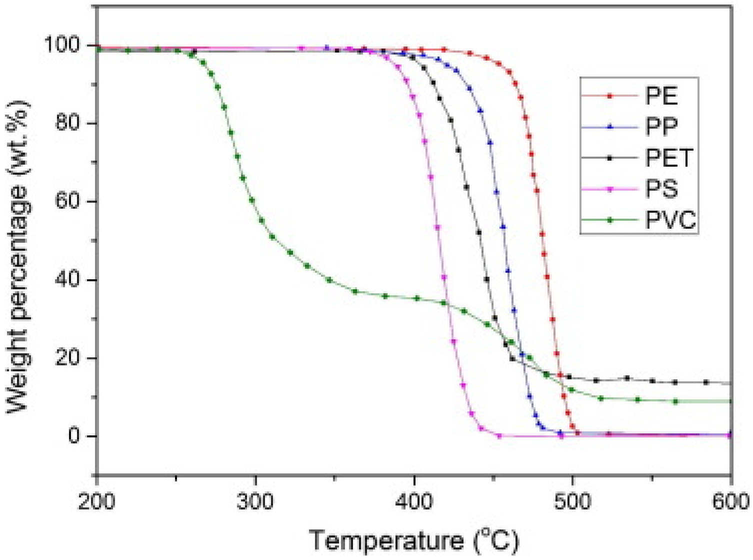

Figure 9. Analysis of the pyrolysis for several plastics at 10 Kmin-1
Source: (Yu et al., 2016)

In general, heat stabilisers can be grouped into metal-free stabilisers and metal-based stabilisers. Nevertheless, metal-based stabilisers are usually used as the primary thermal stabiliser since the ligand part of the stabiliser replaces the labile chlorine atom in the PVC resin and the metal part reacts with the chlorine to form the metal chloride.

In the past cadmium substances and lead substances were used as stabilisers in PVC. Cadmium-based stabilisers were voluntarily phased out by the PVC industry (ECVM, 2000) in the European Union and their uses have also been restricted (ECHA, 2012b). Since 2000 lead-based stabilisers have been gradually replaced by the PVC industry as part of the voluntary commitment (ECVM, 2000) and were phased-out in the European Union and replaced in 2015. The use of lead substances in PVC is also restricted (EU, 2023a).

Currently, the PVC industry in Europe has moved almost entirely to the use of mixed metal stabiliser systems which are mostly Zn and Ca soaps of fatty acids (metal carboxylates). In these systems Zn compounds are the primary stabilisers which are blended with Ca compounds (secondary stabilisers) to mitigate the degradation that the formed Lewis acid

$ZnCl_2$ can exert on the polymer. Thus, Ca compounds will react with $ZnCl_2$ to form $CaCl_2$ which is relatively inert. The mixed metal stabiliser systems (e.g. Zn/Ca soaps) are not further discussed in this section as the substances belonging to this group were not identified as priority substances in section B.2 (low hazard at the time of writing).

Organotin substances have also been widely used in PVC application but currently their use in Europe has been reduced to specific applications where transparency and/or higher stabilising performance is needed.

Following the prioritisation in section B.2, a total of 21 substances used as heat stabilisers were prioritised for further assessment. They can be grouped into the following groups: organotin substances, triphenylphosphite derivatives, mono- and diphenylphosphite derivatives, phenyl 1,3-diones and others.

Table 13. Heat stabilisers prioritised for further assessment

Group	EC	CAS No.	Substance name
Organotin substances	239-622-4	15571-58-1	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DOTE**)
	239-581-2	15535-79-2	2,2-dioctyl-1,3,2-oxathiastannolan-5-one (**DOTTG**)
	248-227-6	27107-89-7	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**MOTE**)
	222-883-3	3648-18-8	dioctyltin dilaurate (**DOTDL**)
	260-829-0	57583-35-4	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DMTE**)
	268-500-3	68109-88-6	Ethyl 9,9-dioctyl-4,7,11-trioxo-3,8,10-trioxa-9-stannatetradeca-5,12-dien-14-oate (**DOT-MalEt**)
	261-645-3	59185-95-4	DioctylTin di(2ethylhexylmercaptopropionate)
	234-186-1	10584-98-2	2-ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DBTE**)
	233-117-2	10039-33-5	2-ethylhexyl 14-ethyl-6,6-dioctyl-4,8,11-trioxo-5,7,12-trioxa-6-stannaoctadeca-2,9-dienoate
	260-828-5	57583-34-3	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**MMTE**)
Phosphites	247-777-4[1]	26544-23-0	Isodecyl diphenyl phosphite
	247-759-6	26523-78-4	Tris(nonylphenyl) phosphite
	202-908-4	101-02-0	Triphenyl phosphite
	700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters
	247-098-3	25550-98-5	Diisodecyl phenyl phosphite
	239-716-5[2]	15647-08-2	2-ethylhexyl diphenyl phosphite
	267-466-7	67874-37-7	Diisotridecyl phenyl phosphite
Phenyl 1,3-diones	204-398-9	120-46-7	1,3-diphenylpropane-1,3-dione
	915-316-2	-	Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione
Others	300-141-0	93922-04-4	barium 4-dodecylphenolate
	800-029-6	1290049-56-7	Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated

B.3.1. Organotin substances

Ten organotin substances were initially identified by industry stakeholders as currently used in PVC (Section B.1). Those substances can be seen in Table 14 below.

These substances can be differentiated between mono- and dialkyltin substances (the alkyl groups are octyl, methyl or butyl) and whether the ligand is a carboxylate (tin carboxylates) or a mercaptide (tin mercaptides). Tin mercaptides are the most efficient heat stabilisers (ESPA, 2023).

B.3.1.1. Manufacture and uses

Organotin stabilisers are normally manufactured from the mono- and/or dialkyltin chloride and the ligand in a closed, continuous running process.

Contrary to North America, where tin systems are used for almost all rigid PVC applications, the main usage in Europe is for rigid PVC in transparent applications and/or where higher stabilising performance is needed (ESPA, 2023). Organotin compounds represent now 6 % of the total stabilisers being used in the EU and the rest corresponds almost entirely to Zn and Ca soaps of fatty acids (solid or liquid stabilisers) (CfE3,#1708). However, there is an uncertainty related to the tonnage imported in articles.

Table 14. Organotin substances identified as currently used in PVC

EC No	CAS No	Substance name	Aggregated tonnage band	Active registrants
239-622-4	15571-58-1	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DOTE**)	1 000-10 000	5
239-581-2	15535-79-2	2,2-dioctyl-1,3,2-oxathiastannolan-5-one (**DOTTG**)	0	0
248-227-6	27107-89-7	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**MOTE**)	1 000-10 000	4
222-883-3	3648-18-8	dioctyltin dilaurate (**DOTDL**)	100-1 000	6
260-829-0	57583-35-4	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DMTE**)	1 000-10 000	15
268-500-3	68109-88-6	Ethyl 9,9-dioctyl-4,7,11-trioxo-3,8,10-trioxa-9-stannatetradeca-5,12-dien-14-oate (**DOT-MalEt**)	100-1 000	3
261-645-3	59185-95-4	DioctylTin di(2ethylhexylmercaptopropionate)	10-100	1
234-186-1	10584-98-2	2-ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DBTE**)	10-100	4
233-117-2	10039-33-5	2-ethylhexyl 14-ethyl-6,6-dioctyl-4,8,11-trioxo-5,7,12-trioxa-6-stannaoctadeca-2,9-dienoate	10-100	2
260-828-5	57583-34-3	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**MMTE**)	1 000-10 000	12

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation.

According to the information provided in the CfE2 and CfE3, from the 10 organotin substances identified as currently being used in PVC only 5 organotin substances may actually be in use in EU: primarily DOTE, MOTE, DMTE and MMTE and in lower quantities DOT-MalEt. Nevertheless, DOTTG was also identified for several applications and quantitative data was provided for pipes and pipe fittings (CfE2,#1596). This seems to contradict the registration status under REACH, since no registrants for that substance are currently active. In any case, it was considered for the purpose of hazard and exposure assessment and risk characterisation.

The registrations dossiers do not provide information on the tonnages in articles (REACH Art. 7(1) and (5)). However, according to ESPA, by far the largest use of organotin compounds is in the stabilisation of PVC (ESPA, 2023) and the information available in the registration dossiers for those substances seems to be in line.

Among the PVC applications under study, organotin substances are mainly used in rigid packaging (food and non-food packaging and blister packs). In addition, from the information collected in the calls for evidence they seem to also be used in:

- window frames: the use of organotin substances seems to be limited to the edge bends, nevertheless considering the volume of PVC in this application, it constitutes the second largest use of these substances.
- pipes and pipe fittings: the information collected in the calls for evidence indicate that they are limited to the use in pressure pipe fittings.
- monofilament profiles in the automotive sector: for the purpose of this investigation report it is assumed to be in car interior.

B.3.1.2. Information on physicochemical properties and hazard

B.3.1.2.1. Physicochemical properties

The organotin substances that are actually used are mainly mono-constituent substances and the physicochemical properties were provided by the registrants in the registration dossiers. Nevertheless, it should be noted that DOTE can be present as an impurity in MOTE up to 10 %. Key physicochemical properties are summarised in Table 15.

Table 15. Key physicochemical properties for organotin substances

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
239-622-4	15571-58-1	DOTE	752	0.00025	1.0E-09	8
239-581-2	15535-79-2	DOTTG	435.2	0.0009804	0.156	4.63
248-227-6	27107-89-7	MOTE	842	0.00287	1.91E-12	14.42
260-829-0	57583-35-4	DMTE	555	0.81	4.51	4.74
268-500-3	68109-88-6	DOT-MalEt	631	0.13	1.19	6.5
260-828-5	57583-34-3	MMTE	744	0.38	2.16	5.06

Source: ECHA dissemination portal consulted on 8 March 2023

B.3.1.2.2. Classification and labelling

Among the organotin substances that are used in PVC applications, DOTE, DMTE and MMTE have a harmonised classification.

Table 16. Harmonised classification for DOTE, DMTE and MMTE according to the CLP Regulation 1271/2008

EC	CAS No.	Substance name	Index No.	Harmonised classification
239-622-4	15571-58-1	DOTE	050-027-00-7	Repr. 1B (H360D) STOT RE 1 (H372, immune system) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

EC	CAS No.	Substance name	Index No.	Harmonised classification
260-829-0	57583-35-4	DMTE	050-028-00-2	Acute Tox. (4 H302) Repr. 2 (H361d) STOT RE 1 (H372, nervous system; immune system) Skin Sens. 1A (H317)
260-828-5	57583-34-3	MMTE	050-026-00-1	Repr. 2 (H361d)

For MOTE and DOT-MalEt the classification provided in the registration dossiers is shown in Table 17 below.

Table 17. Classification provided in the registration dossiers for MOTE and DOT-MalEt

EC	CAS No.	Substance name	Classification
248-227-6	27107-89-7	MOTE	Aquatic Chronic 3 H412*
268-500-3	68109-88-6	DOT-MalEt	Repr. 2 H361 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT RE 1 (H372, thymus)

Source: ECHA dissemination portal consulted on 15 February 2023

*Registrations also include compositions which contain DOTE up to 25 % (w/w) and thus classification for DOTE would apply if the concentration is equal or above 0.3 % (w/w).

Classifications were also notified for DOTTG as shown below.

Table 18. Notified classifications for DOTTG under Art. 40 of the CLP Regulation 1272/2008

EC	CAS No.	Substance name	Notified classification and number of notifiers
239-581-2	15535-79-2	DOTTG	Repr. 2 (H361d) [1 out of 4] STOT RE 1 (H372) [1 out of 4] STOT RE 2 (H373) [1 out of 4] STOT SE 2 (H371) [1 out of 4] STOT SE 2 (H371, immune system) [1 out of 4] Aquatic Chronic 4 (H413) [2 out of 4]

Source: ECHA dissemination portal consulted on 15 February 2023

B.3.1.2.3. Human health hazard assessment

In general, , organotin substances display developmental toxicity and some are classified as Repr. 1A or 1B (DOTE and reaction mass of DOTE and MOTE). Although MOTE (EC 248-227-2) seems to be currently of no concern it should be noted that MOTE is still under data generation and the registrants have not responded yet to ECHA's request for testing data.

Further, several of them display neurotoxicity and/or immunotoxicity (Table 16 and Table 17). An assessment of regulatory needs for this group of substances is currently on going in ECHA but results are not yet available.

Considering the structural similarity and the toxicological profile of these substances, it might be possible that they share a similar mode of action and thus, an additive effect in cases of co-exposure. However, at this moment, this remains unclear for now.

In addition to the hazards described in the classification of the substances above, potential for endocrine disrupting properties are currently under assessment.

An assessment of regulatory needs for this group of substances is currently on-going in ECHA but results are not yet available.

B.3.1.2.4. PBT and vPvB assessment

Based on the information available in the registration dossiers, all substances are (potentially) P or vP.

With regard to bioaccumulation, most of the data available are from QSAR predictions and/or read-across adaptations to the only two studies available for DOTE and DOTO. Both studies show that the substances are not bioaccumulative. However, RAC considered the study with DOTE and the experimental data in the study with DOTO is not conclusive.

An assessment of regulatory needs for this group of substances is currently on-going in ECHA but results are not yet available.

B.3.1.2.5. Summary of existing legal requirements

SVHC

There are two substances identified as SVHC among the organotin compounds for Repr. 1B (H360D): DOTE (EC 239-622-4) and DOTDL (222-883-3).

Companies have legal obligation resulting from the inclusion of substances in the Candidate List. Based on the received Substances in Articles notifications, there are indications for of the presence in articles for both.

Authorisation list

From the substances above only DOTE and the reaction mass of DOTE and MOTE (not registered) are included in the Authorisation List (Annex XIV or the REACH Regulation) with the sunset date set on 01 May 2025.

It is important to note that certain uses are generically exempt from authorisation if the substance is only identified for human health hazards. Those uses are:

- Use in cosmetic products (Art. 56(5)(a) REACH)
- Use in food contact materials (Art. 56(5)(b) REACH)
- Use in medical devices (Art. 60(2) and 62(6) REACH)

Applications for Authorisation (AfA) are expected to be received in H2 2023 (latest application date is 01 November 2023).

Restrictions

Some organotin compounds are restricted under REACH. Below a brief overview of relevant entries in REACH Annex XVII:

- Entry 20: organotin substances cannot be placed on the market as a biocide in free association paints, to prevent the fouling by micro-organisms, plants or animals of crafts, appliances or equipment used in water or for the treatment of industrial waters.

  In addition, dibutyltin compounds cannot be used in concentrations higher than 0.1 % (w/w) in mixtures and articles for supply to the general public and dioctyltin compounds (e.g. DOTE, DOT-MalEt) cannot be used in concentrations higher than

0.1 % (w/w) in the following articles for supply to, or used by, the general public: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies and RTV-2 moulding kits.

- Entry 30 (organotin substances with a harmonised classification as Repr. 1A or 1B, e.g. DOTE): Placing on the market restricted for supply to general public at or above the specific or the generic concentration limit as substances, constituent of other substances or mixtures.

Regulation (EU) 10/2011 'Food Contact Materials'

DOTE, MOTE, DMTE, MMTE, DOTTG, DOTDL and substance EC 233-117-2 are included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU Regulation 10/2011).

B.3.1.2.6. Assumptions and uncertainties

Not applicable.

B.3.2. Mono-, di- and triphenylphosphite derivatives

Seven mono-, di- and triphenylphosphite substances were initially identified by industry stakeholders as currently used in PVC (Section B.1). Those substances can be seen in Table 19 below.

These substances are triesters of phosphorous acid and they can be differentiated between mono-, di- and triphenyl substituted phosphites. For mono- and diphenyl substituted phosphites the other esters are alkylated.

B.3.2.1. Manufacture and uses

Phosphites are phosphorous acid esters with three ester groups which can include phenyl, alkyl, or alkylphenyl groups.

The triphenylphosphite derivatives are manufactured in batches by reacting phosphorus trichloride with the corresponding phenols. Mono- and diphenylphosphite derivatives are manufactured by a catalysed transesterification of a triphenylphosphite derivative. Excess phenols are then removed via distillation.

Even though the substances in Table 19 were identified by industry stakeholders (Section B.1) only two substances have active registrants under REACH: EC 202-908-4 and 700-485-5. Nevertheless, it is important to note that EC 247-098-3 has been adapted to List No. 701-374-4 (100 to 1 000 tpa, 7 active registrants), the registrants for substance EC 247-777-4 have moved to joint submission for substance List No. 701-341-4 (100 to 1000 tpa, 7 active registrants) and the registrants for substance EC 239-716-5 have moved to the joint submission for substance List No. 905-728-0 (100 to 1 000 tpa, 2 active registrants).

Table 19. Mono-, di- and triphenylphosphite substances identified as currently used in PVC

EC No	CAS No	Substance name	Aggregated tonnage band	Active registrants
247-777-4[1]	26544-23-0	Isodecyl diphenyl phosphite	0	0
247-759-6	26523-78-4	Tris(nonylphenyl) phosphite	0	0
202-908-4	101-02-0	Triphenyl phosphite	100-1 000	15
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	1 000-10 000	2
701-374-4 (247-098-3)	25550-98-5	Diisodecyl phenyl phosphite	100-1 000	10
239-716-5[2]	15647-08-2	2-ethylhexyl diphenyl phosphite	0	0
267-466-7	67874-37-7	Diisotridecyl phenyl phosphite	0	0

Source: ECHA dissemination portal consulted on 15 February 2023

Note: all the substances with active registrants are registered under REACH following Art. 10 of the REACH Regulation.

[1] Registrants for substance EC 247-777-4 have moved to the joint submission for substance List No. 701-341-4

[2] Registrants for substance EC 239-716-5 have moved to the joint submission for substance List No. 905-728-0

Based on the information available in the registration dossiers the main uses of these substances are in polymeric preparations, adhesives/sealants and coatings and paints.

From the information provided in the CfE2 the use of this group of substances was only explicitly identified for window frames and automotive uses. Nevertheless, it was not possible to quantify the volumes in the absence of further information (Table 20).

Table 20. Reported use of mono-, di- and triphenylphosphite substances in CfE2

EC No	CAS No	Substance name	Window frames[3]	Automotive[4]
247-777-4[1]	26544-23-0	Isodecyl diphenyl phosphite	X	X
247-759-6	26523-78-4	Tris(nonylphenyl) phosphite		X
202-908-4	101-02-0	Triphenyl phosphite		X
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters		
701-374-4 (247-098-3)	25550-98-5	Diisodecyl phenyl phosphite	X[5]	X[5]
239-716-5[2]	15647-08-2	2-ethylhexyl diphenyl phosphite		X
267-466-7	67874-37-7	Diisotridecyl phenyl phosphite	X[5]	

[1] Registrants for substance EC 247-777-4 have moved to the joint submission for substance List No. 701-341-4

[2] Registrants for substance EC 239-716-5 have moved to the joint submission for substance List No. 905-728-0

[3] (CfE2,#1602)

[4] (CfE2,#1595)

[5] Not in use anymore (CfE3,#1620)

However, during the CfE3 the use of EC 247-759-6 was identified to be used in some PVC formulations related to medical applications (CfE3,#1628) with a typical loading of 0.14 % (w/w). However, as mentioned earlier there are no active registrants under REACH for that substance.

Further, during CfE3 one notifier indicated that substance EC 247-098-3 and 267-466-7 are not used anymore (CfE3,#1620).

Zn/Ca carboxylates are the main heat stabilisers used in the PVC applications considered in this report. Information available in the Baerlocher's website[3] refer to the use of

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[3] https://www.baerlocher.com/products/pvc-stabilizers/liquid-mixed-metal-stabilizer/

organophosphite substances together with Zn/Ca stabilisers for an 'optimal performance' and thus, suggesting that the uses of these substances may not be limited to two sectors/applications only. Further, according to the Phosphites Stabilisers REACH Consortium (CfE2,#1610) phosphites are used in polymers, including PVC, as antioxidants by bonding with oxygen radicals in the polymer to chemically convert to phosphates. It is also indicated that they are typically used at concentrations below 1 % but this can vary and in PVC it ranges from 0.5 to 1 % (w/w). Finally, some notifiers in the CfE3 (#1680 and #1707) indicated that organophosphites are mostly used in plastics other than PVC: PE, PP, PEX, PUR.

B.3.2.2. Information on physicochemical properties and hazard

B.3.2.2.1. Physicochemical properties

The mono-, di- and triphenylphosphite derivatives with active registrants are mostly UVCB substances with the exception of triphenyl phosphite. In addition, substances List No. 701-341-4 and 905-728-0 contain triphenyl phosphite in relevant concentrations.

Table 21. Key physicochemical properties for organotin substances

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
202-908-4	101-02-0	Triphenyl phosphite	310	0.069	0.3	6.62
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	625.5	1.6E-08	0.1	6.58
701-341-4	-	Reaction products of triphenyl phosphite and isodecanol (1:1)	374.5	0.00000698	0.00023	8.52
701-374-4 (247-098-3)	-	Reaction products of triphenyl phosphite and isodecanol (1:2)	438.6	0.00000698	0.00023	8.52
905-728-0	-	Reaction mass of 2-ethylhexyl diphenyl phosphite and bis(2-ethylhexyl) phenyl phosphite and triphenyl phosphite	310-382.5	0.000548	0.00238	8.52

Source: ECHA dissemination portal consulted on 8 March 2023

B.3.2.2.2. Classification and labelling

Among these substances only triphenyl phosphite has a harmonised classification.

Table 22. Harmonised classification for triphenyl phosphite according to the CLP Regulation 1271/2008

EC	CAS No.	Substance name	Index No.	Harmonised classification
202-908-4	101-02-0	Triphenyl phosphite	015-105-00-7	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

For the other substances the classification provided in the registration dossiers is shown in Table 23 below.

Table 23. Classification provided in the registration dossiers for other organophosphites

EC	CAS No.	Substance name	Classification
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	Not classified
701-341-4	-	Reaction products of triphenyl phosphite and isodecanol (1:1)	Skin Sens. 1 (H317) STOT RE 2 (H373, nervous system) Aquatic Chronic 2 (H411)
701-374-4 (247-098-3)	-	Reaction products of triphenyl phosphite and isodecanol (1:2)	Skin Sens. 1 (H317) Aquatic Chronic 3 (H412)
905-728-0	-	Reaction mass of 2-ethylhexyl diphenyl phosphite and bis(2-ethylhexyl) phenyl phosphite and triphenyl phosphite	Skin Sens. 1 (H317) Aquatic Chronic 2 (H411)

Source: ECHA dissemination portal consulted on 15 February 2023

B.3.2.2.3. Human health hazard assessment

This assessment is based on the assessment of regulatory needs (ARN) for triphenylphosphites[4] and mono- and diphenylphosphite derivatives[5].

In those reports it is identified that:

- Triphenyl phosphite: after substance evaluation (UK, 2019) it was recommended that a CLH proposal for Skin Sens. 1A (H317) and STOT RE 2 (H373, nervous system) should be proposed. Nevertheless, in the ARN it was identified a data gap for a 90-day repeated-dose toxicity study and that data could justify a more stringent classification as STOT RE 1.

- EC 700-485-5: potential endocrine disrupting properties were identified for this substance based on alkyl phenol impurities with ED properties (4-tert-pentylphenol and 2,4-di-tert-pentylphenol) and a potential hydrolysis to those substances. Nevertheless the rate of hydrolysis is unclear due to lack of data that is currently subject of compliance check. However, the Phosphites Stabilisers REACH Consortium (CfE2,#1610) stated that phosphites will typically hydrolyse rapidly upon exposure to water due to breaking of the ester bonds.

For the other substances no further findings were identified.

Based on this data it seems that skin sensitisation is a concern for triphenyl phosphites. Further, triphenyl phosphite is potentially a neurotoxicant that could be classified as STOT RE 1 and substance EC 700-485-5 may have endocrine disrupting properties based on impurity and potential hydrolysis to those.

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[4] https://echa.europa.eu/documents/10162/02ea296d-3173-bf94-227e-bba35a33c09e

[5] https://echa.europa.eu/documents/10162/d0991544-8be0-6837-335a-d5651e75bff7

B.3.2.2.4. PBT and vPvB assessment

Potential PBT properties pending of further data to be generated via compliance check were identified for EC 700-485-5.[4]

B.3.2.2.5. Summary of existing legal requirements

SVHC

Only Tris(nonylphenyl) phosphite (EC 247-759-6) has been identified as SVHC among the organophosphite derivatives for endocrine disrupting properties to the environment when containing ≥ 0.1 % w/w of 4-nonylphenol, branched and linear (4-NP).

Companies have legal obligation resulting from the inclusion of substances in the Candidate List. No Substances in Articles notifications have been received.

Regulation (EU) 10/2011 ‘Food Contact Materials’

Tris(nonylphenyl) phosphite (EC 247-759-6) and Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (EC 700-485-5) are included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU Regulation 10/2011).

B.3.2.2.6. Assumptions and uncertainties

Based on the information described above, it is assumed that the use of mono-, di- and triphenylphosphite derivatives in PVC is limited. They are mostly used in other plastics than PVC. Nevertheless, during the calls for evidence they have been identified to be used in window frames, automotive applications and medical applications. However, the concentration of the substances seems to be low when used in PVC. For instance in medical applications, their concentration was identified as 0.14 % (w/w) (CfE3,#1628). Furthermore, only triphenyl phosphite and substance EC 700-485-5 seem to be potentially hazardous. Nevertheless, no use in PVC was identified for substance EC 700-485-5.

It is possible that organophosphites other than the ones identified above might be used in PVC but there is not enough information. Alternative mono-, di- and triphenylphosphites are identified in the corresponding ARNs.[4,5]

Therefore, for now no exposure assessment and risk characterisation was performed for these substances.

B.3.3. Phenyl 1,3-diones

B.3.3.1. Manufacture and uses

The phenyl 1,3-diones identified by industry stakeholders (Section B.1) include one monophenyl dione (List No. 915-316-2) and one diphenyl dione (EC 204-398-9). Those substances are summarised in Table 24. However, it is important to highlight that there are another monophenyl dione (EC 272-599-9) and another diphenyl dione (EC 274-581-

6) registered under REACH Regulation that have not been identified by the stakeholders as being used in PVC.[6]

Phenyl 1,3-diones are typically manufactured via Claisen condensation from a methyl ester of a carboxylate and an acetophenone. Further steps vary depending on the substance.

Table 24. Phenyl 1,3-diones identified as currently used in PVC

EC No	CAS No	Substance name	Aggregated tonnage band	Active registrants
204-398-9	120-46-7	1,3-diphenylpropane-1,3-dione	1 000-10 000	8
915-316-2	-	Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione	1 000-10 000	6

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances with active registrants are registered under REACH following Art. 10 of the REACH Regulation.

Based on the information available in the registration dossiers, the main use of these substances is as stabilisers in plastics. In PVC they are used as co-stabilisers with colour-improving properties with Zn/Ca heat stabilisers. They mainly act as substitute for labile chlorine atoms in the PVC chain but this is only possible in the presence of Zn and thus they are used with Zn/Ca heat stabilisers. This relates to a further stabilizing function and their ability to deactivate Zn ion by complexation also contributes to their stabilising function.

From the information provided in the calls for evidence, the use of these substances was identified in window frames, flooring, toys, and automotive parts. The estimated volumes are in Section B.6.5.2.

However, since they are used together with, Zn/Ca carboxylates, are the main heat stabilisers used in the PVC applications considered in this work and thus, Phenyl 1,3-dionesthey might be used in additional more PVC applications than those mentioned in the previous paragraph.

B.3.3.2. Information on physicochemical properties and hazard

B.3.3.2.1. Physicochemical properties

Both phenyl 1,3-diones are well defined substances and the key physicochemical properties are summarised in Table 25.

Table 25. Key physicochemical properties for phenyl 1,3-diones

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK_{ow}
204-398-9	120-46-7	1,3-diphenylpropane-1,3-dione	224	0.01	0.493	4.59
915-316-2	-	Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione	373	0.000018	<0.2	7.97

Source: ECHA dissemination portal consulted on 8 March 2023

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[6] Assessment of regulatory needs for Phenyl 1,3-diones to be published

B.3.3.2.2. Classification and labelling

No harmonised classification is available for any of the substances. The classification provided in the registration dossiers is shown in Table 26 below.

Table 26. Classification provided in the registration dossiers for the phenyl 1,3-diones

EC	CAS No.	Substance name	Classification
204-398-9	120-46-7	1,3-diphenylpropane-1,3-dione	Skin Sens. 1 (H317)
915-316-2	-	Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione	Not classified

Source: ECHA dissemination portal consulted on 15 February 2023

B.3.3.2.3. Human health hazard assessment

This assessment is based on the assessment of regulatory needs (ARN) for Phenyl 1,3-diones.[6]

In this ARN only a hazard for skin sensitisation is identified for substance EC 204-398-9.

For substance List No. 915-316-2 in addition to a hazard for skin sensitisation, a hazard for reproductive toxicity was also identified. Data generation to clarify this concern has been requested via compliance check. The deadline to provide the data is August 2023.

No other hazards were identified.

B.3.3.2.4. PBT and vPvB assessment

Although a potential PBT/vPvB concern was raised[6] for substance EC 204-398-9 it was later clarified that the substances is ready biodegradable and therefore not PBT/vPvB.

For substance List No. 915-316-2 potential PBT/vPvB properties was identified based on inconsistent data. However this has been clarified under compliance check.

B.3.3.2.5. Summary of existing legal requirements

Not applicable.

B.3.3.2.6. Assumptions and uncertainties

For the purpose of this work, for substance List No. 915-316-2, it will be assumed the hazards identified above, i.e. the substance has PBT/vPvB properties as well as reproductive toxicity and endocrine disrupting properties. Thus, the assessment will be based on the assumption of non-threshold hazards.

For substance EC 204-398-9 only skin sensitising properties are considered. The classification as such already triggers regulatory consequences.

Therefore, exposure assessment and risk characterisation will only be done for substance List No. 915-316-2.

It is possible that other phenyl 1,3-diones than the ones mentioned above might also be used or could be used in PVC as well but there is not enough information. There is one monophenyl dione (EC 272-599-9) and one diphenyl dione (EC 274-581-6) registered under the REACH Regulation that have not been identified by the stakeholders as being used in PVC.[6]

B.3.4. Others

Two additional substances were initially identified by industry stakeholders as currently used in PVC (Section B.1) and further prioritised (Section B.2). Those substances can be seen in table 27.

Table 27. Phenyl 1,3-diones identified as currently used in PVC

EC No	CAS No	Substance name	Aggregated tonnage band	Active registrants
300-141-0	93922-04-4	barium 4-dodecylphenolate	10-100	4
800-029-6	1290049-56-7	Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated	100-1 000	4

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances with active registrants are registered under REACH following Art. 10 of the REACH Regulation.

They were initially identified as heat stabilisers but no information regarding their use was provided in the calls for evidence. Therefore, they will not be further assessed.

B.3.5. Heat stabilisers in other plastics

By far the most common polymer requiring the use of heat stabilisers is PVC. However, other chloro-containing polymers, such as copolymers of PVC, poly(vinylidene chloride) (PVDC) and chlorinated polyethylene (CPE) also require the use of heat stabilisers.

B.4. Plasticisers: information on properties and hazard

According to IUPAC, a plasticiser is a substance or material incorporated in a material (in this report, PVC) to increase its flexibility, workability or distensibility. A plasticiser may reduce the melt viscosity, lower the temperature of a second-order transition, or lower the elastic modulus of the product. Different plasticisers will differ in their capacity to influence how easy is to form the plasticised material as well as the mechanical and physical properties of the flexible product.

For a plasticiser to be effective, it must be thoroughly mixed and incorporated into the PVC polymeric matrix. There are several theories to describe plasticisation (Daniels, 2009):

- Lubricating theory: the plasticiser molecules diffuse into the polymer acting as a molecular lubricant and weakening the polymer-polymer van der Waals interactions, allowing the polymer chains to move freely over one another when a force is applied to the plasticised polymer.
- Gel theory: this theory considers the plasticised polymer to be in an intermediate state between solid and liquid which is held together by a three-dimensional network of weak secondary forces.

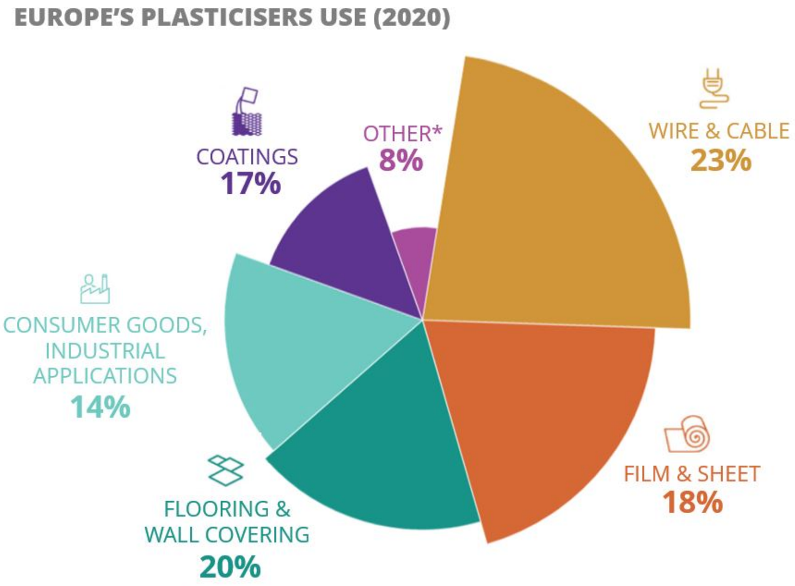
- Free volume theory: as free volume (the internal space available within a polymer) is increased, more space or free volume is provided for polymer chain movement. Free volume in the polymer could come from several sources, motion of polymer end groups, motion of polymer side groups, and internal polymer motions. Below the glass transition temperature, the polymers show limited motion and that would be why unplasticized PVC is hard and rigid. The addition of a plasticiser contributes with more free volume to the polymer resulting in an increase in chain mobility and a reduction of the glass transition temperature.

- Kinetic or mechanistic theories: these theories see the associations between polymer and plasticiser and between plasticiser molecules as transient and ever-changing. At low plasticiser concentrations, the plasticiser-polymer associations predominate but at high concentrations the associations between plasticiser molecules predominate and thus moving between the plasticised polymer chain.

During processing at elevated temperatures, plasticisers are mixed with either S-PVC (suspension PVC) to form a dry powder called ‘dry blend’ or with E-PVC (emulsion PVC) as a paste or plastisol. During this mixing process, plasticiser molecules penetrate the PVC polymer which slowly solvates. The gel that is formed as a consequence (normally at around 80 °C) is further heated at temperatures usually above 150 °C and the PVC polymer and the plasticiser finally melt together forming a homogeneous material (CfE2,#1605). After cooling the material is ready.

Plasticisers can be classified according to function and/or structure. The functional classification differentiates between primary and secondary plasticisers. Primary plasticisers are the main substances granting plasticity to PVC without compatibility problems. Secondary plasticisers are substances exhibiting lower solubility and compatibility with PVC that are mixed with primary plasticisers to reduce costs and/or improve other properties, e.g. fire resistance.

According to the European Plasticisers, over 85 % of all plasticisers consumed in Europe are used in flexible PVC applications, largely for the construction, automotive and wire and cable sectors (European Plasticisers, 2023) (Figure 10).



*Other: elastomers, surface coatings, rubber compounds and medical applications

Source: 2020 IHS and European Plasticisers estimates

Figure 10. Use share of plasticisers in PVC applications by sector

The most common plasticisers include esters such as adipates, azelates, citrates, benzoates, ortho-phthalates, terephthalates, sebacates and trimellitates. Different alcohols and different acids will lead to plasticisers exhibiting a range of performance, permanence and compatibility with PVC. Ortho-phthalates are the most widely used plasticisers.

In the EU, over 900 ktonnes of plasticisers are consumed per year (CfE2,#1601). Ortho-phthalates (usually referred to as simply ‘phthalates’) are the most widely consumed plasticisers due to the high degree of compatibility with PVC. In the EU, there has been a transition from low molecular weight ortho-phthalates (DIBP, DBP, BBP, DEHP), which are identified as SVHC under the REACH Regulation, to higher molecular weight phthalates. Today, the most used ortho-phthalates are DINP, DPHP and DIDP. It is noted that outside of the EU, low molecular weight phthalates continue to account for approximately 35 % of the global consumption because it is widely produced and used in China, India, and other parts of Asia, the Middle East, Africa and Latin America (CfE2,#1601). Figure 11 below shows the distribution in the European market of the most common plasticisers.

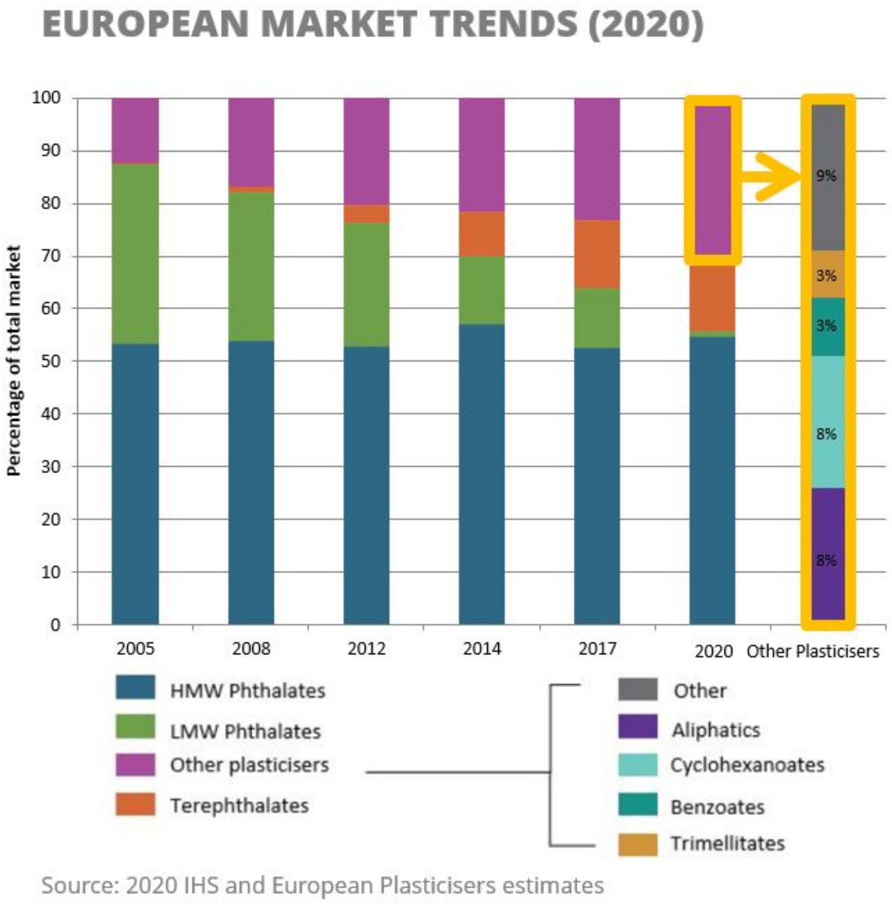


Figure 11. Distribution of most common plasticisers in the European market

Following the prioritisation in Section B.2 a total of 30 substances used as plasticisers were prioritised for further assessment. They can be grouped into the following groups: ortho-phthalates, terephthalates, trimellitates, benzoates and others (Table 28).

It should be noted that other substances identified as plasticisers currently used in PVC (Section B.1) are not further discussed in this section as those substances were not identified as priority substances in section B.2 (low potential hazard at the time of writing). Among those are for example Di(isononyl) cyclohexane-1,2-dicarboxylate (DINCH) (assessed by France[7] and ECHA[8]), citrates (e.g. ATBC[9], BTHC), adipate esters, azelate esters, dibenzoate esters and other carboxylate esters.

Table 28. Plasticisers prioritised for further assessment.

Group	Subgroup	EC	CAS No.	Substance name
Ortho-phthalates	Short-chain (C3)	201-553-2	84-69-5	Diisobutyl phthalate (**DIBP**)
		205-016-3	131-17-9	Diallyl phthalate (**DAP**)
	Medium-chain (C4-C6)	201-557-4	84-74-2	Dibutyl phthalate (**DBP**)
		201-622-7	85-68-7	Benzyl butyl phthalate (**BBP**)
		204-211-0	117-81-7	Bis(2-ethylhexyl) phthalate (**DEHP**)
		276-158-1	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (**DIHP**)
	Medium chain (C7-C8)	249-079-5	28553-12-0	Di-''isononyl'' phthalate (**DINP**)
		258-469-4	53306-54-0	Bis(2-propylheptyl) phthalate (**DPHP**)
		271-082-5	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (**D79P**)
		271-084-6	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (**D711P**)
		271-090-9	68515-48-0	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (**DINP**)
	Long-chain (C9-C18)	222-884-9	3648-20-2	Diundecyl phthalate (**DUP**)
		248-368-3	27253-26-5	Diisotridecyl phthalate (**DITDP**)
		271-085-1	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters (**D911P**)
		271-089-3	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (**D1114P**)
		271-091-4	68515-49-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters,

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[7] https://echa.europa.eu/documents/10162/c06d1a56-dd6a-ab7c-ec71-282e7623aad3
[8] https://echa.europa.eu/documents/10162/9db11d1e-6852-86df-83df-190a7121e022
[9] https://echa.europa.eu/documents/10162/9baad419-51da-76aa-5f9b-368dc5963763

Group	Subgroup	EC	CAS No.	Substance name
				C10-rich (**DIDP**)
		290-580-3	90193-76-3	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters (**D1618P**)
		700-989-5	#N/A	1,2-benzenedicarboxylic acid, di-C10-12-branched alkyl esters (**D1012P**)
		931-251-2	#N/A	bis(decyl and/or dodecyl) benzene-1,2-dicarboxylate (**DDP/DDDP**)
		300-141-0	93922-04-4	barium 4-dodecylphenolate
		800-029-6	1290049-56-7	Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated
Terephthalates		217-803-9	1962-75-0	Dibutyl terephthalate (**DBTP**)
		229-176-9	6422-86-2	Bis(2-ethylhexyl) terephthalate (**DOTP** or **DEHTP**)
Trimellitates		304-780-6	94279-36-4	1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters (**TIDTM**)
		290-754-9	90218-76-1	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters (**T810TM**)
		201-877-4	89-04-3	Trioctyl benzene-1,2,4-tricarboxylate (**TOTM**)
		258-847-9	53894-23-8	Triisononyl benzene-1,2,4-tricarboxylate (**TINTM**)
		253-138-0	36631-30-8	Triisodecyl benzene-1,2,4-tricarboxylate (**TIDTM**)
Benzoates		447-010-5	-	Nonylbenzoate, branched and linear
		421-090-1	-	Benzoic acid, C9-11, C10-rich, branched alkyl esters
Others		700-990-0	-	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate
		264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro

B.4.1. Ortho-phthalates

As mentioned before, ortho-phthalates are the most widely consumed plasticisers due to the high degree of compatibility with PVC.

Even though they are usually referred to as simply ‘phthalates’, the phthalate esters family also includes other subgroups such as isophthalates and terephthalates, which differ in the relative position of the two carboxylates in the benzene ring, i.e. *ortho*, *meta* or *para* positions respectively.

Ortho-phthalates can be subgrouped based on the alkyl backbone length of the alkyl substituent. Following the assessment of regulatory needs performed for ortho-phthalates[10], we consider the following subgrouping: short-chain phthalates (backbone chain length lower than C4), medium-chain phthalates (C4-C6), medium-chain phthalates (C7-C8) and long-chain phthalates (C9-C18).

In the EU, there has been a transition from short-chain ortho-phthalates and medium-chain (C4-C6) ortho-phthalates to higher molecular weight ortho-phthalates (Section B.4.1.2.5).

B.4.1.1. Manufacture and uses

Phthalates, and specifically ortho-phthalates are generally manufactured by the esterification of phthalic anhydride with the alcohol of interest. By using excess alcohol and removing the water, the equilibrium is shifted towards formation of the di-ester. The rate of reaction can be influenced by the choice of catalyst and the reaction temperature.

The composition of these substances therefore depends on the initial composition of the alcohol used for the esterification. Different manufacturing processes are used for producing the alcohols, determining the alkyl chain length and branching type.

Besides the main technical function as plasticisers, ortho-phthalates can have other functions too, e.g. as solvent, binder, lubricating agent, dispersing agent, filler, intermediate, emollient, antioxidant, process regulator, dust suppressant, or phlegmatiser.[10] Thus, there is a wide variety of products in which ortho-phthalates are used, e.g. in polymers, plastic articles, plastisol, dry-blends, thermoplastics, paint/coating/inks, adhesives, rubber, lubricants/waxes/polishes, metal working fluids, curing agents, hydraulic fluids, catalysts, solvents, sealants, construction materials or cosmetics. However, their use as plasticisers in PVC accounts for around 85 % of the total volume.

Table 29 below shows the ortho-phthalates that were identified as currently in use (Section B.1) and that have been prioritised for assessment in this report (Section B.2).

Table 29. Ortho-phthalates identified as currently used in PVC

Subgroup	EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
Short-chain (C3)	201-553-2	84-69-5	Diisobutyl phthalate (**DIBP**)	>1	7[1]
	205-016-3	131-17-9	Diallyl phthalate (**DAP**)	100-1 000	1
Medium-chain (C4-C6)	201-557-4	84-74-2	Dibutyl phthalate (**DBP**)	>1 000	3
	201-622-7	85-68-7	Benzyl butyl phthalate (**BBP**)	1-10	1
	204-211-0	117-81-7	Bis(2-ethylhexyl) phthalate (**DEHP**)	10 000-100 000	11
	276-158-1	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (**DIHP**)	0	0
Medium chain (C7-C8)	249-079-5	28553-12-0	Di-''isononyl'' phthalate	100 000-1 000 000	22

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[10] Assessment of regulatory needs for ortho-phthalates (ECHA, 2021) https://echa.europa.eu/documents/10162/6033b6ce-50d9-4d5f-b762-e84ddb7a3513

Subgroup	EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
			(**DINP**)		
	258-469-4	53306-54-0	Bis(2-propylheptyl) phthalate (**DPHP**)	100 000-1 000 000	5
	271-082-5	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (**D79P**)	0	0
	271-084-6	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (**D711P**)	0	0
	271-090-9	68515-48-0	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (**DINP**)	10 000-100 000	6
Long-chain (C9-C18)	222-884-9	3648-20-2	Diundecyl phthalate (**DUP**)	100-1 000	1
	248-368-3	27253-26-5	Diisotridecyl phthalate (**DITDP**)	0	0
	271-085-1	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters (**D911P**)	1 000-10 000	3
	271-089-3	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (**D1114P**)	1 000-10 000	5
	271-091-4	68515-49-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (**DIDP**)	100 000-100 0000	7
	290-580-3	90193-76-3	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters (**D1618P**)	1 000-10 000	4
	700-989-5	#N/A	1,2-benzenedicarboxylic acid, di-C10-12-branched alkyl esters (**D1012P**)	1 000-10 000	1
	931-251-2	#N/A	bis(decyl and/or dodecyl) benzene-1,2-dicarboxylate (**DDP/DDDP**)	1 000-10 000	1

Source: ECHA dissemination portal consulted on 15 February 2023

Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation except EC 201-553-2

[1] *Only intermediate registrations under Art. 17/18 of the REACH Regulation*

There are 4 ortho-phthalates that do not have active registrants under REACH: DIHP, D79P, D711P and DITDP. Further, according to the information provided in the CfE2 and

CfE3, the short-chain and medium-chain (C4-C6) ortho-phthalates do not seem to be used anymore in the PVC application in focus of this report. A notable exception is DEHP, which has been reported in medical applications, more specifically in PVC blood bags.

The other substances are used in flooring, cables, soft packaging, artificial leather, automotive (artificial leather and tarpaulins) and medical applications.

Except for flooring, no specific volumes were provided per substance per use. Therefore, the volumes were estimated by applying an average compounding to the volume or range of volumes of compounded PVC per use and the distribution provided in Figure 11. The resulting volume was then distributed proportional to the registered tonnage of the substances. More details are available in Section B.6.6.2.

B.4.1.2. Information on physicochemical properties and hazard

B.4.1.2.1. Physicochemical properties

The physicochemical properties for the ortho-phthalates with active registrations and identified as still being used in PVC were provided by the registrants in the registration dossiers. The key physicochemical properties are summarised in Table 30.

Table 30. Key physicochemical properties for ortho-phthalates with active registrations and identified to be used in PVC

Subgroup	EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
Medium chain (C4-C6)	204-211-0	117-81-7	DEHP	391	0.000034	0.003	7.52
Medium chain (C7-C8)	249-079-5	28553-12-0	DINP	419	6.00E-05	0.0006	9.25
	258-469-4	53306-54-0	DPHP	447	3.70E-06	2.20E-06	10.4
	271-090-9	68515-48-0	DINP	418.1	0.0006	2.32E-05	9.25
Long chain (C9-C18)	222-884-9	3648-20-2	DUP	475	1.33E-06	11.7	1.86
	271-085-1	68515-43-5	D911P	446.5	0.0357	0.000875	8.3
	271-089-3	68515-47-9	D1114P	531	3.63E-08	7E-08	12.06
	271-091-4	68515-49-1	DIDP	447	5.10E-05	0.00017	8.8
	290-580-3	90193-76-3	D1618P	643	1.80E-20	1E-12	16.4
	700-989-5	#N/A	D1012P	475	4.97E-7	4.41E-06	10.3
	931-251-2	#N/A	DDP/DDDP	475	0.13	3.9	11

Source: ECHA dissemination portal consulted on 8 March 2023

B.4.1.2.2. Classification and labelling

Among the ortho-phthalates with active registrations and identified as being used in PVC only DEHP has a harmonised classification.

Table 31. Harmonised classification for ortho-phthalates with active registrations and identified to be used in PVC according to the CLP Regulation 1271/2008

EC	CAS No.	Substance name	Index No.	Harmonised classification
204-211-0	117-81-7	DEHP	607-317-00-9	Repr. 1B (H360FD)

For the rest the classification provided in the registration dossiers is shown in Table 32 below which are in accordance with the vast majority of the notifications received under Art. 40 of the CLP Regulation.

Table 32. Classification provided in the registration dossiers for ortho-phthalates

Subgroup	EC	CAS No.	Substance name	Classification
Medium chain (C7-C8)	249-079-5	28553-12-0	DINP	Not classified
	258-469-4	53306-54-0	DPHP	Not classified
	271-090-9	68515-48-0	DINP	Not classified
Long chain (C9-C18)	222-884-9	3648-20-2	DUP	Not classified
	271-085-1	68515-43-5	D911P	Not classified
	271-089-3	68515-47-9	D1114P	Not classified
	271-091-4	68515-49-1	DIDP	Not classified
	290-580-3	90193-76-3	D1618P	Not classified
	700-989-5	#N/A	D1012P	Not classified
	931-251-2	#N/A	DDP/DDDP	Not classified

Source: ECHA dissemination portal consulted on 15 February 2023

B.4.1.2.3. Human health hazard assessment

This assessment is based on the assessment of regulatory needs (ARN) for ortho-phthalates done by ECHA.[10]

Medium chain (C4-C6)

In addition to the harmonised classification as Repr. 1B (H360FD), DEHP is also a SVHC for endocrine disrupting properties (HH and ENV). RAC (ECHA, 2021) evaluated in the context of authorisation the possibility for DNEL and dose-response for DEHP. RAC took into account the endocrine effects -information submitted and concluded that no sufficiently protective DNEL and no dose-response relationship could be derived on the basis of the available assessments and data.

Although DEHP is the only PVC plasticiser identified in this subgroup of ortho-phthalates, it is noted that some other medium-chain orthopthalates and long-chain orthophthalates may contain other short-chain ortho-pthalates. A hazard screening was carried out for these substances in the ARN. Among this group several substances have a CLH as reprotoxicant of category 1. The ARN report concludes that all substances belonging to this group are based on their structure and available data expected to be reprotoxicants (at least for the developmental end-point) and endocrine disruptors for human health and the environment.

Medium chain (C7-C8)

For the medium chain (C7-C8) ortho-phthalates, in the ARN it was identified that, based on the available data, it appears that substances in this subgroup are likely not or not as potent reproductive toxicants as the ortho-phthalates with shorter backbone alkyl chains. However, information from mono-constituent substances with chain backbone length of C7 or C8 is limited, and therefore no firm conclusion can be drawn. Further, those substances might contain constituents with shorter alkyl chains and potential reproductive toxicity and endocrine disrupting properties from the presence of those constituents cannot be excluded.

- For DINP (EC 271-090-9 and EC 249-079-5), the available studies show weak anti-androgenic adverse effects on the development of the male reproductive organs. However, RAC concluded that DINP does not induce irreversible gross-structural malformations such as hypospadias and cryptorchidism in rats, nor permanent decreases of AGD or permanent nipple retention and that reversible histological changes in foetal testes and effects on testosterone production alone are not

considered sufficient to justify classification under CLP.[11] EFSA in its risk-assessment concluded that the reproductive and developmental effects – considered by the RAC as not sufficient for classification in the context of the CLP process – could nevertheless raise concern as it is plausible that even small or transient DINP effects might be able to contribute to the reprotoxic effects of other phthalates after combined exposure (EFSA, 2019).
With regard to endocrine disruption, no effects on thyroid were reported in *in vivo* studies with DINP. However, it is unclear whether and to which extent thyroid toxicity was investigated in those studies. DINP may increase thyroid activity because it enhances iodide uptake in a rat thyroid cell line mediated by sodium/iodide symporter (NIS). DINP also inhibits thyroid hormone (TH)-dependent proliferation of rat pituitary cells (GH3) with and without L-triiodothyronine (T3). However, the effects are rather weak in conditions mimicking the natural availability of the endogenous T3 (ECHA, 2013).
Carcinogenicity was also reviewed by ECHA and it was concluded that renal neoplasms observed are assumed to have modes of actions which are not considered to be relevant for humans (alpha-2u-globulin). DINP also causes liver tumours in rodents, for which peroxisome proliferation is believed to be the underlying mode of action. However, the literature indicates that multiple pathways might exist and some of those pathways might be peroxisome proliferator-activated receptor α (PPARα)-independent (a PPARα-inducing mechanism would not be relevant for humans). Therefore, potential relevance for humans cannot be ruled out.
Data generation is being requested to the registrants via dossier evaluation to clarify these concerns.[12]

- For DPHP an OECD TG 416 study in rats shows no reproductive or developmental toxicity, but clear effects on the thyroid are observed which raises concern for potential ED properties. No maternal or developmental toxicity was observed in an OECD TG 414 study in rats up to the limit dose.
  Adverse effects on the thyroid were reproducibly observed in a 90-day repeated-dose toxicity study and 2-generation reproductive toxicity study. In addition, the pituitary gland was affected in the 90-day study. The effects observed on the thyroid for this substance, raise a concern for potential ED properties.
  This substance is currently under substance evaluation (SEv) by Germany for potential endocrine disrupting properties (the deadline to submit the data is February 2025).[13]
  No carcinogenicity data is available, however based on structural similarity with DINP, similar effects cannot be excluded.

Long-chain (C9-C18)

For long-chain ortho-phthalates, it is concluded that the available experimental data do not show clear reproductive toxicity and it appears that these substances do not share the reprotoxic and ED properties of medium-chain (C4-C6) ortho-phthalates. Nevertheless, no

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[11] https://www.echa.europa.eu/documents/10162/56980740-fcb6-6755-d7bb-bfe797c36ee7

[12] https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status/-/dislist/details/0b0236e186c55e7d and https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status/-/dislist/details/0b0236e186c56013

[13] https://echa.europa.eu/documents/10162/499be14e-7d49-229b-468e-0b1bdb4d6eec

firm conclusion can be made yet on a lack of reproductive toxicity and endocrine disrupting properties because: 1) adequate data are available only for a few substances and in most cases it is not clear whether the composition of the tested material is sufficiently representative of the registered substance, 2) all the registered substances are UVCBs and, for many, the substance identity data indicates that they may contain constituents with shorter backbone (same or similar to medium-chain (C4-C6) ortho-phthalates), 3) where read-across is applied, it appears not to be adequately justified.

Data generation is being requested to the registrants of all the substances (EC 222-884-9, 271-085-1, 271-089-3, 271-091-4, 290-580-3, 700-989-5 and 931-251-2) via dossier evaluation to clarify these concerns.

Carcinogenicity data, is only available for DIDP, which was reviewed by ECHA (ECHA, 2013). In a 2-year carcinogenicity study with rats, no treatment-related tumours were observed. DIDP induced liver adenomas in a 26-week study in rasH2 mice and it is assumed that this is related to peroxisome proliferation. However, the literature indicates that multiple pathways might exist and some of those pathways might be PPARα-independent (a PPARα-inducing mechanism would not be relevant for humans). Therefore, potential relevance for humans cannot be completely ruled out.

B.4.1.2.4. PBT and vPvB assessment

Medium chain (C7-C8)

A potential PBT/vPvB hazard was identified for the substances in this subgroup.

All substances screen as potentially bioaccumulative based on the values for $\log K_{ow}$. There is little experimental data available to assess the bioaccumulation potential, including information on biotransformation in biota. The information requirement is mostly covered using adaptations based on QSAR with a broad range of predicted BCF values. Therefore, as this stage it cannot be excluded that these substances may show a bioaccumulation hazard.

All substances in this subgroup are claimed to be readily biodegradable. However, there are flaws with the available data used to support this conclusion. Currently it cannot be excluded that (at least some) subgroup members may be P/vP.

The available aquatic toxicity information is not sufficient to draw conclusions on the T criterion. As explained above, DPHP show adverse effects on thyroid in mammals, which raise concern for potential HH ED properties.

Data generation has been or is being requested for DPHP and DINP.

Long-chain (C9-C18)

In the ARN, it is proposed to wait for the data for ortho-phthalates with shorter alkyl chains before concluding on this hazard for long-chain (C9-C18) ortho-phthalates. Nevertheless, bioavailability of these substances is expected to be limited considering the values for logKow. However, it should be noted that some substances in this group are UVCBs with some constituents with a backbone alkyl chain <C9.

B.4.1.2.5. Summary of existing legal requirements

SVHC

There are 6 substances identified as SVHC among the ortho-phthalates:

- 3 for Repro. 1B (H360Df) and ED properties for human health (BBP, DBP, DIBP)
- 1 for Repro. 1B (H360FD) and ED properties for human health and the environment (DEHP)
- 2 for Repro. 1B: DIHP (H360D) and D711P (H360Df)

Companies have legal obligation resulting from the inclusion of substances in the Candidate List. Based on the received Substances in Articles notifications, there are indications for the presence in articles for DEHP, DBP, DIBP, BBP and DPHP.

Authorisation list

The substances above are included in the Authorisation List (Annex XIV or the REACH Regulation).

Originally BBP, DBP, DIBP and DEHP were included based on being toxic for reproduction, but the European Commission has amended the entries in the Authorisation List to include the endocrine disruption properties. This means that some uses of the four ortho-phthalates which until now have been exempted may require authorisation: 1) uses in mixtures in concentrations equal or above 0.1 % w/w (so far the concentration limit has been 0.3 % w/w), and 2) some uses of DEHP (e.g. in food contact materials) that will no longer fall under the ‘generic exemptions from the authorisation requirement’ due to the endocrine disrupting effects on the environment of DEHP.

It is important to note that certain uses are exempt from authorisation requirements if the substance only has human health hazards. Those uses are:

- Use in cosmetic products (Art. 56(5)(a) REACH)
- Use in food contact materials (Art. 56(5)(b) REACH)
- Use in medical devices (Art. 60(2) and 62(6) REACH)

Applications for Authorisation (AfA) were received for DEHP and DBP (Table 33). For DEHP, it should be noted that the sunset date for medical devices is 1 July 2030 and latest application date is 1 January 2029.

Table 33. Applications for Authorisation received for DEHP and DBP

Substance name	Application ID	Application type	Applicant	Use name	Status
DEHP	0001-01	Initial	Rolls-Royce plc	The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.	Discontinued as of 01 January 2021
	0002-01	Initial	ARKEMA FRANCE	Formulation of DEHP in compounds, dry-blends and Plastisol formulations	Withdrawn
	0002-02	Initial	ARKEMA FRANCE	Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to	Withdrawn

Substance name	Application ID	Application type	Applicant	Use name	Status
				be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)]	
	0003-01	Initial	Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.	Formulation of DEHP in compounds, dry-blends and Plastisol formulations	Withdrawn
	0003-02	Initial	Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.	Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)]	Withdrawn
	0004-01	Initial	DEZA a.s.	Formulation of DEHP in compounds, dry-blends and Plastisol formulations	Withdrawn
	0004-02	Initial	DEZA a.s.	Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)]	Withdrawn
	0004-03	Initial	DEZA a.s.	Industrial use of DEHP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements	Withdrawn
	0007-01	Initial	Roxel (UK Rocket Motors) Ltd	Industrial use of DEHP in manufacture of solid propellants and motor charges for rockets and tactical missiles	Authorisation expired
	0008-01	Initial	VINYLOOP FERRARA S.p.A.; Stena Recycling AB; Plastic Planet srl	Formulation of recycled soft PVC containing DEHP in compounds and dry-blends	Authorisation expired
	0008-02	Initial	VINYLOOP FERRARA S.p.A.; Stena Recycling AB; Plastic Planet srl	Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles	Authorisation expired
	0122-01	Review report	VINYLOOP FERRARA S.p.A.	Formulation of recycled soft PVC containing DEHP in compounds and dry-blends	Withdrawn
	0122-02	Review report	VINYLOOP FERRARA S.p.A.	Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce	Withdrawn

Substance name	Application ID	Application type	Applicant	Use name	Status
				the following PVC articles: (1) articles used outside of the interior space in applications in the field of construction, civil engineering, garden features such as ponds and roofing, agriculture (including horticulture) and industrials workplaces without potential for mouthing or prolonged contact with human skin or any contact with mucous membranes; (2) articles used in interior space in industrial and agricultural workplaces; or (3) footwear used in professional, industrial and/or agricultural workplaces.	
	0123-01	Review report	Plastic Planet srl	Formulation of recycled soft PVC containing DEHP in compounds and dry-blends	Opinions adopted[1]
	0123-02	Review report	Plastic Planet srl	Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce the following PVC articles: (1) articles used outside of the interior space in applications in the field of construction, civil engineering, garden features such as ponds and roofing, agriculture (including horticulture) and industrial workplaces without potential for mouthing or prolonged contact with human skin or any contact with mucous membranes; (2) articles used in interior space in industrial and agricultural workplaces; or (3) footwear used in professional, industrial and/or agricultural workplaces.	Opinions adopted[2]
DBP	0005-01	Initial	DEZA a.s.	Use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride	Commission decided[3]
	0005-02	Initial	DEZA a.s.	Use of DBP in propellants Formulation: Industrial use of DBP as a burning rate surface moderant, plasticiser and/or coolant in the formulation of nitrocellulose-based propellant grains. Use at industrial site: Industrial use of DBP-containing propellant grains in manufacture of ammunition for military and civilian uses, and pyrocartridges for aircraft ejection seat safety systems [includes propellants for police force ammunition and excludes propellants intended for manual, private reloading of ammunition cartridges by civilian users, i.e., licensed individual sports shooters and hunters. No direct consumer use of DBP or its mixtures is covered by this Use.]	Commission decided[3]

Substance name	Application ID	Application type	Applicant	Use name	Status
	0005-03	Initial	DEZA a.s.	Industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements	Authorisation expired
	0006-01	Initial	Sasol-Huntsman GmbH & Co. KG	Use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride	Commission decided[4]
	0007-02	Initial	Roxel (UK Rocket Motors) Ltd	Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles	Authorisation expired
	0007-03	Initial	Roxel (UK Rocket Motors) Ltd	Industrial use of DBP within a specialty paint in manufacture of motors for rockets and tactical missiles	Authorisation expired
	0126-01	Initial	AVX NI [application transferred from: "AVX Limited" due to a notified legal entity change]	Industrial use in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors.	Commission decided[5]

[1]Compiled opinion: https://echa.europa.eu/documents/10162/8bb24f4f-48c7-e080-af68-3d923e1dc8f5
Minority position: https://echa.europa.eu/documents/10162/8f0d3e22-b52e-80dc-a171-c80c4983f5dd
[2]Compiled opinion: https://echa.europa.eu/documents/10162/59cf6a4c-aca8-d370-1bfc-d039f7ae940d
Minority position: https://echa.europa.eu/documents/10162/a304cd48-adaa-07ea-bc1a-700cc0ebcf43
[3]Decision: http://ec.europa.eu/DocsRoom/documents/16343
[4]Decision: http://ec.europa.eu/DocsRoom/documents/8265
[5]Decision: https://ec.europa.eu/docsroom/documents/34708

Restrictions

Some of the ortho-phthalates are restricted under REACH. Below a brief overview of relevant entries:

- Entry 30 – (All phthalates with a harmonised classification as Repr. 1A or 1B): Placing on the market restricted for supply to general public at or above the specific or the generic concentration limit as substances, constituent of other substances or mixtures.
- Entry 51 (DEHP, DBP, BBP, DIBP): restricted in toys and childcare articles ≥0.1 % (w/w). The restriction was amended to also restrict the use of the substances >0.1 % (w/w) (individually or in combination) in plasticised materials in articles used by consumers or indoors (e.g. cables, coated fabrics, sports equipment). Most elements of the restriction took effect from July 2020. Derogations apply, including medical devices (blood bags).
- Entry 52 (DINP, DIDP, DnOP[14]): restricted in plasticised material, in toys and childcare articles which can be placed in the mouth by children ≥0.1 % (w/w)

Regulation (EU) 10/2011 ‘Food Contact Materials’

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[14] Not identified by industry stakeholders (Section B.1)

DAP, DBP, BBP, DEHP, DINP and DIDP are included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU Regulation 10/2011).

B.4.1.2.6. Assumptions and uncertainties

For the purpose of this report, ortho-phthalates, are assumed to have the hazards identified above, i.e. the substances have endocrine disrupting properties for human health and environment and/or PBT/vPvB properties. Thus, the assessment will be based on the assumption of non-threshold hazards.

Nevertheless, considering the conclusions in the ARNs, a banding approach will be considered, in which medium-chain (C4-C6) are considered of high hazard potential, medium-chain (C7-8) of medium hazard potential (DPHP and DINP) and long-chain (C9-C18) of low hazard potential.

It is possible that other ortho-phthalates than the ones identified above might be used in PVC, but there is not enough information. Alternative ortho-phthalates are identified in the corresponding assessment of regulatory needs.[10] Other ortho-phthalates would share similar concerns in the subgroups highlighted above.

B.4.2. Terephthalates

Terephthalates are esters of 1,4-benzenedicarboxylic acid also named as *para*-phthalic acid. They differ from ortho-phthalates in the relative position of the carboxylic acids in the benzene ring. Thus, the relative position of the carboxylic acids in ortho-phthalates is *ortho* (or 1,2), while for terephthalates is *para* (or 1,4).

B.4.2.1. Manufacture and uses

Para-phthalic acid is typically produced by oxidation of the methyl groups of p-xylene. The acid can be further esterified with methanol to give the methyl ester. Other terephthalates may be manufactured using the acid as starting material or via transesterification of the methyl ester using the alcohol of interest.

The composition of these substances therefore depends on the initial composition of the alcohol used for the esterification.

Based on the information provided in the registration dossiers, and similarly to ortho-phthalates, terephthalates in general are mainly used as plasticisers but other functions have been reported too, e.g. as monomer, lubricating agent, dispersing agent, binding agent, viscosity adjustor, flotation agent, or dust suppressant. They are used in many applications, such as polymers, plastic articles, paints, inks, adhesives, lubricants, metal working fluids, hydraulic fluids, and laboratory use.

As shown in Table 29, only two terephthalates have been identified as currently in use in PVC (Section B.1) and have been prioritised for assessment in this report (Section B.2). The main uses reported for these substances are in polymers, paints/coatings and adhesives/sealants. They are expected to be mostly used in PVC.

Table 34. Terephthalates identified as currently used in PVC

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
217-803-9	1962-75-0	Dibutyl terephthalate (**DBTP**)	1 000-10 000	2
229-176-9	6422-86-2	Bis(2-ethylhexyl) terephthalate	100 000-1 000 000	29

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
		(**DOTP** or **DEHTP**)		

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation.

From the information provided in the CfE2 and CfE3, DOTP is widely used across all uses where soft PVC is required. In the EU there has been a transition from some ortho-phthalates (e.g. DEHP, DINP) to DOTP (CfE3 #1708 and Bywall and Cederlund (2020)). Nevertheless, the use of DBTP has also been identified in flooring and the automotive sector (artificial leather, tarpaulins) and, in the absence of further information, it is assumed that it is also used in artificial leather outside the automotive sector.

Except for flooring, no specific volumes were provided per substance per end use. Therefore, the volumes were estimated by applying an average compounding to the volume or range of volumes of compounded PVC per application and the distribution provided in Figure 11 of Section B.4.1.1. The resulting volume was then distributed proportional to the registered tonnage of the two substances. More details are available in Section B.6.7.2.

B.4.2.2. Information on physicochemical properties and hazard

B.4.2.2.1. Physicochemical properties

The key physicochemical properties for DBTP and DOTP are summarised in Table 35.

Table 35. Key physicochemical properties for DBTP and DOTP

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
217-803-9	1962-75-0	DBTP	278	0.038	0.005	4.74
229-176-9	6422-86-2	DOTP	390.6	0.001	0.0004	8.34

Source: ECHA dissemination portal consulted on 8 March 2023

B.4.2.2.2. Classification and labelling

No harmonised classification is available for DBTP and DOTP. In the registration dossiers, the registrants have not classified the substances for any hazard class.

According to the notifications received under Art. 40 of the CLP Regulation, 50 % of the notifiers classified DBTP as Skin Irrit. 2 (H315), Eye Irrit. 2A (H319) and Aquatic Chronic 3 (H412). The notifications received for DOTP did not include a classification.

B.4.2.2.3. Human health hazard assessment

This assessment is based on the assessment of regulatory needs (ARN) for terephthalates done by ECHA.[15]

In an OECD TG 408 study with substance EC 946-149-3 (C4-C6 mixed terephthalate) hypertrophy of follicular epithelium in thyroid glands is seen in both sexes at 300 and 1000 mg/kg bw/day. Potential thyroid toxicity is assumed also for DBTP, which is the C4 linear constituent, and therefore potential ED concern. Data generation is being requested to the registrants via dossier evaluation to clarify this concern.

No other potential hazards have been identified for DBTP. For DOTP, no hazards or potential hazards have been identified.

B.4.2.2.4. PBT and vPvB assessment

No PBT/vPvB properties have been identified for any of the terephthalates.

There is sufficient information from ready biodegradation studies to conclude that substances are not likely to be P or vP.

B.4.2.2.5. Summary of existing legal requirements

DOTP is included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of Regulation (EU) 10/2011).

B.4.2.2.6. Assumptions and uncertainties

It is possible that other terephthalates than DBTP and DOTP might be used in PVC but there is not enough information. Alternative terephthalates are identified in the corresponding assessment of regulatory needs.[10] Thus, the following terephthalates registered under REACH would share potential ED properties identified for DBTP: List No. 946-149-3 and 940-272-6.

Exposure assessment and risk characterisation will only be performed for DBTP in the absence of hazards for DOTP.

B.4.3. Trimellitates

Trimellitates are triesters of benzene-1,2,4-tricarboxylic acid also named as trimellitic acid. Unlike ortho-phthalates or terephthalates the benzene ring is functionalised with three carboxylates instead of two. They can be seen as a fusion between ortho-phthalates and terephthalates since the relative position of the carboxylates are 1,2,4 (1,2 for ortho-phthalates, 1,4 for terephthalates).

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[15] Assessment of regulatory needs for isophthalates, terephthalates and trimellitates (ECHA, 2021): https://echa.europa.eu/documents/10162/2621e3b4-4298-d62f-9d4b-016848837c99

B.4.3.1. Manufacture and uses

Trimellitates are typically manufactured by the esterification of trimellitic anhydride with an alcohol in the presence of a catalyst. By using excess of alcohol and removing the water the equilibrium is shifted towards formation of the triester. The reaction rate is accelerated by using a catalyst and high temperature.

The composition of these substances therefore depends on the initial composition of the alcohol used for the esterification.

Based on the information provided in the registration dossiers, and similarly to ortho-phthalates and terephthalates, trimellitates are mainly used as plasticisers or softeners but other functions have been reported too. They are used in many applications such as polymers, plastic articles, paints, inks, adhesives, lubricants, metal working fluids, hydraulic fluids, or laboratory use. Frequently, they have been identified as used in medical devices.

As shown in Table 36 five trimellitates have been identified as currently in use in PVC (Section B.1) and have been prioritised to be assessed in this report (Section B.2). They are expected to be mostly used in PVC.

Table 36. Trimellitates identified as currently used in PVC

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
304-780-6	94279-36-4	1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters (**T911M** or **TIDTM**)	1 000-10 000	1
290-754-9	90218-76-1	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters (**T810TM**)	10 000-100 000	10
201-877-4	89-04-3	Trioctyl benzene-1,2,4-tricarboxylate (**TOTM**)	1 000-10 000	3
258-847-9	53894-23-8	Triisononyl benzene-1,2,4-tricarboxylate (**TINTM**)	100-1 000	5
253-138-0	36631-30-8	Triisodecyl benzene-1,2,4-tricarboxylate (**TIDTM**)	1 000-10 000	7

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation.

From the information provided in the CfE2 and CfE3, trimellitates have been identified in cables, the automotive sector (artificial leather, tarpaulins) and medical devices. In the absence of further information, it is assumed that they are also used in artificial leather outside the automotive sector.

No specific volumes were provided in the calls for evidence per substance per end use. Therefore, the volumes were estimated by applying an average compounding to the volume or range of volumes of compounded PVC per application and the distribution provided in Figure 11 of Section B.4.1.1. The resulting volume was then distributed proportional to the registered tonnage of the two substances. More details are available in Section B.6.8.2.

B.4.3.2. Information on physicochemical properties and hazard

B.4.3.2.1. Physicochemical properties

The key physicochemical properties for trimellitates are summarised in Table 37.

Table 37. Key physicochemical properties for trimellitates

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
304-780-6	94279-36-4	T911M/TIDTM	631	1E-10	0.05	10.6
290-754-9	90218-76-1	T810TM	589	1.34E-07	6E-07	12.79
201-877-4	89-04-3	TOTM	547	6.8E-08	1.8E-06	8
258-847-9	53894-23-8	TINTM	589	0.0114	5.40E-06	9.9
253-138-0	36631-30-8	TIDTM	631	5.8E-10	1.24	9.4

Source: ECHA dissemination portal consulted on 8 March 2023

B.4.3.2.2. Classification and labelling

No harmonised classification is available for trimellitates. In the registration dossiers, the registrants have not classified the substances for any hazard class and most notifications received under Art. 40 of the CLP Regulation do not classify the substances either.

B.4.3.2.3. Human health hazard assessment

This assessment is based on the assessment of regulatory needs (ARN) for trimellitates done by ECHA.[15]

Limited toxicokinetic information is available only for TOTM, which indicates poor absorption through gastrointestinal tract. Compared to orthophthalate DEHP, TOTM appears to be more stable in the gastrointestinal tract. Mainly the hydrolysis products 2-ethylhexanol and one monoester (MEHP) are absorbed. The plasma half lives (~ 40 hours) indicate a potential for bioaccumulation, which is higher after intravenous application (~ 40 days).

No conclusion on potential reproductive toxicity and ED properties can be made for this group of substances based on the available data. However, the limited available data indicate that, these substances are likely less potent reproductive toxicants than ortho-phthalates, if at all. There are also some indications that the MoA may not be the same for all substances. However, in the absence of adequate data , potential reproductive toxicity and ED properties are suspected for all substances based on the following information:

- OECD TG 421 studies are available for TOTM and two other trimellitates not identified as used in PVC: EC 219-547-3 and 222-020-0. In the OECD TG 421 study with EC 219-547-3, a statistically significant increase in relative weight of epididymis (without histopathological changes) was observed in P0 males at 1000 mg/kg bw/day. In the same study with EC 222-020-0, adverse effects on spermatogenesis and the testis have been detected in P0 males. No reproductive/developmental effects were observed in OECD TG 421 study with TOTM, but in an OECD 408 study a decrease in absolute uterus weight was observed at all tested doses (stat. significant at the low and highest dose). For EC 222-020-0 transient nipple retention and increased weight of seminal vesicles and the epididymis were observed in males of the high dose group in a pre- and post-natal developmental toxicity test (similar or comparable to OECD TG 414). Based on the information provided in the US EPA ToxCast Screening Library (US EPA, 2023), EC 222-020-0 was identified as agonist in the ToxCast ER model, which predicts the outcome of the Uterotrophic assay (Browne et al., 2015). This information is consistent with the results published by (Ter Veld et al.). reporting estrogen receptor 1 (ER1) and estrogen receptor 2 (ER2) activity of the substance in a transactivation assay (US EPA, 2023).

- No reproductive toxicity study is available for T810TM. In an OECD TG 408 study, no effects on reproductive organs were observed, but mechanistic data indicate a potential ED mode of action.[16] In addition, fetal toxicity (< litter and fetal weight, delayed ossification, visceral malformations) was observed in an OECD 414 study with this substance.

Data generation is ongoing for TIDTM (EC 304-780-6 and 253-138-0), T810TM and TOTM. Additional data generation is ongoing of other trimellitates (EC 222-020-0, 941-303-6, 304-446-4, 700-342-7, 615-086-2 and 276-594-2).

No other potential hazards have been identified for trimellitates.

B.4.3.2.4. PBT and vPvB assessment

Based on the conclusions from the ARN, it is not possible to discount a PBT/vPvB hazard for these substances. The available screening information on degradation is poor or indicate that these substances are not readily biodegradable. The only simulation study available is a sediment simulation study (OECD TG 308) on EC 222-020-0. This substance is highly adsorptive with a predicted log Koc of 7.83 (KOCWIN v2.00). The substance partitions rapidly to the sediment phase, the half-life in the sediment can reasonably be estimated from the half-life for the total water-sediment system. Bi-phasic kinetics were observed in the study for both sediment samples and bi-phasic models were used to calculate the slow-phase (FOCUS, 2014, p. 117, Figure 7-2)[17]. For both water-sediment systems the slow-phase DT50 values is > 10 000 days (DFOP) which indicates the substance may be concluded vP. A sediment simulation study (OECD TG 308) and a soil simulation study (OECD TG 307) were requested in a previous compliance check on EC 201-877-4. The information provided in reply to the final compliance check decision is currently under evaluation.

With regard to bioaccumulation, these substances screen as potentially B/vB with log Kow well above 4.5. The available data on bioaccumulation are mostly QSAR with limited reliability showing low BCF. An experimental fish bioaccumulation study is available on EC 222-020-0 showing low BCF. However, there are major uncertainties with the validity of this study (testing at concentrations above the water solubility of the substance, use of solubilising agent which may lead to an underestimation of the BCF). A study similar to OECD TG 305-III (dietary exposure) is also available on TINTM showing a BMFl of 0.045. The test material used was not radiolabelled and there is no proof that steady state was reached after the uptake phase. Furthermore, high variability in the concentrations of the substances determined in replicates fish tissues was observed. The substance was not detected in fish tissues after 3 days. However, metabolites were not investigated. Overall, due to the above deficiencies, this information is considered inconclusive.

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[16] Decision on Compliance Check, ECHA 2020: https://echa.europa.eu/documents/10162/d4be492f-475f-b7d5-da0e-6077574ce48b

[17] https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/dk/docs/FOCUSkineticsvc1.1Dec2014.pdf

Regarding T, the information on aquatic toxicity is inconclusive due to the absence of adequate information on long-term toxicity. There are also data gaps for relevant human health endpoints.

As mentioned earlier, data generation is ongoing for TIDTM (EC 304-780-6 and 253-138-0), T810TM and TOTM. Additional data generation is ongoing of other trimellitates (EC 222-020-0, 941-303-6, 304-446-4, 700-342-7, 615-086-2 and 276-594-2).

B.4.3.2.5. Summary of existing legal requirements

Not applicable.

B.4.3.2.6. Assumptions and uncertainties

It is possible that other trimellitates than the ones identified in Table 36 might be used in PVC but there is not enough information. Potential alternative trimellitates are identified in the corresponding assessment of regulatory needs.[15] According to the assessment of the regulatory needs, other trimellitates would likely share the same potential ED and PBT/vPvB properties described above.

B.4.4. Benzoates

In the context of this work by ‘benzoates’ it is meant alkyl esters of benzoic acid.

B.4.4.1. Manufacture and uses

Benzoic acid is typically produced by oxidation of the methyl group of toluene. The acid can be further esterified with methanol to give the methyl ester. Other benzoates may be manufactured using the acid as starting material or via transesterification of the methyl ester using the alcohol of interest.

The composition of these substances therefore depends on the initial composition of the alcohol used for the esterification.

Based on the information provided in the registration dossiers, half of the benzoates assessed in a group by ECHA are used as plasticisers.[18] Other benzoates in the group are used mainly in cosmetics or washing and cleaning products, and they range from simple alcohol esters to more branched fatty alcohol esters of benzoic acid.

As shown in Table 38 only two benzoates have been identified as currently in use in PVC (Section B.1) and have been prioritised (Section B.2). The main use for those substances is reported to be as plasticisers.

Table 38. Benzoates identified as currently used in PVC

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
447-010-5	-	Nonylbenzoate, branched and linear	100-1 000	1
421-090-1	-	Benzoic acid, C9-11, C10-rich,	1 000-10 000	2

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[18] Assessment of regulatory needs for Benzoates (ECHA, 2020): https://echa.europa.eu/documents/10162/76e478b2-5533-3114-e175-8d5ee71a5b6b

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
		branched alkyl esters		

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation.

From the information provided in the CfE2 and CfE3, the use of benzoates has only been explicitly mentioned in flooring and specific volumes were provided (CfE2,#1603) and available in Section B.6.9.2. According to the European Resilient Flooring Manufacturers' Institute (ERFMI), only Benzoic acid, C9-11, C10-rich, branched alkyl esters (EC 421-090-1) is currently used in PVC flooring.

B.4.4.2. Information on physicochemical properties and hazard

B.4.4.2.1. Physicochemical properties

The key physicochemical properties for benzoates are summarised in Table 39.

Table 39. Key physicochemical properties for benzoates

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
447-010-5	-	Nonylbenzoate, branched and linear	248	0.024	1	6.25
421-090-1	-	Benzoic acid, C9-11, C10-rich, branched alkyl esters	262	0.00845	0.0686	6.1

Source: ECHA dissemination portal consulted on 8 March 2023

B.4.4.2.2. Classification and labelling

No harmonised classification is available for the two benzoates. The self-classification provided in the registration dossiers is shown in Table 40 below. No other classification proposed in the notifications received under Art. 40 of the CLP Regulation.

Table 40. Self-classification provided in the registration dossiers for benzoates

EC	CAS No.	Substance name	Classification
447-010-5	-	Nonylbenzoate, branched and linear	Repr. 2 (H361d) Aquatic Chronic 2 (H411)
421-090-1	-	Benzoic acid, C9-11, C10-rich, branched alkyl esters	Acute Tox. 4 (H332) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

Source: ECHA dissemination portal consulted on 15 February 2023

B.4.4.2.3. Human health hazard assessment

This assessment is based on the assessment of regulatory needs (ARN) for benzoates done by ECHA.[18]

Based on the available information, it was identified a potential Repr. 1B hazard for both EC 421-090-1 and 447-010-5. This potential hazard was also identified for two additional substances that were not identified as currently used in PVC: 2-ethylhexyl benzoate (EC 226-641-8) and benzoic acid C12-15 alkyl esters (EC 270-112-4).

Thus, EC 226-641-8 is already self-classified as Repr. 1B and EC 447-010-5 is self-classified as Repr. 2. Further, EC 421-090-1 composition overlaps with 447-010-5 and delayed sexual maturation was observed in an OECD TG 416 study with the substance.

B.4.4.2.4. PBT and vPvB assessment

According to the conclusions in the assessment of regulatory needs, based on the available information the substances seem to be readily biodegradable.

There are very limited studies available on bioaccumulation. However, based on available information, the group members do not appear to be bioaccumulative.

Data generation for both EC. 421-090-1 and 447-010-5 among benzoates was requested.

B.4.4.2.5. Summary of existing legal requirements

Not applicable.

B.4.4.2.6. Assumptions and uncertainties

It is possible that other benzoates than the ones identified in Table 38 might be used in PVC but there is not enough information. Potential alternative benzoates are identified in the corresponding assessment of regulatory needs.[18] According to the assessment of the regulatory needs, other benzoates would likely share the same potential Repro. 1B hazard properties.

B.4.5. Others

In addition to the substances described in sections B.4.1 to B.4.4, two additional substances were identified to be used in PVC as plasticisers (Section B.1). Those substances are the reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate (EC 700-990-0) and Paraffin waxes and Hydrocarbon waxes, chloro or LCCP in short (EC 264-150-0) which will be covered in section B.5.1 and B.5.3.

No specific information was received during the calls for evidence for the use of LCCP except that it might be used in PVC cables.

B.4.6. Plasticisers in other plastics

In addition to PVC, plasticisation is also done with other polymers (Walters et al., 2020). Thus, acrylic resins, polyamides, polyethylene terephthalate (PET), polystyrene and fluoroplastics often use phthalates as well as adipate esters. Some of those polymers have been highlighted as alternatives to PVC for some uses (see Appendix C).

Most polyolefins already give adequate physical properties without plasticisation. Nevertheless, adipate esters have been used for plasticising polypropylene (PP).

B.5. Flame retardants: information on properties and hazard

Flame retardants are a diverse group of chemicals that are applied to materials to prevent or slow the growth of fire through interfering with one or several stages of the process of fire. Flame retardants are activated in the presence of a flame or an ignition source and the flame retardancy involves several mechanisms occurring in the gas phase of the fire or in the solid phase (material).

Some of the substances are used in combination to improve effectiveness through synergistic effects (e.g. antimony has a synergistic effect with halogenated compounds by allowing the formation of volatile antimony species, i.e. antimony halides or antimonyoxyhalide) or combining different mechanisms of action (e.g. halogen-phosphorus systems, phosphorus-nitrogen systems and intumescent systems).

In general, flame retardants are normally divided based on whether they contain bromine, chlorine, phosphorus, nitrogen, metals or boron. Nevertheless, there are flame retardants that contain more than one of the elements listed above and even very complex substances for which this simple differentiation by elemental composition does not work.

ECHA has recently published a Regulatory Strategy on Flame Retardants in which halogenated and organophosphorus flame retardants were assessed (ECHA, 2023c).

From the information provided in the calls for evidence, the EU Commission report on the use of PVC in the context of a non-toxic environment and ECHA's Regulatory Strategy on Flame Retardants (ECHA, 2023c), the use of flame retardants in PVC is quite limited compared to other commodity plastics like e.g. polyolefins, stryrenics and acrylics. Thus, any potential risk from the use of flame retardants will not be specific to PVC. On the contrary, the risk would include all plastics and be mostly associated with other plastics than PVC.

The high chlorine content (~57 %) of pure PVC renders the polymer inherently flame retardant and generally, no flame retardants are added to rigid PVC. For flexible PVC, the fire properties of plasticised PVC are largely determined by the type and amount of plasticiser used. The typical plasticisers used in PVC are volatile enough to be emitted from PVC when it is strongly heated by a flame, and they are flammable under those circumstances (Weil et al., 2006). In addition, the higher additive content of flexible PVC results in a lower content of chlorine by weight and decreased inherent flame retardant properties. Flame retardants can therefore be used in PVC when needed to meet specifications (e.g. oxygen index, heat release, smoke evolution) and standards, e.g. in high temperature cables (CfE2,#1569, 1570, 1571, 1575, 1583, 1585 and 1589), flooring (CfE2,#1603), and automotive applications (CfE2,#1595 and 1653). However, higher loadings or more efficient flame retardants/flame retardant systems are needed in other alternative commodity plastics (Polcher et al., 2020).

In PVC composites, smoke production is generally the most important concern and thus, smoke suppression, rather than flame retardancy, is the focus.

Among the substances identified as being in used in PVC (Section B.1), several flame retardants were identified. Following the prioritisation in Section B.2, a total of 12 substances used as flame retardants or plasticising flame retardants were prioritised for further assessment. They can be grouped into the following groups: triphenylphosphate derivatives, halogenated flame retardants and inorganics (Table 41).

It should be noted that other substances identified as flame retardants currently used in PVC (Section B.1) are not further discussed in this section as those substances were not identified as priority substances in section B.2 (low potential hazard at the time of writing). Among those are for example aluminium hydroxide and magnesium hydroxide which are mentioned in the impact assessment (Appendix C).

Table 41. Flame retardants prioritised for further assessment

Group	EC	CAS No.	Substance name
Organophosphates	246-677-8	25155-23-1	Trixylyl phosphate
	273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)
	945-730-9	-	Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate and triphenyl phosphate

Group	EC	CAS No.	Substance name
	809-930-9	1330-78-5	Tris(methylphenyl)phosphat
	939-505-4		tert-butylphenyldiphenyl phosphate (tBuTPP)
	247-693-8	26444-49-5	Diphenyl tolyl phosphate
	201-116-6	78-42-2	Tris(2-ethylhexyl) phosphate
Inorganics	215-175-0	1309-64-4	Diantimony trioxide
	245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide
	215-566-6	1332-07-6	Zinc borate
	235-804-2	12767-90-7	Hexaboron dizinc undecaoxide
Brominated phthalate	247-426-5	26040-51-7	Bis(2-ethylhexyl) tetrabromophthalate

B.5.1. Organophosphates

Organophosphorus flame retardants are often proposed as alternatives to halogenated flame retardants (Blum et al., 2019). Among them are the organophosphate esters which are organic esters of phosphoric acid containing either alkyl chains or aryl groups.

Most of the organophosphorus flame retardants identified to be in use in PVC (Section B.1) and prioritised in this report (Section B.2) are triphenylphosphate derivatives. Only one trialkylphosphate derivative was identified: Tris-(2-ethylhexyl) phosphate (EC 201-116-6).

B.5.1.1. Manufacture and uses

Triphenylphosphate derivatives are typically produced from phosphorus oxychloride and phenols which are reacted together in the presence of a catalyst at elevated temperatures. Excess unreacted organics, which are necessary to achieve a complete reaction, can be up to 10 % in the crude product which is the purified by distillation. Tris-(2-ethylhexyl) phosphate (EC 201-116-6) follows a similar manufacturing process using 2-ethylhexanol to react with phosphorus oxychloride.

The composition of these substances therefore depends on the initial composition of the phenols used in the reaction. Many of the triphenylphosphate derivatives contain triphenylphosphate (TPP) as an impurity in relevant concentrations as a result of that.

Based on the information provided in the registration dossiers, the main uses of triphenylphosphate derivatives are in technical fluids (metal working fluids, heat transfer fluids and hydraulic fluids) and lubricants, and in polymeric materials that end up in articles).[19] In the polymeric materials, the main reported technical functions are plasticiser and flame retardant. The materials mentioned by the registrants are plastics, thermoplastics, rubber and rigid and flexible foams. The sectors highlighted are building and construction work, furniture and electronic and electronic devices.

The main uses for tris-(2-ethylhexyl) phosphate (EC 201-116-6) identified in the registration dossiers are in lubricants, polymeric materials, adhesive/sealants, fillers/putties/plasters, coatings, paper and board treatment products and photochemicals

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[19] Assessment of regulatory needs for Triphenylphosphate derivatives (ECHA, 2021): https://echa.europa.eu/documents/10162/901a4f73-f000-8550-98ac-61e51bf5daaa

Assessment of regulatory needs for Trialkylphosphates is not yet published.

in which its function is as a lubricant, flame retardant, processing aid, defoamer, chelating agent or deafoamer.

As shown in Table 42 seven triphenylphosphate derivatives and tris-(2-ethylhexyl) phosphate (EC 201-116-6) which have been identified as currently in use in PVC (Section B.1) and have been prioritised (Section B.2).

Table 42. Organophosphorus flame retardants identified as currently used in PVC

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
246-677-8	25155-23-1	Trixylyl phosphate	100-1 000	1
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)	1 000-10 000	5
945-730-9	-	Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate and triphenyl phosphate	1 000-10 000	6
809-930-9	1330-78-5	Tris(methylphenyl)phosphat	1 000-10 000	6
939-505-4		tert-butylphenyldiphenyl phosphate (tBuTPP)	100-1 000	4
247-693-8	26444-49-5	Diphenyl tolyl phosphate	0	0
700-990-0	-	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate	1 000-10 000	6
201-116-6	78-42-2	Tris(2-ethylhexyl) phosphate	1 000-10 000	7

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation.

According to some respondents to the calls for evidence, the main use of organophosphates may not be in PVC (CfE2,#1550). However, other respondents identified them as being in used in PVC packaging in pyrotechnic applications (CfE2,#1566), in cables (CfE2,#1564 and 1584) and in automotive applications (CfE2,#1595). However, the data provided for automotive applications (CfE2,#1595) is only indicative as to which substances are most often used based on the number of hits in the International Material Data System and the number of OEMs identifying the substances. Thus, by far diantimony trioxide and zinc borates (Section B.5.2) are the most prevalent substances. Organophosphorus are much less prevalent. In addition, from the Pinfa Product Selector[20] organophosphorus substances are identified for PVC applications only in wire and cables which might include wires and cables in automotive applications. This seems to correlate with the information received for the restriction proposal for medium chain chlorinated paraffins ('MCCP') where organophosphorous flame retardants have been identified as alternatives to MCCP in PVC cables.

Further, according to information received in CfE2 (#1550) and the only Application for Authorisation received for Trixylyl phosphate (EC 246-677-8), this substance has not been used in PVC in the EU for over 15 years or longer. It is only used for hydraulic fluids for turbines in power stations.

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[20] https://www.pinfa.eu/product-selector/

No specific volumes were provided in the calls for evidence per substance per end use. Therefore, the volumes were estimated by applying an average compounding to the volume or range of volumes of compounded PVC per application The resulting volume was then distributed proportional to the registered tonnage of the two substances. More details are available in Section B.6.10.2.

B.5.1.2. Information on physicochemical properties and hazard

B.5.1.2.1. Physicochemical properties

The key physicochemical properties for organophosphates are summarised in Table 43.

Table 43. Key physicochemical properties for triphenylphosphate derivatives

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
246-677-8	25155-23-1	Trixylyl phosphate	431.5	1.60E-06	0.02	6.32
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)	326	1.34E-05	0.33	4.92
945-730-9	-	Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate and triphenyl phosphate	340.3	1.20E-06	0.0026	4.5
809-930-9	1330-78-5	Tris(methylphenyl) phosphate	368	4.70E-06	0.271	5.93
939-505-4		tert-butylphenyldiphenyl phosphate (tBuTPP)	382	0.00108	0.109	5.61
247-693-8	26444-49-5	Diphenyl tolyl phosphate	340.3	1.20E-06	2.6	4.5
700-990-0	-	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate	382	0.000323	3.2	4.68

Source: ECHA dissemination portal consulted on 8 March 2023

B.5.1.2.2. Classification and labelling

Among the organophosphorus flame retardants that are used in PVC applications, only Trixylyl phosphate has a harmonised classification.

Table 44. Harmonised classification for Trixylyl phosphate according to the CLP Regulation 1271/2008

EC	CAS No.	Substance name	Index No.	Harmonised classification
246-677-8	25155-23-1	Trixylyl phosphate	015-201-00-9	Repr. 1B (H360F)

For four substances the registrants provided a self-classification in the registration dossiers, and they are shown in Table 45 below.

Table 45. Self-classifications provided in the registration dossiers for organophosphate flame retardants

EC	CAS No.	Substance name	Classification
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)	Repr. 2 (H361) STOT RE 2 (H373) Aquatic Chronic 4 (H413) Aquatic Chronic 1 (H410)

EC	CAS No.	Substance name	Classification
945-730-9	-	Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate and triphenyl phosphate	Auatic Acute 1 (H400) Aquatic Chronic 3 (H412)
809-930-9	1330-78-5	Tris(methylphenyl)phosphate	Repr. 2 (H361) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
700-990-0	-	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate	Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411) Aquatic Chronic 3 (H412)

Source: ECHA dissemination portal consulted on 15 February 2023

With regard to the other three substances: no classification has been notified for substance List No. 939-505-4 and the notified classifications for diphenyl tolyl phosphate (EC. 247-693-8) and Tris(2-ethylhexyl) phosphate (EC 201-116-6) are provided in Table 46 below.

Table 46. Notified classifications for Diphenyl tolyl phosphate and Tris(2-ethylhexyl) phosphate under Art. 40 of the CLP Regulation 1272/2008

EC	CAS No.	Substance name	Notified classification and number of notifiers
247-693-8	26444-49-5	Diphenyl tolyl phosphate	Aquatic Chronic 1 H410 [13 out of 25] STOT Single Exp. 2 H371 [1 out of 25] Aquatic Chronic 2 H411 [3 out of 25] Acute Tox. 4 H302 [5 out of 25] Acute Tox. 4 H312 [1 out of 25] Aquatic Chronic 3 H412 [3 out of 25] Aquatic Acute 1 H400 [16 out of 25]
201-116-6	78-42-2	Tris(2-ethylhexyl) phosphate	Eye Irrit. 2 H319 [11 out of 39] STOT Single Exp. 3 H335, affected organs: Respiratory tract [1 out of 39] Skin Irrit. 2 H315 [22 out of 39] Aquatic Chronic 4 H413 [1 out of 39] STOT Single Exp. 3 H335 [1 out of 39]

Source: ECHA dissemination portal consulted on 15 February 2023

B.5.1.2.3. Human health hazard assessment

This assessment is based on the assessments of regulatory needs (ARN) for triphenylphosphate derivatives and trialkylphosphates done by ECHA.[19]

The human health endpoints of concern for triphenylphosphates were reproductive toxicity and endocrine disruption for human health and environment:

- TXP (EC 246-677-8) has a harmonised classification as Repr. cat. 1B and it is included on Annex XIV of the REACH Regulation. This potential hazard can also be extrapolated to the rest of the substances although there are some data gaps for some substances that are being addressed via dossier evaluation (see below). ECHA has not received any applications for authorisation for this substance by the latest application date (27 November 2021).

- TPP (EC 204-112-2) was under substance evaluation by UK and France and it was concluded that TPP should be identified as SVHC for endocrine disrupting properties for the environment. In addition, the US NTP is performing an extended one-generation reproductive toxicity study. As mentioned before, TPP is found as a constituent or impurity at relevant concentrations in many of the triphenylphosphate derivatives.

- There are indications of potential ED properties for other alkyl-substituted constituents present in the composition of the substances based on *in vitro* high-throughput tests (CompTox EPA/ToxCast)[21] and QSAR Danish Database.[22]

- EC 273-066-3 is under SEv for potential endocrine disruptor and suspected PBT/vPvB. Following a testing proposal an extended one-generation reproductive toxicity study is being performed.

Generation of data via dossier evaluation has been proposed for substances List No. 809-930-9 and 945-730-9 to clarify reproductive toxicity and ED properties.

For Tris(2-ethylhexyl) phosphate (EC 201-116-6) the data available suggest no hazard for fertility or developmental toxicity. However, the same data suggests a potential ED hazard that needs to be by further data generation.

In addition, several organophosphorus flame retardants are known to cause organophosphorus-induced delayed neuropathy (OPIDN) after single (acute) and repeated exposure. OPIDN was observed not only in animal studies, but also in humans. Metabolic transformation from o-methyl/cresyl isomers to highly neurotoxic derivatives such as saligenin cyclic o-cresyl phosphate is possible (Nordic Expert Group, 2010), therefore all substances containing TOCP (tri-o-cresylphosphate, EC 201-103-5) as constituent or impurity may be neurotoxic.

B.5.1.2.4. PBT and vPvB assessment

In general, substances in this sub-group are unlikely to meet the PBT/vPvB criteria based on the data available. Most of the substances are readily biodegradable. However, potential PBT/vPvB hazard was identified for substances EC 246-677-8 and 273-066-3 which are assessed under substance evaluation.[23]

Some constituents of phenyl substituted phenols (List No 700-393-5) may have also PBT hazards. The substance screens for P and B but no assessment can be done in the absence of definitive data. This substance is registered at 1-10 tpa and thus compliance check cannot be used to generate missing information. Substance evaluation would be required to request further data.

Unlikely PBT/vPvB hazard was identified for Tris(2-ethylhexyl) phosphate (EC 201-116-6) based on the experimental data available which shows very low BCF value.

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[21] https://comptox.epa.gov/dashboard/

[22] https://qsar.food.dtu.dk/

[23] EC 246-677-8: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180686bab and EC 273-066-3: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e184016e9d

B.5.1.2.5. Summary of existing legal requirements

SVHC

Only Trixylyl phosphate (EC 246-677-8) has been identified as SVHC among the organophosphorus flame retardants above for Repr. 1B (H360F).

Companies have legal obligation resulting from the inclusion of substances in the Candidate List. Only one Substances in Articles notification was received.

Authorisation list

Trixylyl phosphate (EC 246-677-8) has also been included in the Authorisation List (Annex XIV or the REACH Regulation).

It is important to note that certain uses are exempt from authorisation requirements if the substance is only identified for human health hazards. Those uses are:

- Use in cosmetic products (Art. 56(5)(a) REACH)
- Use in food contact materials (Art. 56(5)(b) REACH)
- Use in medical devices (Art. 60(2) and 62(6) REACH)

One application for authorisation have been received for two uses in power plants: Industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines and Industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves. The applications are currently in opinion development.

Restrictions

Trixylyl phosphate is also restricted under REACH under Entry 30 due to the harmonised classification as Repr. 1B: Placing on the market restricted for supply to general public at or above the specific or the generic concentration limit as substances, constituent of other substances or mixtures.

B.5.1.2.6. Assumptions and uncertainties

It is possible that other trialkylphosphates or triphenylphosphates than the ones identified in Table 42 might be used in PVC but there is not enough information. Potential alternative trialkylphosphates or triphenylphosphates are identified in the corresponding assessment of regulatory needs.[19] According to the assessment of the regulatory needs, other trialkylphosphates or triphenylphosphates would likely share the same potential hazards properties described above.

Further, although the main use of organophosphorus flame retardants in PVC has been identified in cables, they might be used in other applications to a lower extent.

B.5.2. Inorganic flame retardants

Inorganic flame retardants are the main flame retardants reported to be used in PVC. According to the information provided in the calls for evidence, diantimony trioxide (EC 215-175-0) is the main substance used among the inorganic flame retardants and was therefore prioritised for assessment in this report (Section B.2). The other two substances most often referred to are zinc borates (EC 215-566-6 and 215-804-2). This seems to be in line with the focus on synergists (antimony) to take advantage of the high chlorine content in PVC and smoke suppressants (borates).

Diantimony trioxide is probably the most important flame retardant for PVC. Although usually not effective as a flame retardant in the absence of a halogen, it is a powerful synergist when used with a halogenated flame retardant or in halogenated polymers such as PVC (Weil et al., 2006). Antimony oxide is not volatile but antimony oxyhalide (SbOX) and antimony trihalide (SbX3) formed in the condensed phase, by reaction with the halogenated flame retardant (chlorine in case of PVC), are volatile. They facilitate the transfer of halogen and antimony into the gas phase where they function. Those forms are very effective retardants at typical flame temperatures.

Zinc borates are established in PVC as partial replacement for antimony trioxide with the advantage of reducing the smoke and anti-afterglow action (Weil et al., 2006). By themselves, zinc borates are less effective flame retardants in PVC than diantimony trioxide, but combinations of zinc borates and diantimony trioxide are very effective and thus, they are normally used together.

B.5.2.1. Manufacture and uses

In total four inorganic flame retardants identified as currently in use in PVC (Section B.1) were prioritised (Section B.2). The inorganic flame retardants are shown in Table 47 and the main use for those substances is reported to be flame retardants.

Table 47. Inorganic flame retardants identified as currently used in PVC

EC	CAS No.	Chemical name	Aggregated tonnage	Active registrants
215-175-0	1309-64-4	Diantimony trioxide	>10 000	29
245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide	1-10	1
215-566-6	1332-07-6	Zinc borate	10-100	1
235-804-2	12767-90-7	Hexaboron dizinc undecaoxide	1 000-10 000	12

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances are registered under REACH following Art. 10 of the REACH Regulation.

According to the registration dossiers, diantimony trioxide has a wide variety of uses such as glass, enamels, functional ceramics and semi-conductors solid, pigments, paints, coatings, brake pads. It is also used in plastics and rubbers as a flame retardant.

According to the information provided in the calls for evidence the use of these substances are reported in cables (CfE2,#1564, 1569, 1570, 1571, 1575, 1583, 1585 and 1589), flooring (CfE2,#1603), artificial leather (CfE2,#1565) and automotive applications (CfE2,#1595 and 1653). Diantimony trioxide was also identified to be used in the sealant material of window frames (CfE2,#1602).

B.5.2.2. Information on physicochemical properties and hazard

B.5.2.2.1. Physicochemical properties

The key physicochemical properties for inorganic flame retardants are summarised in Table 43.

Table 48. Key physicochemical properties for triphenylphosphate derivatives

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
215-175-0	1309-64-4	Diantimony trioxide	291.5	N/A	0.37	N/A

EC No	CAS No	Substance	MW	Vapour pressure (Pa)	Water solubility (mg/L)	LogK$_{ow}$
245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide	531.9	N/A	0.35	N/A
215-566-6	1332-07-6	Zinc borate	125.2	N/A	2891	N/A
235-804-2	12767-90-7	Hexaboron dizinc undecaoxide	371.6	N/A	25	N/A

Source: ECHA dissemination portal consulted on 8 March 2023

B.5.2.2.2. Classification and labelling

Among the inorganic flame retardants identified to be used in PVC applications, only Diantimony trioxide has a harmonised classification.

Table 49. Harmonised classification for Diantimony trioxide according to the CLP Regulation 1271/2008

EC	CAS No.	Substance name	Index No.	Harmonised classification
215-175-0	1309-64-4	Diantimony trioxide	051-005-00-X	Carc. 2 (H351)

The registrants for all the substances provided a self-classification in the registration dossiers, and they are shown in Table 50 below.

Table 50. Self-classifications provided in the registration dossiers for inorganic flame retardants

EC	CAS No.	Substance name	Classification
215-175-0	1309-64-4	Diantimony trioxide	Carc. 2 (H351) STOT RE 2 (H373, lungs) Aquatic Chronic 3 (H412)
245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide	Acute Tox. 4 (H332) STOT RE 2 (H373, kidney) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411)
215-566-6	1332-07-6	Zinc borate	Repr. 2 (H361d) Eye Irrit. 2 (H319) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411)
235-804-2	12767-90-7	Hexaboron dizinc undecaoxide	Muta. 2 (H341) Repr. 2 (H361d) Eye Irrit. 2 (H319) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411)

Source: ECHA dissemination portal consulted on 15 February 2023

B.5.2.2.3. Human health hazard assessment

This assessment is based on the assessments of regulatory needs (ARN) for inorganic borates[24], molybdenum simple compounds[25] and the assessment of DE CA in the CoRAP justification document and Substance Evaluation decision for Diantimony Trioxide.[26]

Inorganic borates

In the assessment of regulatory needs for the group inorganic borates group (containing boric acid and salts based on alkali metals, alkaline earth metals or ammonium counter ions), it was identified a general hazard concern for reproductive toxicity was identified. No additional hazard was identified.

Even though zinc salts were not included in the inorganic borates group, the concern still remains regarding their reproductive toxicity. Data generation may be requested to clarify this concern.

Diantimony trioxide

DE CA justified the inclusion of Diantimony trioxide in CoRAP based on inconclusive test results on genotoxicity. Thus, a concern was identified for *in vivo* genotoxicity at site-of-contact tissue after inhalation exposure. Some of the observed carcinoma are suspected to be caused by a systemically available antimony species which would be then independent of the route of exposure. Consequently, a decision following Substance Evaluation was sent to the registrants requesting "*Combined in vivo mammalian alkaline comet assay (test method: OECD TG 489) with in vivo mammalian erythrocyte micronucleus test (test method: OECD TG 474) in mice, inhalation route (nose-only). The comet assay must be performed on the following tissues: nasal mucosa, alveolar epithelium, bronchoalveolar lavage cells, and liver parenchyma with and without additional specific investigation on oxidative DNA damage for each of the tissues mentioned.*"

The data is expected during the second half of 2023.

Dimolybdenum trizinc nonaoxide

In the assessment of regulatory needs for Dimolybdenum trizinc nonaoxide (EC 245-322-4) it was concluded that, based on the current available information, it was not possible to conclude on reproductive toxicity and that further data may be needed. However, no potential human health hazard was identified to date.

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[24] Assessment of regulatory needs for inorganic borates is not yet published.

[25] Assessment of regulatory needs for molybdenum simple compounds: https://echa.europa.eu/documents/10162/a960ada0-8116-648a-f731-74c3acf0521a

[26] CoRAP justification: https://echa.europa.eu/documents/10162/365c162c-dbd5-5b89-58ab-e5260398c74c

Substance evaluation decision: https://echa.europa.eu/documents/10162/d71159df-dd67-5918-b112-f7e41ef9e801

B.5.2.2.4. PBT and vPvB assessment

Not applicable.

B.5.2.2.5. Summary of existing legal requirements

Diantimony trioxide (EC 215-175-0) is included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU Regulation 10/2011).

B.5.2.2.6. Assumptions and uncertainties

Based on the information described above, it is assumed that there is no potential hazard identified for Dimolybdenum trizinc nonaoxide (EC 245-322-4). Only one use for the substance in PVC was reported (flooring) with a rather limited tonnage (100 kg/year). Therefore, no exposure assessment and risk characterisation is performed for this substance in Section B.6.

B.5.3. Halogenated flame retardants

Even though halogenated flame retardants were identified as flame retardants currently used in PVC (Section B.1) and the two substances listed in Table 51 were prioritised for assessment in this report (Section B.2), no specific information regarding their use was provided in the calls for evidence.

It was suggested that they might be used in cables and automotive applications (CfE2,#1564 and #1595) but the information is not sufficient to quantify the use. At the same time, most of the other notifiers in the calls for evidence suggested that halogenated flame retardants are not used in PVC. In fact, as mentioned earlier, the most used flame retardants in PVC are inorganic substances (Section B.5.2). This seems to be somewhat in contradiction with the information received for the restriction proposal for medium chain chlorinated paraffins (‘MCCP’) where organophosphorous flame retardants have been identified as alternatives to MCCP.

Therefore, no further assessment is performed for those substances.

Nevertheless, it should be mentioned that, as highlighted in the Regulatory Strategy for Flame Retardants (ECHA, 2023c), Paraffin waxes and hydrocarbon waxes, chloro (also referred to as ‘LCCP’) may contain alkanes, C14-17, chloro (EC 264-150-0) congeners identified with PBT/vPvB properties (constituents). These are expected to be addressed following ECHA’s restriction proposal for medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17. In addition, data generation (CCH, possibly followed by SEv) is suggested to further clarify human health hazards and PBT properties of paraffin waxes and hydrocarbon waxes, chloro.

Also highlighted in the Regulatory Strategy for Flame Retardants (ECHA, 2023c) is the general concern identified for aromatic brominated flame retardants due to their known or potential PBT/vPvB properties. Among those aromatic brominated flame retardants are the brominated phthalates and specifically Bis(2-ethylhexyl) tetrabromophthalate (EC 247-426-5) which has been identified as a SVHC for vPvB hazard properties. For those substances a wide generic restriction was identified to be the most appropriate regulatory approach.

Although not identified during the calls for evidence, substance bis(2-ethylhexyl) tetrabromophthalate (EC 247-426-5) might be is use (or have been in use) for soft PVC applications (KEMI, 2020) such as wire and cable insulation, film and sheeting, carpet backing, coated fabrics and wall coverings.

Table 51. Halogenated flame retardants identified as currently used in PVC

EC No	CAS No	Substance name	Aggregated tonnage band	Active registrants
264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro (**LCCP**)	10 000-100 000	7
247-426-5	26040-51-7	Bis(2-ethylhexyl) tetrabromophthalate	100-1 000	2

Source: ECHA dissemination portal consulted on 15 February 2023
Note: all the substances with active registrants are registered under REACH following Art. 10 of the REACH Regulation.

B.5.4. Flame retardants in other plastics

As mentioned earlier, the use of flame retardants in PVC is quite limited compared to other commodity plastics like e.g. polyolefins, polystyrene, polyurethanes, polyamides, polyesters and acrylics among others.

Thus, any potential risk from the use of flame retardants will not be specific to PVC. On the contrary, the risk would include all plastics and it is mostly associated with other plastics than PVC.

B.6. Exposure assessment and risk characterisation

B.6.1. Approach

The exposure assessment and risk characterisation for substances in focus (Sections 0, B.4 and B.5) are only performed if the substances were confirmed to be used in PVC during the calls for evidence and if the substances are currently registered under REACH. If not, the uncertainties have been highlighted in the above-mentioned sections.

The assessments of regulatory needs (ARN) published on ECHA website[27] have been taken into account. If a potential non-threshold hazard was identified, i.e. ED and/or PBT/vPvB, this has been assumed as confirmed for the purpose of the assessment. In this case, the assessment is limited to the estimation of releases of the substances to the environment. Nevertheless, human health exposure and risk will were also be considered when appropriate for those prioritised substances, identified in use in PVC, that are classified for human health threshold hazards, i.e. Repr. 1 or STOT RE 1 or when the only potential hazard identified is Repr. 1 or STOT RE 1.

The following exposure scenarios have been identified for the substances prioritised in Sections 0, B.4 and B.5:

- ES1: Formulation (PVC compounding)

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[27] Available: https://echa.europa.eu/assessment-regulatory-needs

- ES2: Article production (PVC conversion)
- ES3: Article service life. Use in pipes and pipe fittings
- ES4: Article service life. Use in window frames
- ES5: Article service life. Use in cables
- ES6: Article service life. Use in flooring
- ES7: Article service life. Use in packaging (food and non-food)
- ES8: Article service life. Use in toys
- ES9: Article service life. Use in artificial leather
- ES10: Article service life. Automotive interiors
- ES11: Article service life. Medical applications
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12.

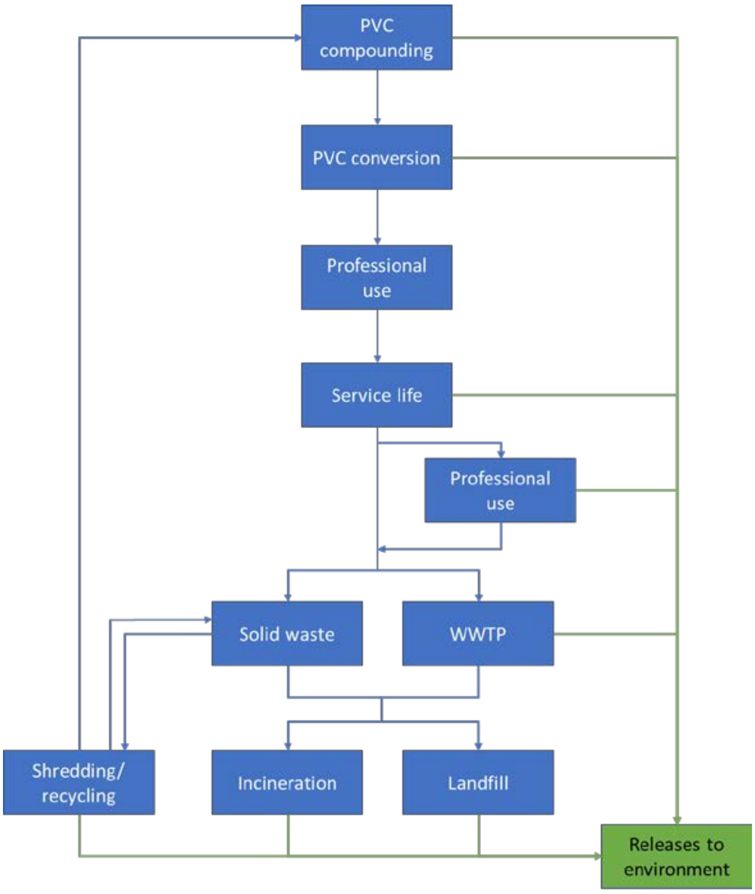

Figure 12. Generic sequence of exposure scenarios

B.6.2. Release estimation

The assumptions and key input parameters for the estimation of release are described in sections B.6.2.1 - B.6.2.5. The volumes per use, which is the basis for the release estimation are provided in Sections B.6.4.2 to B.6.11.2.

B.6.2.1. Assumptions and strategy

In the estimation of releases, the following additional releases are not quantified:

- Releases which occur outside of the EU and subsequently enter the EU via long-range transport.
- Releases from articles that were placed on the market prior to any restriction (‘legacy articles’) as well as from already landfilled waste.
- Releases from recycled materials and articles. Recycling leads to the incorporation of substances in articles which will be released to the environment during the incorporation, the service life, and when becoming waste, in a similar way as described in the exposure scenarios. The releases after recycling are not quantified separately because it is assumed they would be similar (and thus covered) by the release estimates for the ‘virgin’ PVC. Another important reason for this assumption is that the estimated tonnage per use already takes into account the fraction of substance coming from recycled material.

- Releases from landfills in the after-care period (after closure of the landfills) and after the after-care period, when landfills are not monitored anymore.

The following assumptions are made:

- The estimated volume per year per use is assumed to remain constant.
- It is assumed that there are no exports of articles, or that the export is equivalent to import, and the imported articles contain additives in equivalent proportion. However, it should be noted that the market trends in the EU are different for some additives and groups of additives (sections 0, B.4 and B.5).

Table 52. Use descriptors,[28] estimation method and relevant parameters for release estimation per exposure scenario

Exposure scenario	Use descriptors	Estimation method[29]	Relevant parameters
ES1: Formulation (PVC compounding)	ERC2/ERC3	OECD ESD release factors (worst case)	Water[1]: 0.075 %; Air: 0.025 %; Waste: 1 % -> Incineration Tonnage = sum of tonnage per end use per additive minus the fraction recycled[2]
ES2: Article production (PVC conversion)	ERC5	OECD ESD release factors (worst case)	Water: 0.25 %; Air: 0.25 %; Waste: 2.5 % -> Incineration (80 %), Landfill (20 %) Tonnage = sum of tonnage per end use per additive[3]
ES3: Article service life. Use in pipes and pipe fittings	ERC10a (outdoor)	OECD ESD release factors ERC release factor (soil)[4]	water 3.2 %; air 0.05 %; soil 1.6%[5] Indoor: water/air: 0.05 % Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data
ES4: Article service life. Use in window frames	ERC10a (indoor)/ERC11a (outdoor)	OECD ESD release factors ERC release factor (soil)[4]	Share between indoor/outdoor for release -> 50 % water 1.6%; air 0.05%; soil 1.6% Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data
ES5: Article service life. Use in cables	ERC11a (indoor)	OECD ESD release factors	water: 0.05 %; air: 0.05% Waste: 100 % -> 100 % - releases-> share between landfill, incineration and recycling from industry data
ES6: Article service life. Use in flooring	ERC10a (indoor)/ERC11a (outdoor)	OECD ESD release factors ERC release factor	Share between indoor/outdoor for release -> 50 %[6]

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[28] ECHA's Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description

[29] OECD Emission Scenario Documents (ESD)

Exposure scenario	Use descriptors	Estimation method[29]	Relevant parameters
		(soil)[4]	water 1.6%; air 0.05%; soil: 1.6% Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data
ES7: Article service life. Use in packaging (food and non-food)	ERC11a (indoor)	OECD ESD release factors	water: 0.05%; air: 0.05% Waste: 100 % -> 100% - releases -> share between landfill, incineration and recycling from industry data
ES8: Article service life. Use in toys	ERC10a (indoor)/ERC11a (outdoor)	OECD ESD release factors ERC release factor (soil)[4]	Share between indoor/outdoor for release -> 50 %[7] water 1.6%; air 0.05%; soil 1.6% Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data[8]
ES9: Article service life. Use in artificial leather	ERC10a (indoor)/ERC11a (outdoor)	OECD ESD release factors ERC release factor (soil)[4]	Share between indoor/outdoor for release -> 50 %[9] water: 1.6%; air: 0.05%; soil: 1.6% Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data
ES10: Article service life. Automotive interiors	ERC10a (indoor)/ERC11a (outdoor)	OECD ESD release factors ERC release factor (soil)[4]	Share between indoor/outdoor for releases -> 50 % [10] water: 1.6%; air: 0.05%; soil: 1.6% Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data[11]
ES11: Article service life. Medical application	ERC11a	OECD ESD release factors	Indoor: water/air: 0.05 % Waste: 100 % - releases-> share between landfill, incineration and recycling from industry data[8]
ES12: Professional use. Handling plastic articles	ERC12a	ERC release factor for ERC12a	water/air/soil: 2.5 % Waste (all): 0 %[12] Tonnage: from ES covering building material construction (pipes, windows, flooring, cables)
ES13: Waste stage. Recycling	ERC0	Release factors ECHA R18, Table R18-6	air: 10 %[15] Waste[13]: 2.5 % -> 20 % landfill, 80 % incineration Tonnage from additives recycled for each ES
ES14: Waste stage. Landfill	ERC 0 (no descriptor)	Release factors ECHA R18, Table R18-4	water 1.6 %[14]; air 0.05 %; soil; 3.2 % No waste containing the substance generated Tonnage from additives landfilled for each ES
ES15: Waste stage. Incineration	ERC 0 (no descriptor)	Release factors ECHA R18, Table R18-5	Water: 0.01% (org.) - 0.02% (metals) Air: 0.01% (org.) - 0.03/0.1% (metals) No waste containing the

Exposure scenario	Use descriptors	Estimation method[29]	Relevant parameters
			substance generated Tonnage from additives incinerated for each ES

[1] Release to (waste)water are connected (90 %) to sewage treatment plants (STP) and partially (10 %) directly discharged to surface water (from the provisions of the Urban Waste Water Treatment Directive (EC, 2020)). Sludge generated in STP is applied to agricultural soil (48 %), landfilled (32 %) and incinerated (20 %) (Eurostat, 2023a).
[2] Assumption that the fraction recycled takes a role in the conversion, not at the compounding (only virgin material).
[3] It does include the fraction recycled
[4] Releases to soil comes from ERC10a releases factor (appendix 1, R16 ECHA Guidance), where the assumption is that equal releases are accounted for water and soil.
[5] Pipes for conveying wastewater or used in agriculture can be considered as outdoor use for release to water estimation (i.e. 3.2 %) due to contact with water; soil releases are halved (1.6 %) if compared to ERC release factor due to lower impact of weather on pipes.
[6] Outdoor uses include roofing
[7] Outoor uses include inflatable toys for outdoor use
[8] Recycling fraction for miscellaneous consumer plastic articles (CfE2,#1601) used for the estimation since no specific info for toys or medical devices.
[9] Outdoor uses and releases to water assumed for washing clothes or furniture
[10] Outdoor uses assumed for washing car interiors and outdoor use of car tarpaulins
[11] Recycling fraction of “general parts” used for the assessment (CfE2,#1601)
[12] Fraction to waste already taken into account from use in pipes, windows frames, cables and flooring
[13] Releases to waste not reported in ECHA R18 Guidance but derived from similar activities involving shredding (ES2 and ES12)
[14] Release factor to water from landfill assume WWTP with 50 % of effectiveness. Landfill not further connected to municipal STP
[15] Significant releases to waste water from recycling sites can be expected based on recent studies (see section A.2.3.4) as particle releases carry also the additives. However, additive releases to waste water from recycling sites were not estimated for this report.

For some substances (e.g. organotin used as heat stabilisers in rigid PVC or ortho-phthalates (DEHP, DINP, DIDP)) data on migration was received in CfE#2, especially from testing required by other legislation (Drinking Water Directive, Food Contact legislation). These testing results show very low migration and hence compliance with the relevant legislation. However, the transfer of those results to the releases / exposure estimation is not possible. This is mainly due to following reasons: :

- Releases to environment are expressed by different condition (for example the impact of weathering for outdoor use) and different mechanism for release (e.g. abrasive operations leading to particle dispersion)
- Releases towards saliva for consumer exposure cannot be simulated by (controlled) migration to water, while the migration to food does not represent the potential migration to skin.

Moreover, none of the migration tests, can be used to simulate the mechanisms of emission to air leading to inhalation exposure; in fact, emission to air is mainly described by partitioning between air and solid matrix, which is very different than the mechanisms regulating partitioning from solids to water / food simulants.

In this regard, it should be highlighted that even though the migration data suggests a low migration for high molecular weight ortho-phthalates (e.g. DINP, DIDP), they have been nevertheless detected in human biological biomonitoring data. The recent results of the HBM4EU initiative (HBM4EU, 2023) suggest widespread human exposure to these compounds and specially infants/children who seem to be exposed to higher levels than adults (Saravanabhavan and Murray, 2012, Wang et al., 2019). Although the main source of exposure for high molecular weight ortho-phthalates might be via food contact materials, other sources of exposure cannot be completely discarded.

B.6.2.2. Releases from waste

Waste management is described in section A.1.3. No or little information on releases from waste is available in the registration dossiers or provided during the calls for evidence.

Based on the use description and information from ECHA R18 Guidance, Eurostat data, the information received in the calls for evidence, and in line with approaches developed in other restriction dossiers, three generic exposure scenarios have been considered:

- ES13: Waste stage. Recycling (dismantling and shredding of waste/articles)
- ES14: Waste stage. Landfill (disposal of waste/articles to landfill)
- ES15: Waste stage. Incineration (disposal of waste/articles by incineration)

The total tonnage of substances going to waste has been aggregated per substance across all uses and life cycle stages and allocated to one or several of the exposure scenarios ES13 to ES15. These aggregated tonnages have been used as inputs for the calculation of releases to the environmental compartments (water, air and soil) from waste handling, by combining input tonnages to release factors (Section B.6.2.4).

Fractions of waste tonnage to be considered in exposure scenarios ES13 to ES15 have been assumed for each use and life cycle stage, based on data provided by sector organisations under CfE2, while the release factors are based on ECHA R18 guidance (ECHA, 2012a). The main assumptions are summarised as follows:

- Pre-consumer waste: by-products directly recycled/reused (e.g. scrap compounded PVC) are not accounted for in the calculation for the releases from waste. The classification of waste, whether hazardous or not, does not have an impact on the current estimates although it is a relevant issues as to whether the releases can be minimised. This is further discussed in Appendix D.

- Post-consumer waste: comes from the end of life of articles includes building and construction waste (pipes and pipe fittings, window frames, cables, flooring), WEEE (cables), end-of-life vehicles (artificial leather, cables, interior parts), medical waste (blood bags, infusion bags, tubing, masks) and mixed waste (toys, artificial leather).

  Building and construction waste, WEEE and ELV all undergo separate collection (at least to some extent), dismantling, sorting, shredding (breaking down into smaller pieces), and the material is further separated for disposal and recycling. The fraction of waste collected separately (versus disposed of as unsorted municipal waste) and the treatment of collected waste vary depending on the type of articles and materials, the country in the EU and the facilities (NEA, 2021). For instance, PVC waste are collected and sorted to some extent but with greater effectiveness in the construction sector than others where it remains challenging (EC, 2022). Releases occurring during all dismantling, shredding and sorting steps are estimated together in the exposure scenario ‘ES13: Waste stage. Recycling’. Ultimately, the separated fractions will be disposed of in landfills or incinerated (which leads to more releases, quantified under exposure scenarios ‘ES14: Waste stage. Landfill’ and ‘ES15: Waste stage. Incineration’).

- Building and construction waste (pipes and pipe fittings, window frames, cables, flooring): it is assumed that 100 % of the waste are dismantled and shredded during the tearing down of building and further processing of the waste and separation of materials. Based on information provided by Vinylplus (CfE2,#1601) it is estimated that 33 % of building and construction PVC waste is recycled, 44% incinerated and 23 % landfilled. Those are aggregated figures that were made publicly available. More detailed figures per use were provided as confidential information.

- WEEE (cables): it is assumed that mainly cables will be disposed as WEEE. They are included in all the categories of WEEE which encompass different collection and treatment processes. They would also be collected when tearing down buildings and vehicles. According to the Plastics Recyclers Europe Association (CfE2,#1552), cables from demolition activities are sent to copper recyclers, who remove the plastic fraction and send it to other specialised recyclers, who in turn remove the impurities and recycle the flexible PVC into e.g. road furniture. Other electrical and electronic equipment would be shredded to separate the ‘shredder light fraction’ (SLF) containing plastics, from which PVC (on the contrary to other plastics) is incinerated due to the concomitant presence of PBDEs at levels exceeding the limits set under the POP regulation. Based on information provided by Vinylplus (CfE2,#1601) it is estimated that 48 % of PVC cable waste is recycled (after shredding), 39 % incinerated (directly and after shredding) and 13 % landfilled (directly and after shredding). Those are aggregated figures for EEE that were made publicly available. More detailed figures for cables per sector (building and construction, EEE and automotive) were provided as confidential information but used in calculations.

- ELV (artificial leather, cables, interior parts): According to the Plastics Recyclers Europe Association (CfE2,#1552), soft PVC from ELV is not recycled but sent to incineration due to the concomitant presence of PBDEs at levels exceeding the limits set under the POP regulation. Based on information provided by Vinylplus (CfE2,#1601) it is estimated that 9 % of PVC used in the automotive sector is recycled, 61 % incinerated and 30 % landfilled. Those are aggregated figures for the automotive sector that were made publicly available. More detailed figures per use were provided as confidential information.

- Packaging (food and non-food): Although packaging waste is generated not just by households but also from distribution channels and commercial usage, where packaging is normally cleaner and mono-material more suitable for recycling, it will be assumed that the waste process will follow that of household packaging. Thus, according to the Plastics Recyclers Europe Association (CfE2,#1552), household plastic packaging can be collected in one simple bag with all other waste (co-mingled) or separately collected from households. Plastics can be separated from co-mingled collection systems in material recovery facilities. The household plastics normally go to plastics waste sorting facilities where NIR and other object-based sorting technologies are used to create bales of plastics waste. For every type of bale generated a separate processing step is added. PVC packaging is so niche that it is such a material which is not sorted into a separate bale. The residual waste fraction can be either landfilled or incinerated with incineration being the preferred route to recover the energetic value of the material. Based on information provided by Vinylplus (CfE2,#1601) it is estimated that 15 % of PVC used in packaging is recycled, 66 % incinerated and 19 % landfilled. More detailed figures per use were provided as confidential information.

- Other waste: aggregates other sources of PVC waste. As stated above, more detailed figures per use were provided as confidential information (CfE2,#1601).

Table 53. Indicative amounts (public information) of post-consumer waste and fraction at the end of life per sector (CfE2,#1601)[*]

Sector	Post-consumer waste (Ktonnes)	Incineration (%)	Landfilling (%)	Recycling (%)
Packaging	478	66.1	18.6	15.3
Building and construction	1075	44	23	33
Automotive	92	60.9	30.4	8.7
EEE	185	38.9	13.5	47.6
Others	605	61.8	25.6	12.6
TOTAL	2435	53.1	22.3	24.6

[*] Confidential numbers have been used for release estimation

B.6.2.3. Municipal sewage treatment plant (STP) efficiency and connection rate

It is assumed that wastewater from all uses (after any on-site treatment for uses in industrial sites) is generally discharged to a sewage and treated in municipal wastewater treatment plant.

STP efficiency:

The efficiency of the municipal STP does depend on the substance properties, namely the Henry's Law constant (H, Pa m^3 / mol), octanol water partition coefficient (log Kow, dimensionless) and screening biodegradation tests. Simpletreat 2.0 as integrated in EUSES 2.1 (and in Chesar 3) has been used to estimate the fractions in the municipal STP going to: air, sludge, biodegraded and discharged to surface water. It is noted that the fate in the municipal STP was calculated for each additive based on the specific additive physico-chemical properties.

Sludges handling:

It is assumed that the sludges from municipal STP are either applied on land (i.e. directly applied on agricultural land as fertiliser, or to other lands e.g. parks or gardens after composting), incinerated, or landfilled/undergoing other treatment (Eurostat, 2023a), as displayed in Table 54.

Table 54. Municipal STP sludge disposal

Fate of municipal STP sludges	Average of EU countries (2015-2019)
STP sludges applied on land (agricultural or other)	48 %
STP sludges incinerated	18 %
STP sludges landfilled or undergoing other treatment	32 %

Connection rate:

A connection rate of 90 % is used for the releases to water to municipal STP for all the uses and life cycle stages (except landfill), in line with the tenth report on the implementation of the Urban Wastewater Treatment Directive which states that about 95 % of the waste waters in the EU were collected and 88 % received secondary treatment, in compliance with the provisions of the Urban Waste Water Treatment Directive (EC, 2020). Therefore, a small fraction of the wastewater (10 %) is assumed to be discharged to surface water directly.

In addition, with regard to the releases associated to waste the following assumptions have been made:

- Releases from landfill (via leachate, see ES14) are collected and treated in an onsite WWTP (not sent to a municipal STP); the effectiveness of the WWTP serving the landfill is considered in the releases factor to water assumed for this scenario.

- Vice versa, releases from incineration (via scrubbing), will be collected and treated in the municipal STP as for all other scenarios. It is further assumed that the sludges from STP connected to landfill would be incinerated.

B.6.2.4. Release factors

Release factors are considered for all environmental compartments (aquatic, air, soil) from all life cycle stages including for the treatment of waste.

Main assumptions for release estimation are summarised here below:

- Release factors from industrial use before the article service life (compounding and conversion, ES1 and ES2) are derived from OECD Exposure Scenario Document (ESD) of plastics (OECD, 2023), taking into consideration the worst case release factor mentioned for these types of activities. In this way we aim to cover all possible additive types during these processes. The tonnage processed during compounding and conversion has been derived from the sum of the tonnages per use per substance estimated for service life (ES3 to ES11). For compounding, the fraction of tonnage recycled has been subtracted to support the assumption of use of “virgin” material during formulation stage.

- Release factors from article service life have been derived from OECD ESD, where a differentiation has been made between uses where significant contact with water can be assumed (0.16 % of releases per year over 20 years of service life, leading to a release factor of 3.2 %) and uses where no contact with water is considered (0.05 % of release factor over the entire lifespan). In many cases, a mix of uses can be assumed for different type of articles within the same use scenario (e.g. indoor flooring with no water contact and outdoor use in roofing with contact with rain water); in such cases a 50 % rule is used to allocate the different types of articles, and release factor adjusted accordingly (i.e. from 3.2 to 1.6 %)

- Moreover, for the article service life scenarios, a minimal direct release to air is assumed (0.05 %) according to the OECD ESD for plastics. Direct releases to soil are not reported in the OECD ESD, therefore they are assumed equal to releases to water, according to R16 ECHA Guidance, appendix 1 (release factors from ERC10a) (ECHA, 2016b).

- Release factors from professional uses (assembly, dismantling) are derived from R16 Guidance, ERC 12a (2.5% for all routes); the tonnage for this use scenario is calculated from a cumulative tonnage accounting for uses involving building material, namely the ES3 (pipes), ES4 (windows frames), ES 5 (cables) and ES 6 (flooring).

- Release factors from waste stage are those reported in R18 guidance for the different stages (recycling by shredding, landfill, incineration). The tonnage estimated for these scenarios is derived from the release to waste and waste treatment type allocation for each use scenario.

More specific information is available in section B.6.2.1, Table 52. Tonnages per (group) of substances and use scenario are reported in sections B.6.4.2, B.6.5.2, B.6.6.2, B.6.7.2, B.6.8.2, B.6.9.2, B.6.10.2 and B.6.11.2.

B.6.2.5. Release calculation formula

For each path emission, the release calculation is made with the following general formula: [Release] = [Tonnage] x [Release factor].

Releases have been calculated at continental scale for each environmental compartment (water, soil, air) for each exposure scenario (i.e. each use and each life cycle stage) taking into account the tonnage per exposure scenario and release factor per exposure scenario and the receiving environmental compartment.

In addition, release to surface water has been calculated considering the STP efficiency and the STP connection rate, as follows: [Total release to surface water] = [Direct release to surface water] + [Release to surface water from STP]

In some cases (cf. STP connection rate), the waste water might not be treated in a municipal STP and released therefore directly to surface water. Moreover, releases to air includes those coming indirectly from the municipal STP while releases to soil account for those via sludge application on agricultural soil.

The formulae below depict the total release to surface water, air and soil:

[Total release to surface water] = ([Release to WW] x [STP connection rate] x (1 – (STP efficiency rate)) + ([Release to WW] x (1 – [STP connection rate]) = [Release to WW] x (1 – ([STP connection rate] x [STP efficiency]).

[Total release to air] = [Release to air from use] + [Release to air from STP] where [Release to air from STP] = [Release to WW] x [STP connection rate] x [Fraction to air]

[Total release to soil] = [Release to soil from use] + [Release to soil from STP], where [Release to soil from STP] = [Release to WW] x [STP connection rate] x [Fraction to sludges] x [Fraction of sludges applied to agricultural soil]

The output of the calculations is the tonnage released per year for each annual tonnage placed on the market (assuming steady state for service life).

B.6.3. Exposure estimation

B.6.3.1. Assumptions and strategy

For the human health exposure estimation, the following main assumptions are made:

- For PVC compounding and conversion, the exposures estimated by the lead registrants are taken forward. Operational conditions (OCs) and Risk management measures (RMMs) are applied per site and should ensure the safe use of the substances.
- No exposure estimation was done for article service life for pipes and pipe fittings, window frames, cables and medical devices since consumer exposure is considered minimal and/or dealt with another legislation (Water Framework Directive, Medical Devices Regulation).

- ECETOC TRA workers 3.0 and ECETOC TRA Consumer 3.1 as integrated in Chesar 3.7 are used to estimate respectively the worker and consumer exposure. It should be noted that these tools (especially the TRA consumers) are screening tools (Tier I) which give initial realistic worst-case estimates in absence of higher tier information.

- For consumer exposure: relevant TRA subcategories within the same article category (AC), when available, are used to estimate the exposure; these subcategories already include default parameters that are used for the assessment; the only deviations are: a) for concentration (where the actual concentration of the substance in the article is used); b) for the dermal contact that was always corrected for child exposure; c) for packaging where oral exposure is excluded.

- For automotives 2 different scenario were developed, one related to the presence of artificial leather (car seat) and the other related to automotive interiors; in both cases, the room ventilation and air exchange rate has been adapted to the car volume (2 m3) and ventilation rate (3 ACH/hour); these values are reflecting an increase of the pollution concentration in the car of about 2.5 times compared to the one for the indoor standard scenario (characterised by a room volume of 20 m3 and a ventilation of 0.6 ACH/hour); moreover, for the scenario covering car interiors (rigid parts made of plastics), it is assumed 10 kg of product containing the substance.

- Regarding the workers, no exposure assessment was available for recycling in the registration dossiers. Therefore, exposure assessment has been done considering the following process categories: PROC 14, PROC 21 and PROC 24. The concentrations of the substances used was the upper end of the typical average concentrations provided (CfE2,#1587) per function: 3 % for heat stabilisers, 35 % for plasticisers. For flame retardants the concentration depends on the substance. With regard to RMMs two situations have been considered with higher or lower efficiency set of RMMs:

    - Higher RMMs: in this case it is assumed low dustiness, the use of PPE with an efficiency of 90 %, LEV with an efficiency of 90 % for all contributing scenarios except for PROC 24 (80%) and good general ventilation with an efficiency of 30 % for all contributing scenarios.

    - Lower RMMs: in this case it is assumed medium dustiness, the use of PPE with an efficiency of 90 %, LEV with an efficiency of 80 % for PROC 24 only and general ventilation with an efficiency of 30 % for PROC 14 and PROC 21.

Table 55. Use descriptors,[28] estimation method and relevant parameters for exposure estimation in the relevant exposure scenarios

Exposure scenario	Use descriptors	Estimation method	Relevant parameters
ES6: Article service life. Use in flooring	AC13 (subcategory: large plastic articles)	ECETOC TRA consumers (inhalation / dermal)	Inhalation: TRA default Dermal: TRA default corrected for child exposure Plasticiser: 20% Flame retardants: 2%
ES7: Article service life. Use in packaging (food and non-food)	AC 13 (subcategory: small plastic articles)	ECETOC TRA consumers (inhalation / dermal)	Inhalation: TRA default Dermal: TRA default corrected for child exposure Heat stabilisers: 1%
ES8: Article service life. Use in toys	AC 13 (subcategory: plastic toys)	ECETOC TRA consumers (oral / dermal)	TRA default No substance assessed
ES9: Article service life.	AC 6 (subcategory:	ECETOC TRA	Inhalation: TRA default

Exposure scenario	Use descriptors	Estimation method	Relevant parameters
Use in artificial leather	artificial leather, sofa)	consumers (inhalation / dermal)	Dermal: TRA default corrected for child exposure Flame retardants: 2%
ES10a: Article service life. Car seat	AC 6 (subcategory: artificial leather, sofa)	ECETOC TRA consumers (inhalation / dermal)	Inhalation: TRA default corrected for room volume (2 m^3) and exchange rates (3 ACH) Dermal: TRA default correction for child exposure Flame retardants: 2%
ES10b: Article service life. Automotive interiors (rigid)	AC13 (no subcategory available)	ECETOC TRA consumers (inhalation / dermal)	Inhalation: TRA inhalation equation corrected for room volume (2 m^3) and exchange rates (3 ACH) – amount: 10 kg of rigid interiors Dermal: TRA dermal with contact with hands; correction for child exposure Heat stabilisers: 0.5% Flame retardants: 2%
ES12: Professional use. Handling plastic articles	PROC 14, PROC 21	ECETOC TRA workers v3.0 (inhalation / dermal)	
ES13: Waste stage. Recycling	PROC 14, PROC 21 and PROC 24	ECETOC TRA workers v3.0 (inhalation / dermal)	Higher RMMs: low dustiness, PPE (90 %), LEV (90% except for PROC 24, 80%), good general ventilation (30 %) Lower RMMs: medium dustiness, LEV for PROC 24 (80%), good general ventilation for PROC 14 and 21 (30 %) Heat stabilisers: 3% Plasticisers: 35% Flame retardants: 2%

B.6.3.2. Fate of additives in the environment

Fate of PVC additives is tightly connected to the fate of PVC microparticles released to the environment. Although minor part of the additives may be directly released at the point of emission as substance, this project assumes based on ECHA Guidance that the majority of the additives is released in particle form (within the PVC microparticles/dust). In the following the fate of this form of releases is in focus.

EC (2022), ECHA (2018) and industry stakeholders (CfE2,#1605, 1606 and 1607) have discussed the available migration data on additives in PVC. VinylPlus perceives that migration of additives is well understood and very low if not negligible. (Mercea et al.) (2018; also referred to as FABES studies (ECHA, 2018)) reported on migration tests of lead, cadmium, Zn based stabilisers, diantimony trioxide and four phthalates including DEHP in recycled PVC. Howick et al. (2005) discussed on migration of additives in PVC from food contact material. The European Council for Plasticisers and Intermediates (CfE2, #1601) explained the general mechanisms of migration and, more specifically, migration of plasticisers from PVC. The leaching potential is highly dependent on the particle size (CfE2, #1601). Although the studies and reviews mentioned above are relevant for assessments of use-related leaching, these references seem not to address the estimation of migration from plastic microparticles released to the environment. Feng (2020) observed in an experimental study that the leaching rate may vary several orders of magnitude depending on the size and surface structure of the plastic microparticle. UNEP (2023) has also discussed the factors influencing leaching of substances from plastic microparticles.The mechanisms and factors influencing leaching have also been discussed by, e.g., Faraji et al. (2022).

An experimental and simulation leaching study on PVC microparticles was carried out by Henkel et al. (2022). Thee authors observed that desorption half-lives of three studied phthalates DEHP, DOTP and DINP are generally greater than 500 years but can be strongly influenced by environmental factors. The observed leaching rates were dependent on the surface area of the microparticles and the logKow but were independent of the phthalate content of the microparticles. They also concluded that PVC microparticles are a long-term source of phthalates in the environment. It is noted, that the PVC pellet size used in the study was 4 mm, which may be expected to represent the larger size range of the PVC microparticles released to the environment. Hence, also faster desorption half-lives could be expected for smaller particles. For comparison, in another study Endo et al (2013) found that desorption half-lives of PCB congeners from polyethlene pellets (3-4 mm diameter) was in the range of 14 d to 210 years for CB-8 to CB-209 in an actively stirred aqueous solution. Methanol addition to the solution significantly enhanced the desorption rate. In both studies aqueous boundary layer (ABL) diffusion model well approximated the data.

What may be inferred from the studies above is that leaching can be expected to take place at significantly higher rates than indicated by migration data for larger PVC pieces, whereas the leaching rate will vary depending on, i.a., the additive properties, the microparticle size and polymer, surface area to volume -ratio and the surrounding environmental conditions including conditions prevailing in intestines of organisms exposed to microparticles. In conclusion, it appears that there is a data gap for experimental data on leaching and volatilisation of additives from plastic microparticles. The available but scarce information on leaching from smaller plastic particles suggests that industry data indicating negligible migration of additives to the surrounding matrix may apply to articles and raw materials of larger size than microparticles, but may not be representative of migration from PVC microparticles in relevant environmental conditions.

The released PVC microparticles are very persistent in line with ECHA (2020b) and hence can be expected to accumulate in the environment. It is clear from the measured data on leaching described above that a significant part of the plastic additives remain in the plastic material for years after the plastic microparticles are released to the environment, regardless of the size of the plastics. The additives contained in the released PVC (and other plastic) microparticles can be expected to not react/degrade within the microparticle in significant amounts or practically not at all, depending on the additive. The PVC (and other plastic) microparticles released to the environment render the additives released within the material as very persistent, too. The environmental (bio)degradation rates of the additives are decoupled from the (bio)degradation rates of the additives tested as chemical substances and reported in ECHA registrations and sections 0 to B.5.. Correspondingly, it may be expected that the additives within the microparticles would accumulate in the environment as well. The interaction between the releases, very slow degradation of the PVC microparticle particles in the environment, expected highly various migration rates, the increase of the environmental stock and the (bio)degradation rates of the leached additives is highly complex. Furthermore, a small fraction of the releases may be released from some of the activites as such, without the plastic matrix. Due to this complexity, it is likely that estimation of environmental and man via environment exposures of unbound PVC additives is not possible. Nevertheless, there is a need to model this dynamic system in order to better understand the form of additives exposure . As discussed in, e.g., ECHA (2020b) and UNEP (2018), additives exposure can take place also directly from ingested microparticles in biota (and humans). The recent results of the HBM4EU initiative (HBM4EU, 2023) suggest widespread human exposure to many of the prioritised additives and specially infants/children who seem to be exposed to higher levels than adults (Saravanabhavan and Murray, 2012, Wang et al., 2019). Although the main source of exposure for high molecular weight ortho-phthalates might be via food contact materials, other sources of exposure, such as indirect exposure via environment within PVC microparticles or unbound, cannot be discarded.

Overall, the PVC additives are expected to gradually increase in concentrations in sediment and soil bound within the PVC microparticle matrix. . The PVC microparticles ending up to the environment can be expected to function as the carrier and a source for the environmental exposures of the prioritised (and other) additives. The fate of the additives is mainly dependent on the fate of PVC microparticles. Most of the prioritised substances have a high $\log K_{ow}$ which suggests that when they are released as such they likely end up and/or prevail further in sediment and soil.

B.6.4. Organotin substances

B.6.4.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for organotin substances:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)
- ES3: Article service life. Use in pipes and pipe fittings (pressure fittings)
- ES4: Article service life. Use in window frames (edge bends)
- ES7: Article service life. Packaging (food and non-food)
- ES10: Article service life. Automotive interiors (monofilament profile parts)
- ES11: Article service life. Medical application (blister packs)
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential non-threshold hazards of the organotin substances as ED (human health and environment) and/or PBT, the assessment will be limited to the estimation of releases of the substances to the environment. Nevertheless, for those substances that are classified for threshold hazards, i.e. DOTE, DMTE and MMTE, human health exposure and risk is also considered when appropriate, i.e. packaging and automotive interiors.

Human health exposure and risks for some applications are covered by other specific regulations. Organotin substances used in PVC are addressed, but not directly restricted in food contact materials (Regulation EU No. 10/2011, Annex I), in medical devices (Regulation EU 2017/745/EC) and the human health exposure and risks from migration of organotin substances to drinking water are handled by the Drinking Water Directive (Directive 2020/2184). Organotin substances are currently present in the positive list.

Therefore, from the human health point of view, exposure assessment will be limited to the use in packaging (from the point of view of children) and automotive interiors.

B.6.4.2. Tonnage used in the EU

Organotin substances are used in PVC in a concentration between 0.5 and 2.5 % (w/w) depending on the application and the provided or estimated volume per application in this work are shown in Table 56.

When needed, the estimation was done by applying an average compounding to the volume or range of volumes of compounded PVC per application. The volume was then distributed considering shares provided in the calls for evidence or, when not provided, proportional to the registered tonnage. More details are provided in Table 56 below. Values are rounded up.

The estimated tonnages are assumed to remain constant.

Table 56. Estimated volumes per use for organotin substances

EC No	**CAS No**	**Substance name**	**Pipes and pipe fittings**[1] (tonnes/year)	**Window frames (edge bends)**[2] (tonnes/year)	**Packaging (food and non-food)**[3] (tonnes/year)	**Medical applications (blister packs)**[4] (tonnes/year)	**Automotive parts (monofilament profiles)**[5] (tonnes/year)
239-622-4	15571-58-1	DOTE	50	50-335	45-270	45-280	10-70
239-581-2	15535-79-2	DOTTG	1.6	1-6	N/A	N/A	0-1
248-227-6	27107-89-7	MOTE	17	10-85	245-1465	255-1535	3-20
260-829-0	57583-35-4	DMTE	67	85-575	60-355	60-370	20-120
268-500-3	68109-88-6	DOT-MalEt	9	7-50	N/A	N/A	2-10
260-828-5	57583-34-3	MMTE	1	15-95	60-355	60-370	3-20

[1] (CfE2,#1596)

[2] Estimated values based on an average compounding (CfE2,#1601) and assuming share is proportional to the registered tonnage

[3] Estimated values based on an average compounding of 1 % and share provided (CfE3,#1708)

[4] Estimated values based on an average compounding of 1 % and share provided (CfE3,#1708)

[5] Estimated values based on an average compounding (CfE2,#1601) and assuming share is proportional to the registered tonnage

B.6.4.3. Release and exposure assessment per use

The release estimates for organotin substances per exposure scenario are presented in Table 57. Values are rounded up.

Table 57. Release estimates for organotin substances used in PVC (tonnes/year)

Exposure scenario	Compartment	DOTE	DOTTG	MOTE	DMTE	DOT-MalEt	MMTE
ES1: Formulation (PVC compounding)	Surface water	0.02 to 0.08	0	0.06 to 0.35	0.07 to 0.34	0 to 0.01	0.03 to 0.19
	Air	0.06 to 0.29	0	0.11 to 0.68	0.1 to 0.54	0 to 0.01	0.06 to 0.37
	Soil	0.03 to 0.17	0	0.14 to 0.81	0.02 to 0.08	0 to 0.01	0.01 to 0.07
	Total	0.11 to 0.54	0	0.31 to 1.83	0.18 to 0.96	0.01 to 0.03	0.1 to 0.63
ES2: Article production (PVC conversion)	Surface water	0.07 to 0.36	0	0.23 to 1.34	0.32 to 1.62	0.01 to 0.05	0.13 to 0.77
	Air	0.6 to 3.01	0.01 to 0.02	1.33 to 7.79	0.98 to 5.02	0.05 to 0.19	0.47 to 2.86
	Soil	0.16 to 0.79	0 to 0.01	0.53 to 3.1	0.07 to 0.38	0.01 to 0.05	0.04 to 0.27
	Total	0.84 to 4.17	0.01 to 0.03	2.09 to 12.23	1.37 to 7.02	0.08 to 0.3	0.64 to 3.9
ES3: Article service life. Use in pipes and pipe fittings	Surface water	0.11 to 0.23	0.01 to 0.01	0.05 to 0.09	0.47 to 0.93	0.04 to 0.08	0.01 to 0.01
	Air	0.18 to 0.34	0	0.01 to 0.01	0.41 to 0.79	0.02 to 0.03	0.01 to 0.01
	Soil	0.65 to 1.31	0.02 to 0.04	0.24 to 0.49	0.65 to 1.29	0.11 to 0.23	0.01 to 0.02
	Total	0.95 to 1.88	0.03 to 0.06	0.3 to 0.59	1.52 to 3.01	0.18 to 0.35	0.02 to 0.04
ES4: Article service life. Use in window frames	Surface water	0.06 to 0.76	0 to 0.02	0.02 to 0.23	0.29 to 4	0.02 to 0.24	0.04 to 0.56
	Air	0.1 to 1.24	0	0.01 to 0.04	0.27 to 3.53	0.01 to 0.11	0.05 to 0.6
	Soil	0.51 to 7.07	0.01 to 0.12	0.14 to 1.89	0.73 to 10.13	0.08 to 1.05	0.12 to 1.71
	Total	0.67 to 9.07	0.01 to 0.15	0.16 to 2.16	1.29 to 17.65	0.1 to 1.4	0.21 to 2.86
ES7: Article service life. Use in packaging (food and non-food)	Surface water	0 to 0.02	0	0.02 to 0.13	0.01 to 0.08	0	0.01 to 0.06
	Air	0.03 to 0.16	0	0.12 to 0.73	0.04 to 0.24	0	0.04 to 0.24
	Soil	0.01 to 0.04	0	0.05 to 0.29	0 to 0.02	0	0 to 0.02
	Total	0.04 to 0.22	0	0.19 to 1.15	0.06 to 0.33	0	0.06 to 0.33
ES10: Article service life. Automotive interiors	Surface water	0.01 to 0.16	0 to 0	0 to 0.05	0.07 to 0.84	0 to 0.05	0.01 to 0.12
	Air	0.02 to 0.26	0 to 0	0 to 0.01	0.07 to 0.74	0 to 0.02	0.01 to 0.12
	Soil	0.12 to 1.48	0 to 0.03	0.03 to 0.39	0.17 to 2.12	0.02 to 0.22	0.03 to 0.36
	Total	0.16 to 1.89	0 to 0.03	0.04 to 0.45	0.31 to 3.69	0.02 to 0.29	0.05 to 0.6
ES11: Article service life. Medical application	Surface water	0 to 0.02	0 to 0	0.02 to 0.13	0.01 to 0.08	0 to 0	0.01 to 0.07
	Air	0.03 to 0.17	0 to 0	0.13 to 0.77	0.04 to 0.25	0 to 0	0.04 to 0.25
	Soil	0.01 to 0.04	0 to 0	0.05 to 0.3	0 to 0.02	0 to 0	0 to 0.02
	Total	0.04 to 0.23	0 to 0	0.2 to 1.2	0.06 to 0.35	0 to 0	0.06 to 0.34
ES12: Professional	Surface water	0.35 to 1.37	0.01 to 0.04	0.13 to 0.44	1.63 to 6.98	0.12 to 0.44	0.13 to 0.88

Exposure scenario	Compartment	DOTE	DOTTG	MOTE	DMTE	DOT-MalEt	MMTE
use. Handling plastic articles	Air	2.95 to 11.56	0.06 to 0.18	0.73 to 2.54	5.07 to 21.69	0.45 to 1.65	0.5 to 3.26
	Soil	3.24 to 12.69	0.08 to 0.25	1.02 to 3.54	4.13 to 17.67	0.53 to 1.93	0.41 to 2.7
	Total	6.54 to 25.62	0.16 to 0.47	1.87 to 6.52	10.82 to 46.34	1.1 to 4.02	1.05 to 6.83
ES13: Waste stage. Recycling	Surface water	0	0	0	0	0	0
	Air	5.86 to 27.55	0.11 to 0.38	7.37 to 41.39	8.88 to 43.85	0.78 to 3.23	2.28 to 14.09
	Soil	0	0	0	0	0	0
	Total	5.86 to 27.55	0.11 to 0.38	7.37 to 41.39	8.88 to 43.85	0.78 to 3.23	2.28 to 14.09
ES14: Waste stage. Landfill	Surface water	0.42 to 4.08	0.01 to 0.03	1.15 to 13.47	0.59 to 5.89	0.04 to 0.26	0.29 to 3.55
	Air	0.03 to 0.13	0	0.07 to 0.42	0.04 to 0.18	0 to 0.01	0.02 to 0.11
	Soil	0.84 to 8.16	0.01 to 0.06	2.3 to 26.94	1.18 to 11.78	0.07 to 0.52	0.59 to 7.1
	Total	1.28 to 12.37	0.02 to 0.1	3.52 to 40.84	1.81 to 17.86	0.11 to 0.79	0.9 to 10.77
ES15: Waste stage. Incineration	Surface water	0.02 to 0.1	0	0.07 to 0.4	0.03 to 0.14	0	0.02 to 0.1
	Air	0.1 to 0.51	0	0.33 to 1.98	0.14 to 0.71	0.01 to 0.02	0.08 to 0.5
	Soil	0	0	0	0	0	0
	Total	0.12 to 0.61	0	0.4 to 2.37	0.16 to 0.86	0.01 to 0.03	0.1 to 0.61
TOTAL	Surface water	1.06 to 7.18	0.03 to 0.11	1.74 to 16.62	3.48 to 20.89	0.24 to 1.14	0.68 to 6.31
	Air	9.96 to 45.22	0.18 to 0.59	10.22 to 56.35	16.04 to 77.54	1.32 to 5.29	3.56 to 22.43
	Soil	5.57 to 31.76	0.13 to 0.52	4.49 to 37.76	6.96 to 43.49	0.82 to 4.01	1.23 to 12.27
	Total	16.59 to 84.15	0.34 to 1.22	16.45 to 110.73	26.47 to 141.92	2.38 to 10.43	5.47 to 41.01

Exposure estimates were produced for organotin substances that are classified for human health hazards, i.e. DOTE, DMTE and MMTE. It is recognized that compounding and conversion stages are subject to the authorisation scheme as DOTE and Reaction mass of DOTE and MOTE are included in Annex XIV to REACH under entries 58 and 59 respectively. Therefore, the exposure assessment of compounding and conversion is provided as indicative only for the purpose of comparison with worker exposure in recycling. Recycling is not subject to the authorisation process but considered as manufacture. Hence risk assessment of workers at recycling sites is relevant in this project.

The exposure estimates for workers are presented in Table 58. The exposure estimates for consumers are presented in Table 59.

Table 58. Exposure estimates for workers for DOTE, DMTE and MMTE

Scenario	Contributing scenario[30]	Route	DOTE	DMTE	MMTE
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)[1]	PROC 5	Inhalation (mg/m^3)	N/A	[redacted]	[redacted]
		Dermal (mg/kg bw/day)		[redacted]	[redacted]
	PROC 6	Inhalation (mg/m^3)	[redacted]	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	Not estimated	[redacted]	[redacted]
	PROC 8a	Inhalation (mg/m^3)	N/A	[redacted]	[redacted]
		Dermal (mg/kg bw/day)		[redacted]	[redacted]
	PROC 8b	Inhalation (mg/m^3)	[redacted]	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	Not estimated	[redacted]	[redacted]
	PROC 9	Inhalation (mg/m^3)	N/A	[redacted]	[redacted]
		Dermal (mg/kg bw/day)		[redacted]	[redacted]
	PROC 14	Inhalation (mg/m^3)	[redacted]	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	Not estimated	[redacted]	[redacted]
	PROC 21	Inhalation (mg/m^3)	[redacted]	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	Not estimated	[redacted]	[redacted]
	PROC 24	Inhalation (mg/m^3)	N/A	[redacted]	[redacted]
		Dermal (mg/kg bw/day)		[redacted]	[redacted]
	PROC 28	Inhalation (mg/m^3)	[redacted]	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	Not estimated	[redacted]	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation (mg/m^3)	0.07	0.07	0.07
		Dermal (mg/kg bw/day)	0.0345	0.0345	0.0345
	PROC 21	Inhalation (mg/m^3)	0.21	0.21	0.21
		Dermal (mg/kg bw/day)	0.0285	0.0285	0.0285
	PROC 24	Inhalation (mg/m^3)	0.2	0.2	0.2
		Dermal (mg/kg bw/day)	0.0285	0.0285	0.0285
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation (mg/m^3)	0.0007	0.0007	0.0007
		Dermal (mg/kg bw/day)	0.0345	0.0345	0.0345
	PROC 21	Inhalation (mg/m^3)	0.007	0.007	0.007
		Dermal (mg/kg bw/day)	0.0285	0.0285	0.0285
	PROC 24	Inhalation	0.14	0.14	0.14

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[30] ECHA's Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description

Scenario	Contributing scenario[30]	Route	DOTE	DMTE	MMTE
		(mg/m^3)			
		Dermal (mg/kg bw/day)	0.0285	0.0285	0.0285

[1] Exposure estimates available in the CSR provided by the lead registrant. The exposure scenario covers both compounding and conversion.
[2] Exposure estimates (ECETOC TRA v3.1)

Table 59. Exposure estimates for consumers for DOTE, DMTE and MMTE

Scenario	Route	DOTE	DMTE	MMTE
ES7: Article service life. Use in packaging (food and non-food)	Inhalation (mg/m^3)	0.0065	0.0065	0.0065
	Dermal (mg/kg bw/day)	0.011	0.011	0.011
	Oral (mg/kg bw/day)	N/A	N/A	N/A
ES10: Article service life. Automotive interiors	Inhalation (mg/m^3)	0.076	10.77	10.77
	Dermal (mg/kg bw/day)	0.127	0.127	0.127
	Oral (mg/kg bw/day)	N/A	N/A	N/A

B.6.4.4. Risk characterisation

The risk characterisation is performed using the estimated exposures (Table 58 and Table 59) and comparing these result with the DNELs derived by RAC (when available) or the registrants (Table 60). The resulting risk characterisation ratios (RCRs) for each use are described in this chapter.

Table 60. DNELs for DOTE, DMTE and MMTE for the calculation of RCRs

Population	Route	DOTE	DMTE	MMTE
Workers	Inhalation (mg/m3)	0.025[1]	0.18[2]	5.75[2]
	Dermal (mg/kg bw/day)	1.8[1]	0.52[2]	16.3[2]
General population	Inhalation (mg/m3)	0.0045[1]	0.045[3]	1.43[3]
	Dermal (mg/kg bw/day)	0.64[1]	0.26[3]	8.31[3]
	Oral (mg/kg bw/day)	0.0032[1]	0.026[3]	0.84[3]

[1] DNELs derived by RAC (https://echa.europa.eu/documents/10162/17086/afa_rac_final_note_dote_dnel_en.pdf/df88501b-8bb2-2466-0d66-301c611f9256?t=1671002497042).
[2] Derived by the registrants in the registration dossiers.
[3] Not derived by the registrants. Estimated using default assessment factors for general population.

Table 61. Calculated RCRs for workers for DOTE, DMTE and MMTE

Scenario	Contributing scenario[30]	Route	DOTE	DMTE	MMTE
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)[1]	PROC 5	Inhalation	N/A	[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 6	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 8a	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]

Scenario	Contributing scenario[30]	Route	DOTE	DMTE	MMTE
	PROC 8b	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 9	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 14	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 21	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 24	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
	PROC 28	Inhalation		[redacted]	[redacted]
		Dermal		[redacted]	[redacted]
		Combined		[redacted]	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation	2.80	0.39	0.01
		Dermal	0.02	0.07	0.00
		Combined	2.82	0.46	0.01
	PROC 21	Inhalation	8.40	1.17	0.04
		Dermal	0.02	0.05	0.00
		Combined	8.42	1.22	0.04
	PROC 24	Inhalation	8.00	1.11	0.03
		Dermal	0.02	0.05	0.00
		Combined	8.02	1.17	0.04
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation	0.03	0.00	0.00
		Dermal	0.02	0.07	0.00
		Combined	0.05	0.07	0.00
	PROC 21	Inhalation	0.28	0.04	0.00
		Dermal	0.02	0.05	0.00
		Combined	0.30	0.09	0.00
	PROC 24	Inhalation	5.60	0.78	0.02
		Dermal	0.02	0.05	0.00
		Combined	5.62	0.83	0.03

Table 62. Calculated RCRs for consumers for DOTE, DMTE and MMTE

Scenario	Route	DOTE	DMTE	MMTE
ES7: Article service life. Use in packaging (food and non-food)	Inhalation	1.4	0.14	<0.01
	Dermal	0.02	0.04	<0.01
	Oral	N/A	N/A	N/A
	Combined	1.46	0.19	0.01
ES10: Article service life. Automotive interiors	Inhalation	16.9	239.3	7.5
	Dermal	0.2	0.49	0.02
	Oral	N/A	N/A	N/A
	Combined	17.1	239.82	7.6

B.6.5. Phenyl 1,3-diones

B.6.5.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for substance List No. 915-316-2:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)

- ES4: Article service life. Use in window frames
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential non-threshold hazards of substance List No. 915-316-2, i.e. PBT, the assessment will be limited to the estimation of releases of the substance to the environment.

B.6.5.2. Tonnage used in the EU

Phenyl 1,3-diones are used as co-stabilisers in stabilisers packages where the concentration can be 1-4 % (w/w), which means that in PVC the concentration would be below 0.04 % (w/w) if stabilisers are represent 1 % (w/w).

Where the phenyl 1,3-diones were identified to be used the estimation was done applying 0.04 % as the average compounding to the volume or range of volumes of compounded PVC per application.

Thus, for substance List No. 915-316-2 it has been estimated a volume of 110 to 760 tonnes/year for window frames. The estimated tonnage is assumed to remain constant.

B.6.5.3. Release and exposure assessment

The release estimates for List No. 915-316-2 per exposure scenario are presented in Table 63. Values are rounded up.

Table 63. Release estimates for List No. 915-316-2 (tonnes/year)

Exposure scenario	Compartment	List No. 915-316-2
ES1: Formulation (PVC compounding)	Surface water	0.01 to 0.04
	Air	0.01 to 0.09
	Soil	0.01 to 0.09
	Total	0.03 to 0.22
ES2: Article production (PVC conversion)	Surface water	0.04 to 0.31
	Air	0.27 to 1.9
	Soil	0.09 to 0.63
	Total	0.4 to 2.84
ES4: Article service life. Use in window frames	Surface water	0.14 to 1.96
	Air	0.06 to 0.41
	Soil	1.17 to 16.2
	Total	1.37 to 18.57
ES12: Professional use. Handling plastic articles	Surface water	0.44 to 3.06
	Air	2.75 to 19.05
	Soil	3.65 to 25.31
	Total	6.84 to 47.42
ES13: Waste stage. Recycling	Surface water	0
	Air	6.04 to 41.18
	Soil	0
	Total	6.04 to 41.18
ES14: Waste stage. Landfill	Surface water	0.18 to 2.45
	Air	0.01 to 0.08
	Soil	0.36 to 4.89
	Total	0.55 to 7.42

Exposure scenario	Compartment	List No. 915-316-2
ES15: Waste stage. Incineration	Surface water	0 to 0.02
	Air	0 to 0.02
	Soil	0
	Total	0 to 0.04
TOTAL	Surface water	0.8 to 7.8
	Air	9.1 to 62.7
	Soil	5.3 to 47.1
	Total	15.2 to 117.7

No exposure estimates were produced for List No. 915-316-2 considering the main potential hazard identified is for PBT/vPvB properties.

B.6.5.4. Risk characterisation

Not applicable.

B.6.6. Ortho-phthalates

B.6.6.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for ortho-phthalates:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)
- ES5: Article service life. Use in cables
- ES6: Article service life. Use in flooring
- ES7: Article service life. Use in packaging (food and non-food)
- ES9: Article service life. Use in artificial leather
- ES10: Article service life. Automotive interiors
- ES11: Article service life. Medical application
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2). Considering the potential non-threshold hazards of ortho-phthalates as ED (human health and environment) and/or PBT, the assessment will be limited to the estimation of releases of the substances to the environment.

From the ortho-phthalates with active registrations and identified to be used in PVC only DEHP has a harmonised classification for human health threshold hazard, i.e. Repr. 1B.

Human health exposure and risks is only considered for PVC compounding and conversion and PVC recycling steps. Human health exposure and risks for the use in medical devices is covered by other specific regulation, i.e. Directive 2007/47/EC.

B.6.6.2. Tonnage used in the EU

Plasticisers are used in PVC in a concentration between 20 and 37 % (w/w) depending on the application (CfE2,#1587) and the provided or estimated volume for ortho-phthalates per application in this work are shown in Table 64.

When needed, the estimation was done by applying an average compounding to the volume or range of volumes of compounded PVC per application. The volume was then distributed considering shares provided in the calls for evidence or, when not provided, proportional to the registered tonnage. More details are provided in Table 64 below.

The estimated tonnages are assumed to remain constant.

Table 64. Estimated volumes per use for ortho-phthalates

Subgroup	**EC No**	**CAS No**	**Substance name**	**Flooring**[1] (tonnes/year)	**Cables**[2] (tonnes/year)	**Packaging (food and non-food)**[3] (tonnes/year)	**Artificial leather**[2] (tonnes/year)	**Automotive (Artificial leather)**[2] (tonnes/year)	**Automotive (Tarpaulins)**[2] (tonnes/year)	**Medical devices**[4] (tonnes/year)
Medium chain (C4-C6)	204-211-0	117-81-7	DEHP	-	-	-	-	-	-	1680-10200
Medium chain (C7-C8)	249-079-5	28553-12-0	DINP	26600	44360	1255	4505-26930	2320-14020	965-5695	-
	258-469-4	53306-54-0	DPHP	-	15840	-	1600-9555	830-5010	345-2035	-
	271-090-9	68515-48-0	D810P (DINP branched)	250	2260	65	170-1025	120-715	50-290	-
Long chain (C9-C18)	222-884-9	3648-20-2	DUP	-	115	-	10-70	6-35	2-15	-
	271-085-1	68515-43-5	D911P	-	685	-	70-415	35-215	15-90	-
	271-089-3	68515-47-9	D1114P	-	835	-	85-510	45-265	20-105	-
	271-091-4	68515-49-1	DIDP	540	16180	1320	1645-9825	845-5115	355-2075	-
	290-580-3	90193-76-3	D1618P	-	-	-	30-165	-	-	-
	700-989-5	-	D1012P	-	825	-	85-495	-	-	-
	931-251-2	-	DDP/DDDP	-	1120	-	115-680	-	-	-

[1] Volumes provided (CfE2,#1603)

[2] Estimated values based on an average compounding of plasticisers (CfE2,#1587), share of ortho-phthalates (54 %) (CfE2,#1601) and distributing the share proportionally to the registered tonnage of the substances

[3] Estimated values based on an average compounding of plasticisers (CfE2,#1587), assuming a share of 10 % for both DINP and DIDP (In CfE2,#1601 and CfE3,#1708 it was stated that the main plasticisers in flexible packaging are DOTP, DINCH, ATBC and DEHA and “some DINP and DIDP”. It is assumed a share of 10 % for both DINP and DIDP) and distributing the share proportionally to the registered tonnage of the substances

[4] Estimated values based on an average compounding of plasticisers (CfE2,#1587) and assuming a share of 20 % for DEHP (In CfE2,#1601 and CfE3,#1708 it was stated that DEHP, DINCH, TOTM, DOTP and ATBC are the main plasticisers in medical applications. Thus, it was assumed that the share for each of them is 20 %).

B.6.6.3. Release and exposure assessment

The release estimates for ortho-phthalates per exposure scenario are presented in Table 65 and Table 66. Values are rounded up.

Table 65. Release estimates for DEHP and medium chain C7-C8 ortho-phthalates used in PVC (tonnes/year)

Exposure scenario	Compartment	DEHP	DINP	DPHP	DINP branched
ES1: Formulation (PVC compounding)	Surface water	0.18 to 1.1	7.11 to 11.38	1.35 to 2.89	0.21 to 0.38
	Air	0.38 to 2.29	14.3 to 22.9	2.76 to 5.89	0.53 to 0.97
	Soil	0.35 to 2.13	15.96 to 25.56	3.12 to 6.65	0.48 to 0.88
	Total	0.91 to 5.52	37.37 to 59.84	7.23 to 15.43	1.22 to 2.23
ES2: Article production (PVC conversion)	Surface water	0.67 to 4.08	33.42 to 49.65	7.84 to 13.67	1.13 to 1.78
	Air	4.2 to 25.5	200.61 to 298.04	47.01 to 81.92	7.76 to 12.26
	Soil	1.3 to 7.9	75.07 to 111.53	18.07 to 31.48	2.62 to 4.14
	Total	6.17 to 37.48	309.1 to 459.22	72.92 to 127.07	11.51 to 18.18
ES5: Article service life. Use in cables	Surface water	0	3.71 to 3.71	1.34 to 1.34	0.18 to 0.18
	Air	0	22.25 to 22.25	8 to 8	1.2 to 1.2
	Soil	0	8.32 to 8.32	3.08 to 3.08	0.41 to 0.41
	Total	0	34.28 to 34.28	12.42 to 12.42	1.79 to 1.79
ES6: Article service life. Use in flooring	Surface water	0	35.56 to 71.12	0	0.31 to 0.62
	Air	0	13.94 to 14.58	0	0.25 to 0.38
	Soil	0	292.69 to 585.38	0	2.73 to 5.45
	Total	0	342.19 to 671.08	0	3.29 to 6.45
ES7: Article service life. Use in packaging (food and non-food)	Surface water	0	0.1 to 0.1	0	0
	Air	0	0.63 to 0.63	0	0.03 to 0.03
	Soil	0	0.24 to 0.24	0	0.01 to 0.01
	Total	0	0.97 to 0.97	0	0.04 to 0.04
ES9: Article service life. Use in artificial leather	Surface water	0	6.02 to 72	2.15 to 25.77	0.21 to 2.54
	Air	0	2.36 to 14.76	0.93 to 6.34	0.17 to 1.57
	Soil	0	49.55 to 592.54	17.75 to 212.19	1.87 to 22.33
	Total	0	57.93 to 679.3	20.83 to 244.3	2.25 to 26.44
ES10: Article service life. Automotive interiors	Surface water	0	4.39 to 52.71	1.58 to 18.99	0.21 to 2.49
	Air	0	1.72 to 10.81	0.68 to 4.67	0.17 to 1.54
	Soil	0	36.15 to 433.85	13.03 to 156.4	1.82 to 21.86
	Total	0	42.26 to 497.37	15.29 to 180.06	2.2 to 25.89
ES11: Article service life. Medical application	Surface water	0.13 to 0.82	0	0	0
	Air	0.84 to 5.1	0	0	0
	Soil	0.26 to 1.58	0	0	0
	Total	1.23 to 7.5	0	0	0
ES12: Professional use. Handling plastic articles	Surface water	0	296.44 to 296.44	66.76 to 66.76	9.73 to 9.73
	Air	0	1779.33 to 1779.33	400.11 to 400.11	66.84 to 66.84
	Soil	0	2439.82 to 2439.82	549.81 to 549.81	85.36 to 85.36
	Total	0	4515.59 to 4515.59	1016.68 to 1016.68	161.93 to 161.93
ES13: Waste stage. Recycling	Surface water	0	0	0	0
	Air	16.95 to 102.92	2330.98 to 2806.73	789.64 to 959.48	113.85 to 134.65
	Soil	0	0	0	0
	Total	16.95 to 102.92	2330.98 to 2806.73	789.64 to 959.48	113.85 to 134.65
ES14: Waste stage. Landfill	Surface water	4.61 to 55.97	193.09 to 578.36	35.34 to 139.85	5.88 to 20.35
	Air	0.29 to 1.75	12.07 to 18.07	2.21 to 4.37	0.37 to 0.64
	Soil	9.22 to 111.93	386.18 to	70.68 to 279.69	11.75 to 40.7

Exposure scenario	Compartment	DEHP	DINP	DPHP	DINP branched
			1156.72		
	Total	14.12 to 169.65	591.34 to 1753.15	108.23 to 423.91	18 to 61.69
ES15: Waste stage. Incineration	Surface water	0.1 to 0.6	3.6 to 5.81	0.72 to 1.51	0.12 to 0.21
	Air	0.1 to 0.6	3.6 to 5.81	0.72 to 1.51	0.12 to 0.21
	Soil	0 to 0	0 to 0	0 to 0	0 to 0
	Total	0.2 to 1.2	7.2 to 11.62	1.44 to 3.02	0.24 to 0.42
TOTAL	Surface water	5.7 to 62.56	583.45 to 1141.29	117.09 to 270.77	17.97 to 38.29
	Air	22.76 to 138.17	4381.8 to 4993.91	1252.06 to 1472.3	191.3 to 220.3
	Soil	11.13 to 123.55	3303.98 to 5353.95	675.53 to 1239.29	107.04 to 181.13
	Total	39.59 to 324.28	8269.23 to 11489.15	2044.68 to 2982.36	316.31 to 439.72

Table 66. Release estimates for long chain C9-C18 ortho-phthalates used in PVC (tonnes/year)

Exposure scenario	Compartment	DUP	D911P	D1114P	DIDP	D1618P	D1012 P	DDP/ DDDP
ES1: Formulation (PVC compounding)	Surface water	0.02 to 0.05	0.05 to 0.1	0.07 to 0.16	1.54 to 3.06	0 to 0.02	0.06 to 0.11	0.09 to 0.15
	Air	0.02 to 0.04	0.16 to 0.34	0.14 to 0.3	3.28 to 6.52	0.01 to 0.04	0.13 to 0.22	0.17 to 0.3
	Soil	0 to 0	0.11 to 0.24	0.17 to 0.36	3.42 to 6.79	0.01 to 0.04	0.15 to 0.25	0.2 to 0.35
	Total	0.04 to 0.09	0.32 to 0.68	0.38 to 0.82	8.24 to 16.37	0.02 to 0.1	0.34 to 0.58	0.46 to 0.8
ES2: Article production (PVC conversion)	Surface water	0.13 to 0.23	0.28 to 0.49	0.42 to 0.74	8.5 to 14.28	0.01 to 0.07	0.39 to 0.56	0.53 to 0.77
	Air	0.33 to 0.58	2.26 to 3.95	2.46 to 4.29	52.91 to 88.83	0.07 to 0.42	2.28 to 3.31	3.08 to 4.49
	Soil	0	0.65 to 1.13	0.97 to 1.7	18.86 to 31.67	0.03 to 0.17	0.89 to 1.29	1.21 to 1.77
	Total	0.46 to 0.81	3.19 to 5.57	3.85 to 6.73	80.27 to 134.78	0.11 to 0.66	3.56 to 5.16	4.82 to 7.03
ES5: Article service life. Use in cables	Surface water	0.02 to 0.02	0.05 to 0.05	0.07 to 0.07	1.32 to 1.32	0	0.07 to 0.07	0.1 to 0.1
	Air	0.06 to 0.06	0.38 to 0.38	0.42 to 0.42	8.2 to 8.2	0	0.41 to 0.41	0.56 to 0.56
	Soil	0 to 0	0.11 to 0.11	0.17 to 0.17	2.92 to 2.92	0	0.16 to 0.16	0.22 to 0.22
	Total	0.08 to 0.08	0.54 to 0.54	0.66 to 0.66	12.44 to 12.44	0	0.64 to 0.64	0.88 to 0.88
ES6: Article service life. Use in flooring	Surface water	0	0	0	0.7 to 1.41	0	0	0
	Air	0	0	0	0.33 to 0.39	0	0	0
	Soil	0	0	0	5.88 to 11.77	0	0	0
	Total	0	0	0	6.91 to 13.57	0	0	0
ES7: Article service life. Use in packaging (food and non-food)	Surface water	0	0	0	0.11 to 0.11	0	0	0
	Air	0	0	0	0.67 to 0.67	0	0	0
	Soil	0	0	0	0.24 to 0.24	0	0	0
	Total	0	0	0	1.02 to	0	0	0

Exposure scenario	Compartment	DUP	D911P	D1114P	DIDP	D1618P	D1012P	DDP/DDDP
					1.02			
ES9: Article service life. Use in artificial leather	Surface water	0.04 to 0.43	0.08 to 0.93	0.12 to 1.4	2.14 to 25.61	0.04 to 0.46	0.11 to 1.35	0.16 to 1.86
	Air	0.01 to 0.03	0.1 to 1.05	0.04 to 0.26	1 to 7.05	0.01 to 0.08	0.04 to 0.26	0.06 to 0.34
	Soil	0.09 to 1.1	0.73 to 8.77	0.95 to 11.36	17.9 to 214	0.31 to 3.71	0.92 to 11.04	1.27 to 15.13
	Total	0.14 to 1.56	0.91 to 10.75	1.11 to 13.02	21.04 to 246.66	0.36 to 4.25	1.07 to 12.65	1.49 to 17.33
ES10: Article service life. Automotive interiors	Surface water	0.03 to 0.31	0.06 to 0.68	0.09 to 1.02	1.56 to 18.74	0	0	0
	Air	0 to 0.03	0.08 to 0.77	0.03 to 0.19	0.73 to 5.16	0	0	0
	Soil	0.07 to 0.8	0.54 to 6.43	0.69 to 8.3	13.05 to 156.63	0	0	0
	Total	0.1 to 1.14	0.68 to 7.88	0.81 to 9.51	15.34 to 180.53	0	0	0
ES11: Article service life. Medical application	Surface water	0	0	0	0	0	0	0
	Air	0	0	0	0	0	0	0
	Soil	0	0	0	0	0	0	0
	Total	0	0	0	0	0	0	0
ES12: Professional use. Handling plastic articles	Surface water	1.1 to 1.1	2.39 to 2.39	3.59 to 3.59	68.09 to 68.09	0	3.52 to 3.52	4.79 to 4.79
	Air	2.82 to 2.82	19.25 to 19.25	20.9 to 20.9	423.65 to 423.65	0	20.68 to 20.68	27.95 to 27.95
	Soil	2.83 to 2.83	22.59 to 22.59	29.17 to 29.17	569 to 569	0	28.71 to 28.71	38.97 to 38.97
	Total	6.75 to 6.75	44.23 to 44.23	53.66 to 53.66	1060.74 to 1060.74	0	52.91 to 52.91	71.71 to 71.71
ES13: Waste stage. Recycling	Surface water	0	0	0	0	0	0	0
	Air	5.62 to 6.83	34.06 to 41.41	41.65 to 50.65	827.09 to 1001.22	0.35 to 2.04	40.4 to 45.47	54.69 to 61.61
	Soil	0	0	0	0	0	0	0
	Total	5.62 to 6.83	34.06 to 41.41	41.65 to 50.65	827.09 to 1001.22	0.35 to 2.04	40.4 to 45.47	54.69 to 61.61
ES14: Waste stage. Landfill	Surface water	0.24 to 0.97	1.52 to 6.02	1.87 to 7.4	39.99 to 150.75	0.06 to 0.74	1.66 to 5.16	2.25 to 7.01
	Air	0.02 to 0.03	0.09 to 0.19	0.12 to 0.23	2.5 to 4.71	0 to 0.02	0.1 to 0.16	0.14 to 0.22
	Soil	0.49 to 1.95	3.04 to 12.04	3.73 to 14.79	79.98 to 301.49	0.12 to 1.48	3.33 to 10.32	4.51 to 14.03
	Total	0.75 to 2.95	4.65 to 18.25	5.72 to 22.42	122.47 to 456.95	0.18 to 2.24	5.09 to 15.64	6.9 to 21.26
ES15: Waste stage. Incineration	Surface water	0.01 to 0.01	0.03 to 0.07	0.04 to 0.08	0.86 to 1.67	0 to 0.01	0.03 to 0.06	0.05 to 0.08
	Air	0.01 to 0.01	0.03 to 0.07	0.04 to 0.08	0.86 to 1.67	0 to 0.01	0.03 to 0.06	0.05 to 0.08
	Soil	0	0	0	0	0	0	0
	Total	0.02 to 0.02	0.06 to 0.14	0.08 to 0.16	1.72 to 3.34	0 to 0.02	0.06 to 0.12	0.1 to 0.16

Exposure scenario	Compartment	DUP	D911P	D1114P	DIDP	D1618P	D1012P	DDP/DDDP
TOTAL	Surface water	1.59 to 3.12	4.45 to 10.73	6.27 to 14.46	124.81 to 285.03	0.12 to 1.3	5.85 to 10.84	7.96 to 14.76
	Air	8.87 to 10.42	56.42 to 67.4	65.79 to 77.32	1321.21 to 1548.05	0.44 to 2.61	64.07 to 70.56	86.7 to 95.55
	Soil	3.48 to 6.69	27.77 to 51.3	35.86 to 65.85	711.25 to 1294.5	0.47 to 5.4	34.16 to 51.78	46.38 to 70.47
	Total	13.94 to 20.23	88.64 to 129.43	107.92 to 157.63	2157.27 to 3127.58	1.03 to 9.31	104.08 to 133.18	141.04 to 180.78

Exposure estimates for workers were produced for DEHP for PVC compounding and conversion as well as for recycling activities. It is recognized that compounding and conversion stages are subject to the authorisation scheme as DEHP is included in Annex XIV to REACH under entry 04. Therefore, the exposure assessment of compounding and conversion is provided as indicative only for the purpose of comparison with worker exposure in recycling. Recycling is not subject to the authorisation process but considered as manufacture. Hence risk assessment of workers at recycling sites is relevant in this project. The exposure estimates for workers are presented in Table 67.

Table 67. Exposure estimates for workers for DEHP

Scenario	Contributing scenario[30]	Route	DEHP
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)[1]	PROC 2	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 3	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 4	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 6	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 8b	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 10	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 13	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 14	Inhalation (mg/m^3)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 21	Inhalation (mg/m^3)	[redacted]
		Dermal	[redacted]

Scenario	Contributing scenario[30]	Route	DEHP
		(mg/kg bw/day)	
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation (mg/m^3)	0.7
		Dermal (mg/kg bw/day)	0.343
	PROC 21	Inhalation (mg/m^3)	2.1
		Dermal (mg/kg bw/day)	0.283
	PROC 24	Inhalation (mg/m^3)	2
		Dermal (mg/kg bw/day)	0.283
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation (mg/m^3)	0.007
		Dermal (mg/kg bw/day)	0.343
	PROC 21	Inhalation (mg/m^3)	0.07
		Dermal (mg/kg bw/day)	0.283
	PROC 24	Inhalation (mg/m^3)	1.4
		Dermal (mg/kg bw/day)	0.283

[1] Exposure estimates available in the CSR provided by the lead registrant. The exposure scenario covers both compounding and conversion.

[2] Exposure estimates (ECETOC TRA v3.1) assuming a 35 % compounding (maximum for plasticisers (CfE2,#1587))

B.6.6.4. Risk characterisation – human health threshold risks

The risk characterisation is performed using the estimated exposures (Table 67) and comparing these results with the DNELs derived by RAC[31] in 2013 (Table 68). The resulting risk characterisation ratios (RCRs) for each use are described in this chapter. Based on the latest RAC opinion (ECHA, 2021) it cannot be concluded whether DNELs derived by RAC in 2013 are sufficiently protective for the endocrine effects. Hence the resulting risk ratios need to be taken as indicative minimum risk levels only (see also discussion in section B.4.1.2.3 and B.6.6.3) and the overall conclusions can only be therefore qualitative.

The risks of DEHP on workers at industrial stages are covered by the authorisation scheme. However, risks from recycling are not covered by authorisation. The indicative RCRs from compounding and conversion are provided for the purpose of rough comparison only. As far as no threshold assessment is available, it is recommended to take the working approach that exposures of endocrine disruptors are minimised. This pragmatic approach was already taken in the authorisation process of alkyl phenol ethoxylates by RAC. Analogously, it should be concluded that there is a need to act at recycling sites to minimise exposures to DEHP.

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[31] https://echa.europa.eu/documents/10162/21961120/rac_24_dnel_dehp_comments_en.pdf/e0506f6b-35f7-433e-99da-35464a26e2df

Table 68. Indicative DNELs for DEHP for the calculation of RCRs

Population	Route	DEHP
Workers	Inhalation (mg/m3)	0.88
	Dermal (mg/kg bw/day)	1.882
General population	Inhalation (mg/m3)	0.16
	Dermal (mg/kg bw/day)	0.672
	Oral (mg/kg bw/day)	0.034

Table 69. Calculated indicative RCRs for workers for DEHP

Scenario	Contributing scenario[30]	Route	DEHP
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation	0.80
		Dermal	0.18
		Combined	0.98
	PROC 21	Inhalation	2.39
		Dermal	0.15
		Combined	2.54
	PROC 24	Inhalation	2.27
		Dermal	0.15
		Combined	2.42
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation	0.01
		Dermal	0.18
		Combined	0.19
	PROC 21	Inhalation	0.08
		Dermal	0.15
		Combined	0.23
	PROC 24	Inhalation	1.59
		Dermal	0.15
		Combined	1.74

B.6.7. Terephthalates (DBTP)

B.6.7.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for DBTP:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)
- ES6: Article service life. Use in flooring
- ES9: Article service life. Use in artificial leather
- ES10: Article service life. Automotive interiors
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill

- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential non-threshold hazard for DBTP as ED (human health and environment), the assessment will be limited to the estimation of releases of the substances to the environment.

B.6.7.2. Tonnage used in the EU

Plasticisers are used in PVC in a concentration between 20 and 37 % (w/w) depending on the application (CfE2,#1587) and the provided or estimated volume per application in this work are shown in Table 70.

When needed, the estimation was done by applying an average compounding to the volume or range of volumes of compounded PVC per application. The volume was then distributed considering shares provided in the calls for evidence or, when not provided, proportional to the registered tonnage. More details are provided in Table 70 below.

The estimated tonnages are assumed to remain constant.

Table 70. Estimated volumes per use for terephthalates

EC No	**CAS No**	**Substance name**	**Flooring**[1] (tonnes/year)	**Artificial leather**[2] (tonnes/year)	**Automotive (Artificial leather)**[2] (tonnes/year)	**Automotive (Tarpaulins)**[2] (tonnes/year)
217-803-9	1962-75-0	DBTP	3135	35-200	15-100	7-40
229-176-9	6422-86-2	DOTP	52045	2140-12785	1070-6480	445-2630

[1] Volumes provided (CfE2,#1603)

[2] Estimated values based on an average compounding of plasticisers (CfE2,#1587), share of terephthalates (14 %) (CfE2,#1601) and distributing the share proportionally to the registered tonnage of the substances.

The estimated volumes of DOTP are provided in Table 70 to compare relative to other plasticisers. No hazards were identified for DOTP and conventional quantitative risk characterisation will be done.

In addition to the uses in Table 70, DOTP is also used in:

- Toys (1920-11520 tonnes/year): only plasticiser identified in the calls for evidence (CfE2,#1546 and #1579)

- Packaging (5940 tonnes/year): Estimated values based on an average compounding of plasticisers (CfE2,#1587), assuming a share of 22.5 % for DOTP (in CfE2,#1601 and CfE3,#1708 it was stated that the main plasticisers in flexible packaging are DOTP, DINCH, ATBC and DEHA and “some DINP and DIDP”. It is assumed a share of 10 % for both DINP and DIDP and the rest distributed equally to DOTP, DINCH, ATBC and DEHA)

- Medical devices (1680-10200 tonnes/year): Estimated based on an average compounding of plasticisers (CfE2,#1587) and assuming a share of 20 % for DOTP (In CfE2,#1601 and CfE3,#1708 it was stated that DEHP, DINCH, TOTM, DOTP and ATBC are the main plasticisers in medical applications. Thus, it was assumed that the share for each of them is 20 %).

B.6.7.3. Release and exposure assessment

The release estimates for DBTP per exposure scenario are presented in Table 71. Values are rounded up.

Table 71. Release estimates for DBTP (tonnes/year)

Exposure scenario	Compartment	DEHP
ES1: Formulation (PVC compounding)	Surface water	0.38 to 0.41
	Air	1.14 to 1.24
	Soil	0.2 to 0.22
	Total	1.72 to 1.87
ES2: Article production (PVC conversion)	Surface water	1.31 to 1.43
	Air	9.29 to 10.11
	Soil	0.69 to 0.75
	Total	11.29 to 12.29
ES6: Article service life. Use in flooring	Surface water	4.12 to 8.25
	Air	5.68 to 9.79
	Soil	27.25 to 54.5
	Total	37.05 to 72.54
ES9: Article service life. Use in artificial leather	Surface water	0.04 to 0.52
	Air	0.06 to 0.62
	Soil	0.29 to 3.47
	Total	0.39 to 4.61
ES10: Article service life. Automotive interiors	Surface water	0.03 to 0.37
	Air	0.04 to 0.44
	Soil	0.21 to 2.47
	Total	0.28 to 3.28
ES12: Professional use. Handling plastic articles	Surface water	12.89 to 12.89
	Air	91.2 to 91.2
	Soil	85.16 to 85.16
	Total	189.25 to 189.25
ES13: Waste stage. Recycling	Surface water	0 to 0
	Air	12.74 to 16.03
	Soil	0 to 0
	Total	12.74 to 16.03
ES14: Waste stage. Landfill	Surface water	10.83 to 22.74
	Air	0.68 to 0.71
	Soil	21.66 to 45.49
	Total	33.17 to 68.94
ES15: Waste stage. Incineration	Surface water	0.18 to 0.19
	Air	0.18 to 0.19
	Soil	0 to 0
	Total	0.36 to 0.38
TOTAL	Surface water	29.79 to 46.81
	Air	121 to 130.34
	Soil	135.46 to 192.05
	Total	286.25 to 369.2

B.6.7.4. Risk characterisation

N/A

B.6.8. Trimellitates

B.6.8.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for ortho-phthalates:

- ES1: Formulation (PVC compounding)

- ES2: Article production (PVC conversion)
- ES5: Article service life. Use in cables
- ES9: Article service life. Use in artificial leather
- ES10: Article service life. Automotive interiors
- ES11: Article service life. Medical application
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential non-threshold hazards of trimellitates as ED (human health and environment) and/or PBT, the assessment will be limited to the estimation of releases of the substances to the environment.

B.6.8.2. Tonnage used in the EU

Plasticisers are used in PVC in a concentration between 20 and 37 % (w/w) depending on the application (CfE2,#1587) and the estimated volume for trimellitates per application in this work are shown in Table 72.

The estimation was done by applying an average compounding to the volume or range of volumes of compounded PVC per application. The volume was then distributed considering shares provided in the calls for evidence or, when not provided, proportional to the registered tonnage. More details are provided in Table 72. The estimated tonnages are assumed to remain constant.

Table 72. Estimated volumes per use for trimellitates

EC No	**CAS No**	**Substance name**	**Cables**[1] (tonnes/year)	**Artificial leather**[1] (tonnes/year)	**Automotive (Artificial leather)**[1] (tonnes/year)	**Automotive (Tarpaulins)**[1] (tonnes/year)	**Medical applications**[2] (tonnes/year)
304-780-6	94279-36-4	T911M/TIDTM	145	15-90	7-45	3-20	
290-754-9	90218-76-1	T810TM	2945	300-1795	150-910	60-370	
201-877-4	89-04-3	TOTM	785	80-480	40-245	15-100	1680-10200
258-847-9	53894-23-8	TINTM	205	20-125	10-65	4-25	
253-138-0	36631-30-8	TIDTM	485	50-295	25-150	10-60	

[1] Estimated values based on an average compounding of plasticisers (CfE2,#1587), share of trimellitates (14 %) (CfE2,#1601) and distributing the share proportionally to the registered tonnage of the substances

[4] Estimated values based on an average compounding of plasticisers (CfE2,#1587) and assuming a share of 20 % for TOTM (In CfE2,#1601 and CfE3,#1708 it was stated that DEHP, DINCH, TOTM, DOTP and ATBC are the main plasticisers in medical applications. Thus, it was assumed that the share for each of them is 20 %)

B.6.8.3. Release and exposure assessment

The release estimates for trimellitates per exposure scenario are presented in Table 73. Values are rounded up.

Table 73. Release estimates for trimellitates used in PVC (tonnes/year)

Exposure scenario	Compartment	T911M/TIDTM	T810TM	TOTM	TINTM	TIDTM
ES1: Formulation (PVC compounding)	Surface water	0.01 to 0.03	0.26 to 0.55	0.26 to 1.32	0.02 to 0.04	0.04 to 0.09
	Air	0.02 to 0.05	0.5 to 1.06	0.52 to 2.6	0.04 to 0.07	0.08 to 0.17
	Soil	0.03 to 0.06	0.59 to 1.26	0.61 to 3.06	0.04 to 0.09	0.1 to 0.21
	Total	0.06 to 0.14	1.35 to 2.87	1.39 to 6.98	0.1 to 0.2	0.22 to 0.47
ES2: Article production (PVC conversion)	Surface water	0.08 to 0.14	1.49 to 2.59	1.12 to 5.06	0.1 to 0.18	0.26 to 0.44
	Air	0.43 to 0.74	8.64 to 15.04	6.53 to 29.62	0.61 to 1.06	1.42 to 2.48
	Soil	0.16 to 0.28	3.43 to 5.97	2.58 to 11.68	0.24 to 0.42	0.56 to 0.98
	Total	0.67 to 1.16	13.56 to 23.6	10.23 to 46.36	0.95 to 1.66	2.24 to 3.9
ES5: Article service life. Use in cables	Surface water	0.01 to 0.01	0.25 to 0.25	0.07 to 0.07	0.02 to 0.02	0.04 to 0.04
	Air	0.07 to 0.07	1.47 to 1.47	0.39 to 0.39	0.1 to 0.1	0.24 to 0.24
	Soil	0.03 to 0.03	0.58 to 0.58	0.16 to 0.16	0.04 to 0.04	0.1 to 0.1
	Total	0.11 to 0.11	2.3 to 2.3	0.62 to 0.62	0.16 to 0.16	0.38 to 0.38
ES9: Article service life. Use in artificial leather	Surface water	0.02 to 0.27	0.41 to 4.94	0.11 to 1.31	0.03 to 0.35	0.07 to 0.85
	Air	0.01 to 0.04	0.15 to 0.9	0.04 to 0.27	0.01 to 0.07	0.02 to 0.15
	Soil	0.16 to 1.95	3.35 to 40.09	0.89 to 10.7	0.24 to 2.82	0.55 to 6.59
	Total	0.19 to 2.26	3.91 to 45.93	1.04 to 12.28	0.28 to 3.24	0.64 to 7.59
ES10: Article service life. Automotive interiors	Surface water	0.02 to 0.19	0.29 to 3.52	0.08 to 0.94	0.02 to 0.25	0.05 to 0.6
	Air	0.01 to 0.03	0.11 to 0.64	0.03 to 0.19	0.01 to 0.05	0.02 to 0.11
	Soil	0.12 to 1.39	2.38 to 28.56	0.63 to 7.62	0.17 to 2.01	0.39 to 4.7
	Total	0.15 to 1.61	2.78 to 32.72	0.74 to 8.75	0.2 to 2.31	0.46 to 5.41
ES11: Article service life. Medical application	Surface water	0	0	0.14 to 0.87	0	0
	Air	0	0	0.84 to 5.12	0	0
	Soil	0	0	0.33 to 2.02	0	0
	Total	0	0	1.31 to 8.01	0	0
ES12: Professional use. Handling plastic articles	Surface water	0.7 to 0.7	12.67 to 12.67	3.37 to 3.37	0.89 to 0.89	2.18 to 2.18
	Air	3.63 to 3.63	73.61 to 73.61	19.72 to 19.72	5.18 to 5.18	12.13 to 12.13
	Soil	5 to 5	102.84 to 102.84	27.44 to 27.44	7.23 to 7.23	16.91 to 16.91
	Total	9.33 to 9.33	189.12 to 189.12	50.53 to 50.53	13.3 to 13.3	31.22 to 31.22
ES13: Waste stage.	Surface water	0	0	0	0	0
	Air	7.23 to 8.78	146.71 to	56.14 to	10.31 to	24.18 to

Exposure scenario	Compartment	T911M/TIDTM	T810TM	TOTM	TINTM	TIDTM
Recycling			178.14	150.49	12.52	29.36
	Soil	0	0	0	0	0
	Total	7.23 to 8.78	146.71 to 178.14	56.14 to 150.49	10.31 to 12.52	24.18 to 29.36
ES14: Waste stage. Landfill	Surface water	0.32 to 1.28	6.56 to 25.9	6.36 to 62.92	0.46 to 1.82	1.08 to 4.27
	Air	0.02 to 0.04	0.41 to 0.81	0.4 to 1.97	0.03 to 0.06	0.07 to 0.13
	Soil	0.65 to 2.55	13.13 to 51.8	12.73 to 125.83	0.92 to 3.64	2.16 to 8.54
	Total	0.99 to 3.87	20.1 to 78.51	19.49 to 190.72	1.41 to 5.52	3.31 to 12.94
ES15: Waste stage. Incineration	Surface water	0.01 to 0.01	0.13 to 0.28	0.14 to 0.68	0.01 to 0.02	0.02 to 0.05
	Air	0.01 to 0.01	0.13 to 0.28	0.14 to 0.68	0.01 to 0.02	0.02 to 0.05
	Soil	0	0	0	0	0
	Total	0.02 to 0.02	0.26 to 0.56	0.28 to 1.36	0.02 to 0.04	0.04 to 0.1
TOTAL	Surface water	1.18 to 2.64	22.07 to 50.69	11.64 to 76.54	1.55 to 3.56	3.74 to 8.52
	Air	11.43 to 13.41	231.74 to 271.96	84.75 to 211.05	16.29 to 19.12	38.19 to 44.81
	Soil	6.15 to 11.27	126.31 to 231.12	45.37 to 188.5	8.88 to 16.24	20.76 to 38
	Total	18.76 to 27.32	380.12 to 553.77	141.76 to 476.09	26.72 to 38.92	62.69 to 91.33

B.6.8.4. Risk characterisation

N/A

B.6.9. Benzoates

B.6.9.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for benzoate EC 421-090-1:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)
- ES6: Article service life. Use in flooring
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential threshold hazard for benzoate EC 421-090-1 as Repr. 1B, the assessment will consider an estimation of releases of the substance to the environment as well as human health exposure and risks.

B.6.9.2. Tonnage used in the EU

The use of benzoates has only been explicitly mentioned in flooring and specific volumes were provided (CfE2,#1603). According to the European Resilient Flooring Manufacturers' Institute (ERFMI) only Benzoic acid, C9-11, C10-rich, branched alkyl esters (EC 421-090-1) is currently used in PVC.

- Benzoic acid, C9-11, C10-rich, branched alkyl esters (EC 421-090-1): 430 tonnes/year

The estimated tonnage is assumed to remain constant.

B.6.9.3. Release and exposure assessment

The release estimates for benzoate EC 421-090-1 per exposure scenario are presented in Table 71. Values are rounded up.

Table 74. Release estimates for EC 421-090-1 (tonnes/year)

Exposure scenario	Compartment	EC 421-090-1
ES1: Formulation (PVC compounding)	Surface water	0.05 to 0.05
	Air	0.11 to 0.11
	Soil	0.07 to 0.07
	Total	0.23 to 0.23
ES2: Article production (PVC conversion)	Surface water	0.18 to 0.18
	Air	1.11 to 1.11
	Soil	0.23 to 0.23
	Total	1.52 to 1.52
ES6: Article service life. Use in flooring	Surface water	0.56 to 1.13
	Air	0.3 to 0.37
	Soil	4.18 to 8.37
	Total	5.04 to 9.87
ES12: Professional use. Handling plastic articles	Surface water	1.76 to 1.76
	Air	11.05 to 11.05
	Soil	13.07 to 13.07
	Total	25.88 to 25.88
ES13: Waste stage. Recycling	Surface water	0 to 0
	Air	1.66 to 1.63
	Soil	0 to 0
	Total	1.66 to 1.63
ES14: Waste stage. Landfill	Surface water	1.48 to 2.93
	Air	0.09 to 0.09
	Soil	2.97 to 5.86
	Total	4.54 to 8.88
ES15: Waste stage. Incineration	Surface water	0.02 to 0.02
	Air	0.02 to 0.02
	Soil	0 to 0
	Total	0.04 to 0.04
TOTAL	Surface water	4.06 to 6.07
	Air	14.34 to 14.39
	Soil	20.52 to 27.59
	Total	38.92 to 48.05

Exposure estimates were produced also produced for benzoate EC 421-090-1. The exposure estimates for workers are presented in Table 75. The exposure estimates for consumers (flooring) are presented in Table 76.

Table 75. Exposure estimates for workers for benzoate EC 421-090-1

Scenario	Contributing scenario[30]	Route	EC 421-090-1
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)[1]	PROC 1	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 2	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 3	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 4	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 5	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 6	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 8b	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 9	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 13	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
	PROC 14	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation (mg/m³)	0.07
		Dermal (mg/kg bw/day)	0.0343
	PROC 21	Inhalation (mg/m³)	0.21
		Dermal (mg/kg bw/day)	0.0283
	PROC 24	Inhalation (mg/m³)	0.2
		Dermal (mg/kg bw/day)	0.0283
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation (mg/m³)	0.0007
		Dermal (mg/kg bw/day)	0.0343
	PROC 21	Inhalation (mg/m³)	0.007
		Dermal (mg/kg bw/day)	0.0283
	PROC 24	Inhalation (mg/m³)	0.14
		Dermal (mg/kg bw/day)	0.0283

[1] Exposure estimates available in the CSR provided by the lead registrant. The exposure scenario covers both compounding and conversion.
[2] Exposure estimates (ECETOC TRA v3.1)

Table 76. Exposure estimates for consumers for benzoate EC 421-090-1

Scenario	Route	EC 421-090-1
ES6: Article service life. Use in flooring	Inhalation (mg/m^3)	0.894
	Dermal (mg/kg bw/day)	48
	Oral (mg/kg bw/day)	N/A

B.6.9.4. Risk characterisation

The risk characterisation is performed using the estimated exposures (Table 75 and Table 76) and comparing these result with the DNELs derived by the registrant (Table 77). The resulting risk characterisation ratios (RCRs) for each use are described in this chapter.

Table 77. DNELs for benzoate EC 421-090-1 for the calculation of RCRs

Population	Route	EC 421-090-1
Workers	Inhalation (mg/m3)	181
	Dermal (mg/kg bw/day)	206
General population	Inhalation (mg/m3)	53
	Dermal (mg/kg bw/day)	29
	Oral (mg/kg bw/day)	15.48

Table 78. Calculated RCRs for workers for benzoate EC 421-090-1

Scenario	Contributing scenario[30]	Route	EC 421-090-1
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)[1]	PROC 1	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 2	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 3	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 4	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 5	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 6	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 8b	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 9	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
	PROC 13	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]

Scenario	Contributing scenario[30]	Route	EC 421-090-1
	PROC 14	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation	<0.01
		Dermal	<0.01
		Combined	<0.01
	PROC 21	Inhalation	<0.01
		Dermal	<0.01
		Combined	<0.01
	PROC 24	Inhalation	<0.01
		Dermal	<0.01
		Combined	<0.01
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation	<0.01
		Dermal	<0.01
		Combined	<0.01
	PROC 21	Inhalation	<0.01
		Dermal	<0.01
		Combined	<0.01
	PROC 24	Inhalation	<0.01
		Dermal	<0.01
		Combined	<0.01

Table 79. Calculated RCRs for consumers for benzoate EC 421-090-1

Scenario	Route	EC 421-090-1
ES6: Article service life. Use in flooring	Inhalation	0.02
	Dermal	1.66
	Oral	N/A
	Combined	1.67

B.6.10. Organophosphates

B.6.10.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for organophosphates:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)
- ES5: Article service life. Use in cables
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential non-threshold hazards of organophosphates as ED (human health and environment), the assessment will be limited to the estimation of releases of the substances to the environment.

B.6.10.2. Tonnage used in the EU

Organophosphorus flame retardants are identified to be used in PVC in cables where high temperature performance is important or long-term heat resistance in a concentration of at least 10 % (w/w) (Weil et al., 2006).

The estimation of the tonnage was done assuming that 30 % of the volume of compounded PVC is used in cables requiring high temperature performance. A 10 % (w/w) (Weil et al., 2006) compounding for organophosphorus flame retardants was then applied to the volume of compounded PVC for cables. The volume was then distributed proportional to the registered tonnage of the substances. More details are provided in Table 80 below.

The estimated tonnages are assumed to remain constant.

Table 80. Estimated volumes for organophosphates

EC No	**CAS No**	**Substance name**	**Cables (High-temperature performance)** (tonnes/year)
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)	1355
945-730-9	-	Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate and triphenyl phosphate	4580
809-930-9	1330-78-5	Tris(methylphenyl) phosphate	1665
939-505-4		tert-butylphenyldiphenyl phosphate (tBuTPP)	555
247-693-8	26444-49-5	Diphenyl tolyl phosphate	5330
700-990-0	-	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate	2265

Considering the registered tonnage under REACH and the other uses of the substances, it is likely that the estimated volumes for PVC cables might be an overestimation.

B.6.10.3. Release and exposure assessment

The release estimates for the organophosphates per exposure scenario are presented in Table 81. Values are rounded up.

Table 81. Release estimates for organophosphates used in PVC (tonnes/year)

Exposure scenario	**Compartment**	**273-066-3**	**945-730-9**	**809-930-9**	**939-505-4**	**700-990-0**
ES1: Formulation (PVC compounding)	Surface water	0.38 to 0.38	0.35 to 0.35	0.11 to 0.11	0.04 to 0.04	0.17 to 0.17
	Air	0.18 to 0.18	0.6 to 0.6	0.22 to 0.22	0.07 to 0.07	0.3 to 0.3
	Soil	0.07 to 0.07	0.13 to 0.13	0.13 to 0.13	0.04 to 0.04	0.07 to 0.07
	Total	0.63 to 0.63	1.08 to 1.08	0.46 to 0.46	0.15 to 0.15	0.54 to 0.54
ES2: Article production (PVC conversion)	Surface water	2.44 to 2.44	2.26 to 2.26	0.71 to 0.71	0.24 to 0.24	1.1 to 1.1
	Air	3.39 to 3.39	11.45 to 11.45	4.17 to 4.17	1.39 to 1.39	5.67 to 5.67
	Soil	0.46 to 0.46	0.82 to 0.82	0.81 to 0.81	0.23 to 0.23	0.48 to 0.48
	Total	6.29 to 6.29	14.53 to 14.53	5.69 to 5.69	1.86 to 1.86	7.25 to 7.25

Exposure scenario	Compartment	273-066-3	945-730-9	809-930-9	939-505-4	700-990-0
ES5: Article service life. Use in cables	Surface water	0.49 to 0.49	0.45 to 0.45	0.14 to 0.14	0.05 to 0.05	0.22 to 0.22
	Air	0.68 to 0.68	2.29 to 2.29	0.83 to 0.83	0.28 to 0.28	1.13 to 1.13
	Soil	0.09 to 0.09	0.16 to 0.16	0.16 to 0.16	0.05 to 0.05	0.1 to 0.1
	Total	1.26 to 1.26	2.9 to 2.9	1.13 to 1.13	0.38 to 0.38	1.45 to 1.45
ES12: Professional use. Handling plastic articles	Surface water	24.35 to 24.35	22.56 to 22.56	7.13 to 7.13	2.43 to 2.43	11.01 to 11.01
	Air	33.92 to 33.92	114.49 to 114.49	41.66 to 41.66	13.89 to 13.89	56.65 to 56.65
	Soil	38.51 to 38.51	122.66 to 122.66	49.81 to 49.81	16.11 to 16.11	61.42 to 61.42
	Total	96.78 to 96.78	259.71 to 259.71	98.6 to 98.6	32.43 to 32.43	129.08 to 129.08
ES13: Waste stage. Recycling	Surface water	0	0	0	0	0
	Air	64.66 to 64.66	218.16 to 218.16	79.41 to 79.41	26.35 to 26.35	107.98 to 107.98
	Soil	0	0	0	0	0
	Total	64.66 to 64.66	218.16 to 218.16	79.41 to 79.41	26.35 to 26.35	107.98 to 107.98
ES14: Waste stage. Landfill	Surface water	2.37 to 4.75	7.97 to 15.93	2.93 to 5.86	0.97 to 1.94	3.95 to 7.9
	Air	0.15 to 0.15	0.5 to 0.5	0.18 to 0.18	0.06 to 0.06	0.25 to 0.25
	Soil	4.75 to 9.5	15.93 to 31.87	5.86 to 11.72	1.94 to 3.88	7.9 to 15.79
	Total	7.27 to 14.4	24.4 to 48.3	8.97 to 17.76	2.97 to 5.88	12.1 to 23.94
ES15: Waste stage. Incineration	Surface water	0.05 to 0.05	0.16 to 0.16	0.06 to 0.06	0.02 to 0.02	0.08 to 0.08
	Air	0.05 to 0.05	0.16 to 0.16	0.06 to 0.06	0.02 to 0.02	0.08 to 0.08
	Soil	0	0	0	0	0
	Total	0.1 to 0.1	0.32 to 0.32	0.12 to 0.12	0.04 to 0.04	0.16 to 0.16
TOTAL	Surface water	30.08 to 32.45	33.75 to 41.72	11.09 to 14.02	3.75 to 4.72	16.53 to 20.48
	Air	103.03 to 103.03	347.65 to 347.65	126.53 to 126.53	42.06 to 42.06	172.05 to 172.05
	Soil	43.88 to 48.63	139.71 to 155.65	56.78 to 62.64	18.36 to 20.3	69.97 to 77.86
	Total	176.99 to 184.11	521.11 to 545.02	194.4 to 203.19	64.17 to 67.08	258.55 to 270.39

B.6.10.4. Risk characterisation

N/A

B.6.11. Inorganic flame retardants

B.6.11.1. Relevant exposure scenarios

Based on further details gathered during the calls for evidence, several exposure scenarios have been identified for the inorganic flame retardants used in PVC:

- ES1: Formulation (PVC compounding)
- ES2: Article production (PVC conversion)
- ES5: Article service life. Use in cables
- ES6: Article service life. Use in flooring
- ES9: Article service life. Use in artificial leather

- ES10: Article service life. Automotive interiors
- ES12: Professional use. Handling plastic articles
- ES13: Waste stage. Recycling
- ES14: Waste stage. Landfill
- ES15: Waste stage. Incineration

The generic sequence of the exposure scenarios described above are illustrated in Figure 12 (Section B.6.2).

Considering the potential non-threshold hazards of diantimony trioxide as Carc 1B., the assessment will consider the estimation of releases of the substances to the environment. Nevertheless, since the substance is already classified as Carc. 2 estimation of human health exposure and risks will also be considered. This will also be done for the zinc borates considering the potential hazard as Repr. 1B.

B.6.11.2. Tonnage used in the EU

According to the information provided in the calls for evidence the use of these substances are reported in cables (CfE2,#1564, 1569, 1570, 1571, 1575, 1583, 1585 and 1589), flooring (CfE2,#1603), artificial leather (CfE2,#1565) and automotive applications (CfE2,#1595 and 1653). Diantimony trioxide was also identified to be used in the sealant material of window frames (CfE2,#1602) but no specific data was provided and therefore not possible to quantify.

Only specific volumes were provided for flooring. For the other uses had to be estimated. The estimation of the tonnage was done by applying an average compounding to the volume or range of volumes of compounded PVC per application. For the zinc borates, when both were identified for one use, the volume was proportional to the registered tonnage of the substances. More details are provided in Table 82 below.

Table 82. Estimated volumes for inorganic flame retardants

EC No	**CAS No**	**Substance**	**Flooring**[1] (tonnes/year)	**Cables**[2] (tonnes/year)	**Artificial leather**[3] (tonnes/year)	**Automotive (parts)**[2] (tonnes/year)	**Automotive (artificial leather)**[2] (tonnes/year)	**Automotive (tarpaulins)**[2] (tonnes/year)
215-175-0	1309-64-4	Diantimony trioxide	280	10500	-	160-900	420-2540	180-1060
245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide	0.1	-	-	-	-	-
215-566-6	1332-07-6	Zinc borate	20	100	-	1-8	4-25	2-10
235-804-2	12767-90-7	Hexaboron dizinc undecaoxide	0	10400	940-5620	160-890	415-2515	180-1050

[1] Volumes provided (CfE2,#1603)

[2] Estimated values based on an average compounding of 2 % (Schiller, 2022). For zinc borates the share was distributed proportionally to the registered tonnage of the substances.

[3] Estimated value based on an average compounding of 2 % (Schiller, 2022).

B.6.11.3. Release and exposure assessment

The release estimates for the inorganic flame retardants per exposure scenario are presented in Table 83. Values are rounded up.

Table 83. Release estimates for inorganic flame retardants used in PVC (tonnes/year)

Exposure scenario	Compartment	Diantimony trioxide (EC 215-175-0)	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
ES1: Formulation (PVC compounding)	Surface water	1.39 to 2.09	0.06 to 0.08	5.19 to 10.7
	Air	1.61 to 2.43	0.02 to 0.03	1.73 to 3.57
	Soil	1.65 to 2.49	0	0
	Total	4.64 to 7.01	0.08 to 0.11	6.92 to 14.28
ES2: Article production (PVC conversion)	Surface water	8.29 to 10.97	0.31 to 0.4	30.21 to 51.15
	Air	28.85 to 38.2	0.31 to 0.4	30.24 to 51.2
	Soil	9.87 to 13.07	0	0.01 to 0.02
	Total	47.01 to 62.24	0.63 to 0.8	60.46 to 102.37
ES5: Article service life. Use in cables	Surface water	1.51 to 1.51	0.05 to 0.05	5.2 to 5.2
	Air	5.25 to 5.25	0.05 to 0.05	5.2 to 5.2
	Soil	1.8 to 1.8		
	Total	8.55 to 8.55	0.1 to 0.1	10.4 to 10.4
ES6: Article service life. Use in flooring	Surface water	0.64 to 1.29	0.16 to 0.32	0 to 0
	Air	0.14 to 0.14	0.01 to 0.01	0 to 0
	Soil	3.01 to 6.01	0.16 to 0.32	0 to 0
	Total	3.79 to 7.44	0.33 to 0.65	0 to 0
ES9: Article service life. Use in artificial leather	Surface water	0	0	7.51 to 89.84
	Air	0	0	0.47 to 2.81
	Soil	0	0	7.52 to 89.96
	Total	0	0	15.51 to 182.61
ES10: Article service life. Automotive interiors	Surface water	1.75 to 20.68	0.06 to 0.67	6.02 to 71.26
	Air	0.38 to 2.25	0 to 0.02	0.38 to 2.23
	Soil	8.16 to 96.63	0.06 to 0.67	6.03 to 71.36
	Total	10.29 to 119.56	0.12 to 1.37	12.42 to 144.85
ES12: Professional use. Handling plastic articles	Surface water	77.4 to 77.4	2.95 to 2.95	259.81 to 259.81
	Air	269.5 to 269.5	2.95 to 2.95	260.05 to 260.05
	Soil	361.71 to 361.71	2.96 to 2.96	260.16 to 260.16
	Total	708.61 to 708.61	8.86 to 8.86	780.01 to 780.01
ES13: Waste stage. Recycling	Surface water	0	0	0
	Air	510.99 to 557.13	4.84 to 5.28	516.89 to 619.93
	Soil	0	0	0
	Total	510.99 to 557.13	4.84 to 5.28	516.89 to 619.93
ES14: Waste stage. Landfill	Surface water	21.89 to 65.33	0.26 to 0.71	22.26 to 85.95
	Air	1.37 to 2.04	0.02 to 0.02	1.39 to 2.69
	Soil	43.78 to 130.65	0.52 to 1.43	44.51 to 171.89
	Total	67.04 to 198.02	0.79 to 2.16	68.16 to 260.53
ES15: Waste stage. Incineration	Surface water	0.85 to 1.24	0.01 to 0.01	0.92 to 1.88
	Air	4.26 to 6.22	0.01 to 0.02	1.38 to 2.81
	Soil	0	0	0
	Total	5.12 to 7.47	0.02 to 0.03	2.3 to 4.69
TOTAL	Surface water	113.71 to 180.51	3.86 to 5.2	337.12 to 575.79
	Air	822.35 to 883.16	8.23 to 8.78	817.72 to 950.49
	Soil	429.97 to 612.36	3.69 to 5.38	318.24 to 593.4
	Total	1366.04 to 1676.03	15.77 to 19.36	1473.08 to 2119.67

Exposure estimates were produced for diantimony trioxide and the zinc borates. The exposure estimates for workers are presented in Table 85. The exposure estimates for consumers are presented in Table 86.

Table 84. Exposure estimates for workers for Diantimony trioxide

Scenario	Contributing scenario[30]	Route	Diantimony trioxide (EC 215-175-0)
ES1: Formulation (PVC compounding)[1]	PROC 1 PROC 2 PROC 3 PROC 4	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
ES2: Article production (PVC conversion)[1]	PROC 6 PROC 10 PROC 13 PROC 14 PROC 15 PROC 21 PROC 24	Inhalation (mg/m³)	[redacted]
		Dermal (mg/kg bw/day)	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation (mg/m³)	0.14
		Dermal (mg/kg bw/day)	0.069
	PROC 21	Inhalation (mg/m³)	0.42
		Dermal (mg/kg bw/day)	0.057
	PROC 24	Inhalation (mg/m³)	0.4
		Dermal (mg/kg bw/day)	0.057
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation (mg/m³)	0.0014
		Dermal (mg/kg bw/day)	0.069
	PROC 21	Inhalation (mg/m³)	0.014
		Dermal (mg/kg bw/day)	0.057
	PROC 24	Inhalation (mg/m³)	0.28
		Dermal (mg/kg bw/day)	0.057

[1] Exposure estimates available in the CSR provided by the lead registrant

[2] Exposure estimates (ECETOC TRA v3.1)

Table 85. Exposure estimates for workers for zinc borates

Scenario	Contributing scenario[30]	Route	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)[1]	PROC 1	Inhalation (mg/m³)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 2	Inhalation (mg/m³)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 3	Inhalation (mg/m³)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 4	Inhalation (mg/m³)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 5	Inhalation	[redacted]	[redacted]

Scenario	Contributing scenario[30]	Route	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
		(mg/m^3)		
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 6	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 8a	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 8b	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 9	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 14	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 21	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
	PROC 24a	Inhalation (mg/m^3)	[redacted]	[redacted]
		Dermal (mg/kg bw/day)	[redacted]	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)[2]	PROC 14	Inhalation (mg/m^3)	0.14	0.14
		Dermal (mg/kg bw/day)	0.069	0.069
	PROC 21	Inhalation (mg/m^3)	0.42	0.42
		Dermal (mg/kg bw/day)	0.057	0.057
	PROC 24	Inhalation (mg/m^3)	0.4	0.4
		Dermal (mg/kg bw/day)	0.057	0.057
ES13: Waste stage. Recycling (Higher RMMs)[2]	PROC 14	Inhalation (mg/m^3)	0.0014	0.0014
		Dermal (mg/kg bw/day)	0.069	0.069
	PROC 21	Inhalation (mg/m^3)	0.014	0.014
		Dermal (mg/kg bw/day)	0.057	0.057
	PROC 24	Inhalation (mg/m^3)	0.28	0.28
		Dermal (mg/kg bw/day)	0.057	0.057

[1] Exposure estimates available in the CSR provided by the lead registrant. The exposure scenario covers both compounding and conversion.

[2] Exposure estimates (ECETOC TRA v3.1)

Table 86. Exposure estimates for consumers for inorganic flame retardants

Scenario	Route	Diantimony trioxide (EC 215-175-0)	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
ES6: Article service life. Use in flooring	Inhalation (mg/m^3)	1E-9	1E-9	1E-9
	Dermal (mg/kg bw/day)	4.8	4.8	4.8
	Oral (mg/kg bw/day)	N/A	N/A	N/A
ES9: Article service life. Use in artificial leather	Inhalation (mg/m^3)	N/A	N/A	1E-9
	Dermal (mg/kg bw/day)	N/A	N/A	4.8
	Oral (mg/kg bw/day)	N/A	N/A	N/A
ES10: Article service life. Automotive interiors (car seat)	Inhalation (mg/m^3)	1E-9	1E-9	1E-9
	Dermal (mg/kg bw/day)	4.8	4.8	4.8
	Oral (mg/kg bw/day)	N/A	N/A	N/A
ES10: Article service life. Automotive interiors (interior parts)	Inhalation (mg/m^3)	1E-9	1E-9	1E-9
	Dermal (mg/kg bw/day)	0.51	0.51	0.51
	Oral (mg/kg bw/day)	N/A	N/A	N/A

B.6.11.4. Risk characterisation

The risk characterisation is performed using the estimated exposures (Table 84, Table 85 and Table 86) and comparing these result with the DNELs derived by the registrants (Table 87). The resulting risk characterisation ratios (RCRs) for each use are described in this chapter.

Table 87. DNELs for inorganic flame retardants for the calculation of RCRs

Population	Route	Diantimony trioxide (EC 215-175-0)	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
Workers	Inhalation (mg/m3)	0.315	26.8	2.48
	Dermal (mg/kg bw/day)	67	1893	35.49
General population	Inhalation (mg/m3)	0.095	9.9	0.88
	Dermal (mg/kg bw/day)	33.5	1439	25.35
	Oral (mg/kg bw/day)	33.5	2.88	0.507

Table 88. Calculated RCRs for workers for Diantimony trioxide

Scenario	Contributing scenario[30]	Route	Diantimony trioxide (EC 215-175-0)
ES1: Formulation (PVC compounding)	PROC 1 PROC 2 PROC 3 PROC 4	Inhalation	[redacted]
		Dermal	[redacted]
		Combined	[redacted]
ES2: Article production (PVC conversion)	PROC 6 PROC 10 PROC 13 PROC 14	Inhalation	[redacted]
		Dermal	[redacted]

Scenario	**Contributing scenario[30]**	**Route**	**Diantimony trioxide (EC 215-175-0)**
	PROC 15 PROC 21 PROC 24	Combined	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)	PROC 14	Inhalation	0.44
		Dermal	0.00
		Combined	0.45
	PROC 21	Inhalation	1.33
		Dermal	0.00
		Combined	1.33
	PROC 24	Inhalation	1.27
		Dermal	0.00
		Combined	1.27
ES13: Waste stage. Recycling (Higher RMMs)	PROC 14	Inhalation	0.00
		Dermal	0.00
		Combined	0.01
	PROC 21	Inhalation	0.04
		Dermal	0.00
		Combined	0.05
	PROC 24	Inhalation	0.89
		Dermal	0.00
		Combined	0.89

Table 89. Calculated RCRs for workers for zinc borates

Scenario	**Contributing scenario[30]**	**Route**	**Zinc borate (EC 215-566-6)**	**Hexaboron dizinc undecaoxide (EC 235-804-2)**
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)	PROC 1	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 2	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 3	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 4	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 5	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 6	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 8a	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 8b	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 9	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 14	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 21	Inhalation	[redacted]	[redacted]
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
	PROC 24a	Inhalation	[redacted]	[redacted]

Scenario	Contributing scenario[30]	Route	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
		Dermal	[redacted]	[redacted]
		Combined	[redacted]	[redacted]
ES13: Waste stage. Recycling (Lower RMMs)	PROC 14	Inhalation	0.01	0.06
		Dermal	0.00	0.00
		Combined	0.01	0.06
	PROC 21	Inhalation	0.02	0.17
		Dermal	0.00	0.00
		Combined	0.02	0.17
	PROC 24	Inhalation	0.01	0.16
		Dermal	0.00	0.00
		Combined	0.01	0.16
ES13: Waste stage. Recycling (Higher RMMs)	PROC 14	Inhalation	0.00	0.00
		Dermal	0.00	0.00
		Combined	0.00	0.00
	PROC 21	Inhalation	0.00	0.01
		Dermal	0.00	0.00
		Combined	0.00	0.01
	PROC 24	Inhalation	0.01	0.11
		Dermal	0.00	0.00
		Combined	0.01	0.11

Table 90. Calculated RCRs for consumers for inorganic flame retardants

Scenario	Route	Diantimony trioxide (EC 215-175-0)	Zinc borate (EC 215-566-6)	Hexaboron dizinc undecaoxide (EC 235-804-2)
ES6: Article service life. Use in flooring	Inhalation	0.00	0.00	0.00
	Dermal	0.14	0.00	0.19
	Oral	N/A	N/A	N/A
	Combined	0.14	0.00	0.19
ES9: Article service life. Use in artificial leather	Inhalation	N/A	N/A	0.00
	Dermal	N/A	N/A	0.19
	Oral	N/A	N/A	N/A
	Combined	N/A	N/A	0.19
ES10: Article service life. Automotive interiors (car seat)	Inhalation	0.00	0.00	0.00
	Dermal	0.14	0.00	0.19
	Oral	N/A	N/A	N/A
	Combined	0.14	0.00	0.19
ES10: Article service life. Automotive interiors (interior parts)	Inhalation	0.00	0.00	0.00
	Dermal	0.02	0.00	0.02
	Oral	N/A	N/A	N/A
	Combined	0.02	0.00	0.02

B.6.12. Risks related to multiple substances from PVC

B.6.12.1. General

Concentration addition has been suggested as a first tier to assess risks of co-occurring substances, irrespective of the modes/mechanisms of action (Backhaus and Faust, 2012). This may give a realistic worst-case estimation of combined toxicities for risk assessment procedures even if similarity of components is unknown (Backhaus et al., 2000; Martin et al., 2021). Dose/concentration addition has also been adopted as the default assessment approach in EFSA's "Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals" (EFSA, 2019). One of the applications of this approach is to sum up risk characterisation ratios, a method used in the environmental risk assessments of the Existing Substances Regulation

EC/793/93 (e.g., risk characterisation of CBS degradation products and hydrocarbon block method for petroleum substances (ECB, 2008, ECB, 2003)). ECHA Guidance (ECHA, 2016a) also requests to take into account co-exposures (term applied therein: 'combined exposure').

B.6.12.2. Exposures and risks to multiple substances

Several life-cycle steps of PVC induce exposure to multiple substances (co-exposures). In particular this is the case for recycling and landfilling but several preceding steps also are relevant (see further discussion on the releases in section B.6.13).Environment is the recipient of all prioritised additives simultaneously and all end-uses contribute to the co-exposure (see sections B.6.4 to B.6.11 and section B.6.13 for the release estimates). Of the prioritised substances the most relevant contribution to the environmental co-exposure comes from soft PVC applications in which all three functions are necessary, i.e. heat stabilisers, plasticisers and flame retardants. The end-uses contributing most to the risks from co-exposure are cables, flooring, (artificial leather) and automotive interiors (see Figure 13). When looking at the various life-cycle steps, the highest amount of releases originates from handling of plastic articles (professional use) and recycling (recycling of soft PVC in particular). It is noted that the same uncertainties apply for the estimation of environmental co-exposures as for the estimation of releases and exposures of individual additives (see section A.1 for the uncertainties).

For the purpose of discussion on the co-exposures of consumers and workers, the estimated exposure levels and the risk characterisation ratios, as provided in sections B.6.4 to B.6.11 were looked at. Only for those additives, which have a hazard classification and hence a DNEL, quantitation of exposures and risks was carried out on a screening basis for individual substances. Co-exposure from flooring is relevant for in particular phthalates combined with flame retardancy. The realistic worst-case risk from co-exposure consists of flooring containing a long-chain phthalate EC 447-010-5 as plasticiser and diantimony trioxide or hexaboron dizinc undecaoxide as flame retardant. Another relevant co-exposure situation of consumers seems to take place from automotive interiors where organotins are used as stabiliser together with a prioritised flame retardant. As the information in CfE2 was provided at end-use level, it needs to be further scrutinised whether these two situations actually appear in reality. It is noted that the dose addition risk approach would not seem to be applicable for these two cases, but the differences of the mode of action would need to be further reflected.

Of the industrial/professional life-cycle steps, conversion of soft PVC may cause relevant co-exposure to plasticisers and flame retardants. The most concerning scenario for co-exposure of workers is, however, recycling, where the exposure situations vary. Such scenarios may be expected to be, e.g., day long processing of well sorted batches of unplasticized PVC, well sorted batches of plasticised PVC, mixed soft PVC waste and PVC waste mixed with other plastics. A realistic worst-case scenario from the point of view of co-exposures to the prioritised additives would be recycling of well sorted soft PVC containing DEHP and trixylyl phosphate. Again, as discussed under the previous paragraph, risks caused by such co-exposures would need to be explored taking into account the different mode of actions of the additives.

Man via environment exposure route may be relevant for co-exposures of additives for at least some human subpopulations. Analogous to the environmental species, humans may be expected to be exposed to all PVC (and other plastic) additives released to the environment or their intermittent degradation products. Due to the working hypothesis of case-by-case assessment for risks (see section B.6.13), no attempt to estimate man via environment dose was made. The relevance of the various sources for this route can be expected to be analogous to the contributors to the releases. Roughly speaking the fate of the prioritised additives is to such extent similar that the environmental release amounts (see above) can be also in such case considered as indicative of the relevance of the various additives to man via environment if the exposure would be quantified by Tier 1 tools. The form of exposure takes place either indirectly with the exposure to PVC (section B.6.3) microparticles or directly as 'free' additive in the compartments of human uptake. Monitoring data on co-exposure levels of the prioritised additives (or their relevant metabolites) in general population in appropriate sample types could provide an indication of the on-going co-exposures. It is acknowledged, however, that a biomonitoring campaign tailored to the prioritised PVC additives would be very complex due to the requirement to sample the same population for such a high number of substances, relevant metabolites and appropriate sample types. Also, the contribution of PVC to the levels would be further necessary to be extrapolated from the results.

Co-exposure to plastic additives is not only an issue for PVC but also for other plastics. However, soft PVC needs generally more additives (in number, function and concentration) than alternative plastics (exceptions may apply but were not explored further). A realistic worst case maximum concentration of the additives together would be up to 90 % w/w in the case of the compounded soft, flame retarded PVC, based on the average typical compounding received in CfE2 (#1587). For further discussion on the comparison of PVC and other plastics, see sections B.3.5, B.4.6 and B.5.4. Soft PVC volume is higher than rigid PVC volume (see section A.1.2). It can be correspondingly expected that the relative contribution of especially soft PVC to plastic additives co-exposures is higher than of the alternative plastic materials.

B.6.13. Overall results and conclusions (prioritised additives)

Conclusions

Risks were identified based on Tier 1 estimations for environment (and man via environment), applying a case-by-case approach according to REACH Annex I, para 0.10. The main contributors to the risk to the environment are the soft-PVC uses. This is due to the high absolute volumes of additives (and PVC) used as well as due to the higher overall concentrations of additives needed in the soft-PVC applications. From the end-uses, cables and flooring followed by artificial leather and automotive interiors are the main contributors to the risk (see Figure 13). The pivotal life-cycle steps for the risk are professional handling of articles, recycling and landfilling since all covered end-uses and hence all priority additives contribute to these releases.

From the prioritised additive functions, plasticisers are the main contributors to the releases followed by flame retardants. It is noted that the prioritisation approach has an impact on this observation (the number of the prioritised additives in the different function classes was defined by the prioritisation scheme). In relation to the comparison to PVC plastic alternatives, it can be concluded that generally more additives are needed for PVC than other plastics (exceptions may apply). This is particularly true for plasticisers, which are mostly used in PVC (> 85 % of the total volume of plasticisers). This would mean that the use of PVC, especially soft PVC, can be expected to trigger higher risk to the environment than its alternatives, with some reservations. No risk assessment was carried out for additives in alternative plastics, but releases of additives contained in any plastics are generally linearly dependent on the volume and concentration of the used and hence releases can be expected to be generally lower, even if the hazards of the additives in alternative plastics would be at similar level as of the prioritised PVC additives.

Due to the non-threshold nature of the risk (see discussion below), the minimisation of the releases of additives should be in focus of the (regulatory and industry) actions. The releases of additives are strongly linked with the releases of PVC microparticles and the release minimisation can be expected to be most effective when minimisation of both the additives and microparticles releases is reached. However, this needs further assessment. Minimisation potential of the releases from the key life-cycle steps as listed above need further exploration. Effectiveness of specific release reduction measures was not assessed in quantitative manner in this project but some qualitative discussion is provided in the description on benefits in the main report.

Risks to workers and consumers were quantified for relevant end-uses for the prioritised additives for which DNELs were available (see section B.6.3).

Table 94 indicates risks for workers in particular for the recycling stage for two (DOTE, DEHP) to four (DOTE, DMTE, DEHP and Diantimony trioxide) additives depending on whether higher or lower risk management level was assumed for the sites. For DEHP, exposure minimisation would, however, seem necessary based on the current state of knowledge of hazards.

Table 95 indicates risks for consumers from organotin stabilisers in automotive interiors (DOTE, DMTE, MMTE) and from packaging (DOTE). A risk from flooring was also identified for a benzoate (Benzoic acid, C9-11, C10-rich, branched alkyl esters) used as plasticiser. Given some uncertainties regarding the end-uses, further information from these specific sectors are needed to verify and potentially refine the risk assessment (see section A.1 for details).

Further information collected from specific car manufacturers on the use (e.g., the specific car parts where these additives are used) indicates that organotin substances are not used in car interiors, but in exterior parts. However, specifications have not been requested from all non-EU car manufacturers and some uncertainty regarding this risk therefore remains. The exposure results for DOTE in packaging might be also overestimated since, in the absence of further information, a concentration of 1 % (w/w) in articles was assumed. It is however more likely that the use of DOTE is in combination with MOTE and thus concentrations of DOTE might be much lower. Further clarification was sought from the packaging industry with mixed results. At least in pharmaceutical packaging, DOTE seems to have been replaced completely with MOTE, and it this might well be happening for all packaging uses. In the case flooring, the flooring industry highlighted the possibility that DNEL derived by the registrants of Benzoic acid, C9-11, C10-rich, branched alkyl esters could be over-conservative.

It is noted that this project did not assess the potential threshold risks to other substances than those mentioned above as no DNELs were available for other priority additives (several reasons apply). Hence the identified risks to workers and consumers give only an indication of the whole range of the potential risks, including risks due to co-exposure of humans. Especially the workers at recycling facilities are likely to be exposed practically to the whole set of prioritised (and other) PVC additives. Also exposure of general public via the environment to potentially all prioritised PVC additives can be expected based on the release estimates, but conventional quantitative risk assessment was not carried out as DNELs cannot be derived or were not available for all substances and the environmental exposure levels cannot be currently estimated due to the very complex fate of the PVC microparticles and the unknown leaching rates of additives from PVC microparticles.These are data/analysis gaps.

Releases as proxy of risk

The points related to PVC additives, as further elaborated in the next paragraphs, i.e. the very persistent fate of the particle form additive emissions in combination with the co-exposure to several additives simultaneously from the PVC matrix, supported by the available effects data on the additives, give rise to a concern which is of non-threshold nature. For the purpose of this investigation report it is considered sufficient to assume as a work hypothesis that emissions of the additives can be taken as a proxy for risk for the environment and man via environment. Consequently, the application of Annex I para 0.10 and hence a case-by-case environmental risk assessment is recommended as a general approach.

In the realistic worst-case release estimation of individual additives, the releases of additives can be assumed to be mainly bound in the PVC microparticles matrix.

A rough approximation can be made that the additives incorporated in the PVC matrix are very persistent the same way as the PVC is very persistent (See Section A.2.4 and B.6.3.2).

The environmental fate of the additives can be assumed therefore to be to a large extent the same as of PVC microparticles (see discussion in section A.2.3 and A.2.4 and B.6.3.2). As discussed in section B.6.3.2 the leaching of additives from PVC and the further fate after leaching of the additives are very complex phenomena but a relevant fraction of additives remains in PVC microparticles for very long times. The working assumption for this project report is, therefore, that the additives are generally rendered as vP when released within PVC microparticles to the environment and the fate of the additives as chemical substances is not considered further in this assessment. Accumulation of PVC and additives contained therein can be expected in the environment in the similar manner as for vP substances. Currently, conventional exposure assessment cannot be carried out for additives due to the very complex fate of the PVC microparticles and the unknown leaching rates of additives from PVC microparticles. However, it is acknowledged that experimental or estimated leaching data for PVC microplastics released and present in the environment would be useful to better understand the environmental concentrations of additives bound in PVC and of unbound but originating from PVC microparticles. Such data are not available for the substances in focus of this report.

For a part of the additives the effects are of non-threshold nature and hence no DNELs, dose-responses and/nor PNECs can be estimated or the current data do not allow quantitation of no-effect thresholds. Also therefore a quantitative environmental risk assessment is not possible for all prioritised additives.

A further concern of PVC is co-exposure to several additives (see section B.6.12). This is especially the case for the environmental exposures. Likelihood of co-exposures of man via environment to practically all prioritised PVC additives is also high, but currently not quantified. A quantitation of environmental risks (incl. man via environment) due to co-exposures is for the prioritised additives likely not possible to carry out within a reasonable timeframe. As pointed out above, the environmental exposure levels cannot be currently reliably estimated due to the very complex fate of the PVC microparticles and lack of data on leaching of additives from PVC microparticles. Considering also the variety of of the prioritised (and CLH classified) additives and the type of their effects data (threshold effects/non-threshold effects) it is likely that only a small part of the risks from co-exposures could become quantified within the next years, whereas for the remaining part of the prioritised additives no quantitation of risks would become possible due to non-threshold hazards or lack of data to derive sufficient thresholds or dose-responses. While making such an attempt to quantify risks from co-exposures over the tens of prioritised additives, their accumulation in the environment would continue and levels once reached in the environment would be difficult to reverse.

Environmental risk (total releases)

As discussed above, releases of prioritised additives are considered as a proxy for environmental (and man via environment) risks. The overall releases per environmental compartment per group of prioritised substances, per function and the total are shown in Table 92. Aggregating the releases of multiple substances together on a mass unit per year basis is providing a straight-forward picture of the releases at stake. Due to the applied case-by-case (non-threshold) risk approach, there is no need to normalise these releases to be presented, e.g., by molar weight, as no comparison to a no-effect level is carried out. Similar approach for aggregating releases of multiple substances has been taken in various restriction proposals, e.g., on poly- and perfluorinated substances (PFASs).

As expected, considering the average typical compounding of the substances, plasticisers are the main contributors to the overall release of the prioritised substances. The total releases are higher to air (~52 % of the total) followed by soil (~38 % of the total) and water being the environmental compartment receiving the lower number of releases (~10 % of the total). It is important to note that the recycling activities are the main contributor to the releases to air.

The total releases through the lifecycle are shown in Table 91 and Table 93. The results show that the major contributors to the overall release are the ES12 (Professional use. Handling of plastic articles), ES13 (Waste stage. Recycling) and ES14 (Waste stage. Landfilling) with an overall of ~45 %, ~31 % and ~11 % of the total releases respectively. Releases from the service life of articles have a low contribution to the overall.

In terms of type of PVC, soft PVC is the main contributor to the overall releases (> 98 %) considering plasticisers and flame retardants are used in soft PVC and the high concentration of those substances in compounded soft PVC when compared to heat stabilisers.

Per use, the main contributor to the overall releases are cables (67%) followed by flooring (15%), artificial leather (8%) and automotive interiors (7%) as shown in Figure 13. The rest of the uses have a minor contribution to the overall releases.

Table 91. Overall releases per exposure scenario in tonnes/year

Exposure scenario	Heat stabilisers	Plasticisers	Flame retardants	Total
ES1: Formulation (PVC compounding)	0.69 to 4.18	60.73 to 115.54	14.53 to 24.29	75.95 to 144.01
ES2: Article production (PVC conversion)	5.46 to 30.55	538.89 to 886.37	140.8 to 198.11	685.15 to 1115.03
ES3: Article service life. Use in pipes and pipe fittings	3 to 5.93	0 to 0	0 to 0	3 to 5.93
ES4: Article service life. Use in window frames	3.6 to 50.69	0 to 0	0 to 0	3.6 to 50.69
ES5: Article service life. Use in cables	0 to 0	63.65 to 63.65	25.84 to 25.84	89.49
ES6: Article service life. Use in flooring	0 to 0	395.5 to 769.8	4.12 to 8.09	399.62 to 777.89
ES7: Article service life. Use in packaging	0.35 to 2.03	1.94 to 1.94	0 to 0	2.29 to 3.97
ES8: Article service life. Use in toys	0 to 0	0 to 0	0 to 0	0 to 0
ES9: Article service life. Use in artificial leather	0 to 0	117.21 to 1324.72	15.51 to 182.61	132.72 to 1507.33
ES10: Article service life. Automotive interiors	0.58 to 6.95	84.57 to 957.51	22.83 to 265.78	107.98 to 1230.24
ES11: Article service life. Medical application	0.36 to 2.12	2.4 to 15.7	0 to 0	2.76 to 17.82
ES12: Professional use. Handling plastic articles	28.94 to 137.8	7501.6 to 7501.6	2116.48 to 2116.48	9647.02 to 9755.88

Exposure scenario	Heat stabilisers	Plasticisers	Flame retardants	Total
ES13: Waste stage. Recycling	31.28 to 170.49	4510.3 to 5610	1532.72 to 1682.34	6074.3 to 7462.83
ES14: Waste stage. Landfill	8.25 to 89.81	957.98 to 3312.94	191.05 to 565.77	1157.28 to 3968.52
ES15: Waste stage. Incineration	0.79 to 4.52	12.84 to 24.82	8.26 to 13.01	21.89 to 42.35
Total	80.83 to 502.2	14221 to 20591	4068.89 to 5085.06	18370.72 to 26178.26

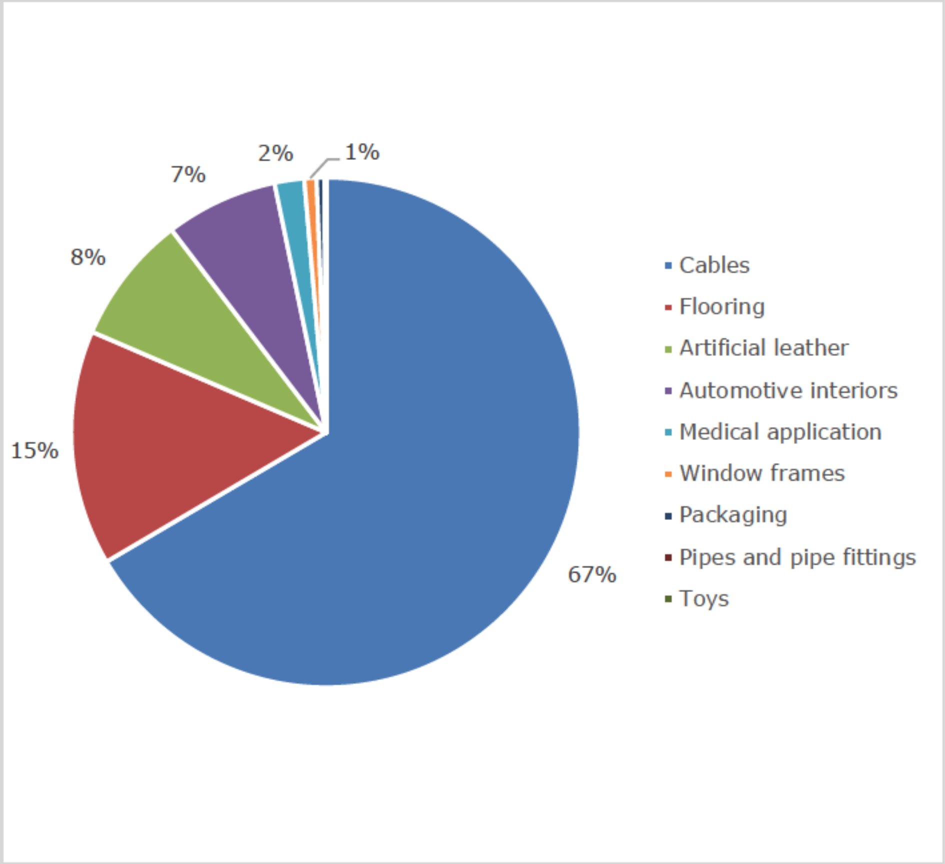

Figure 13. Contribution per use to the overall releases

From the prioritised plasticisers, ortho-phthalates are the major contributors to the overall release (Table 93). More specifically, medium chain (C7-C8) ortho-phthalates account for 49 % of the total releases followed by long-chain (C9-C18) ortho-phthalates with 12 % of the total releases. It should be also noted that the medium-chain ortho-phthalates have a higher migration potential than the long-chain ortho-phthalates. In this regard, it should be highlighted that even though the migration data suggests a low migration for these ortho-phthalates, they have been nevertheless detected in human biological biomonitoring data and suggesting widespread human exposure to these compounds and specially infants/children who seem to be exposed to higher levels than adults (Saravanabhavan and Murray, 2012, Wang et al., 2019).

It is noted that relevance of roofing material (a soft PVC end-use) for the release estimation was only understood after the CfE2. Those releases were not yet estimated (analysis gap).

Furthermore, in the next step it is pivotal for the risk management strategy to acquire further information on the representative site RMMs, in particular for professional handling of articles, recycling sites and landfilling. This would be essential for understanding whether releases from these life-cycle steps can be minimised as all end-uses contribute to these releases. Refinement of the release estimates per end-use may also bring some added value to the impact assessment.

Risks to workers and consumers

With regard to the human exposure data and subsequent risk characterisation, the results described in sections B.6.4.4, B.6.5.4, B.6.6.4, B.6.7.4, B.6.8.4, B.6.9.4, B.6.10.4 and B.6.11.4 above are collected in Table 94 and Table 95. The data suggests that there might be risks for workers during PVC compounding and conversion and at recycling facilities from DOTE and DEHP. For DMTE and Diantimony trioxide risk might only arise to workers in recycling facilities depending on the operational conditions and risk management measures in place. For MMTE and Zn borates, no risks were identified. Further refinement of exposure estimation (e.g., considering actual OCs and RMMs implemented in the recycling facilities) and DNEL derivation (in most cases the DNELs derived by the registrants were used) may be needed.

For consumers during article service life, risks were identified for organotin substances in automotive interiors. It needs to be mentioned that the RCRs were particularly elevated for DMTE and MMTE (specially for DMTE the RCR is above 100) and they are mainly driven by the higher vapour pressure when compared to e.g. DOTE. However, it has to be considered that organotins in the automotive sector were identified in monofilament profiles (CfE2,#1601) and, in the absence of further information, it was assumed that those were used only in automotive interiors. Further information on the use (e.g., the specific car parts where these additives are used) and exposure (e.g., measured exposure data) is recommended to refine the exposure estimation as the estimations were carried out with Tier 1 model and are hence initial realistic worst-case estimates. Further information collected from specific car manufacturers on the use (e.g., the specific car parts where these additives are used) indicates that organotin substances are not used in car interiors, but in exterior parts. However, specifications have not been requested from all non-EU car manufacturers and some uncertainty regarding this risk therefore remains.

For DOTE, the risk identified in packaging needs to be considered carefully since the combined RCR is slightly above 1. The exposure results for DOTE in packaging might be also overestimated since, in the absence of further information, a concentration of 1 % (w/w) in articles was assumed. It is however more likely that the use of DOTE is in combination with MOTE and thus concentrations of DOTE might be much lower. Further clarification was sought from the packaging industry with mixed results. At least in pharmaceutical packaging, DOTE seems to have been replaced completely with MOTE, and it this might well be happening for all packaging uses.

Further, based on the realistic worst-case default approach a risk for consumers was also identified for benzoate EC 421-090-1 which is mainly related to dermal exposure. However, further information would need to be carefully considered to either confirm or refine this result since the RCR is also only slightly higher than 1.

No quantification of risks from co-exposures was attempted in this project but following scenarios were considered of concern and needing follow-up: (1) Co-exposure of workers in industrial and professional steps where soft PVC containing both plasticisers and flame retardants are handled. (2) Workers at recycling plants can be expected to be co-exposed to the whole spectrum of prioritised additives. (3) Consumer co-exposure from flooring and from automotive interiors.

Table 92. Overall releases per group of substances per environmental compartment in tonnes/year

Environmental compartment	Heat stabilisers		Plasticisers						Flame retardants		
	Organotin substances	Phenyl 1,3-diones	Ortho-phthalates			Terephthalates (DBTP)	Trimellitates	Benzoates	Organophosphates	Diantimony trioxide	Zinc borates
			DEHP	C7-C8	C9-C18						
Surface water	6.93 to 49.1	0.8 to 8	6 to 65	720 to 1450	151.1 to 339	30 to 45	37 to 141	4 to 6	94 to 110	115 to 180	339 to 580
Air	40.2 to 205.6	9 to 65	25 to 140	5820 to 6685	1599.4 to 1868	120 to 130	380 to 560	15 to 15	790 to 790	820 to 885	828 to 959
Soil	18.9 to 129.5	5 to 45	10 to 125	4085 to 6775	858.5 to 1542	135 to 190	205 to 485	20 to 30	330 to 370	430 to 610	324 to 600
Subgroup total	66.03 to 384.2	14.8 to 118	41 to 330	10625 to 14910	2609 to 3749	285 to 365	622 to 1186	39 to 51	1214 to 1270	1366.04 to 1676.03	1488.85 to 2139.03
Function total	80.83 to 502.2		14221 to 20591						4068.89 to 5085.06		
Overall total	18370.72 to 26178.26										

Table 93. Overall releases per group of substances per exposure scenario in tonnes/year

Exposure scenario	Organotin substances	Phenyl 1,3-diones	Ortho-phthalates			Terephthalates (DBTP)	Trimellitates	Benzoates	Organo-phosphates	Diantimony trioxide	Zinc borates
			DEHP	C7-C8	C9-C18						
ES1: PVC compounding	0.66 to 3.96	0.03 to 0.22	1 to 5	45.2 to 78.3	9.53 to 20.09	1.6 to 1.6	3.18 to 10.33	0.22 to 0.22	2.89 to 2.89	4.64 to 7.01	7 to 14.39
ES2: PVC conversion	5.03 to 27.65	0.43 to 2.9	5.7 to 37	395 to 601	98.61 to 160.07	10.7 to 11.8	27.48 to 75.1	1.4 to 1.4	32.7 to 32.7	47.01 to 62.24	61.09 to 103.17
ES3: ASL. Pipes and pipe fittings	3 to 5.93	0	0	0	0	0	0	0	0	0	0
ES4: ASL. Window frames	2.44 to 33.29	1.16 to 17.4	0	0	0	0	0	0	0	0	0
ES5: ASL. Cables	0	0	0	45.6 to 45.6	14.87 to 14.87	0	3.18 to 3.18	0 to 0	6.79 to 6.79	8.55 to 8.55	10.5 to 10.5
ES6: ASL. Use in flooring	0	0	0	348.6 to 676	7 to 11.4	35 to 73	0	4.9 to 9.4	0	3.79 to 7.44	0.33 to 0.65
ES7: ASL. Use in packaging	0.35 to 2.03	0	0	0.94 to 0.94	1 to 1	0	0	0	0	0	0
ES8: ASL. Use in toys	0	0	0	0	0	0	0	0	0	0	0
ES9: ASL. Use in artificial leather	0	0	0	83.3 to 946	27.71 to 303.81	0.4 to 4.1	5.8 to 70.81	0	0	0	15.51 to 182.61

Exposure scenario	Organotin substances	Phenyl 1,3-diones	Ortho-phthalates			Terephthalates (DBTP)	Trimellitates	Benzoates	Organo-phosphates	Diantimony trioxide	Zinc borates
			DEHP	C7-C8	C9-C18						
ES10: ASL. Automotive interiors	0.58 to 6.95	0	0	61.1 to 704	19.26 to 197.83	0.27 to 2.8	3.94 to 52.88	0	0	10.29 to 119.56	12.54 to 146.22
ES11: ASL. Medical application	0.36 to 2.12	0	1.2 to 7.8	0	0	0	1.2 to 7.9	0	0	0	0
ES12: Professional use. Handling plastic articles	21.54 to 89.8	7.4 to 48	0	5690 to 5690	1302 to 1302	190 to 190	292.6 to 292.6	27 to 27	619 to 619	708.61 to 708.61	788.87 to 788.87
ES13: Waste stage. Recycling	25.28 to 130.49	6 to 40	15 to 105	3235 to 3900	1001.3 to 1204	15 to 15	242 to 384	2 to 2	500 to 500	510.99 to 557.13	521.73 to 625.21
ES14: Waste stage. Landfill	7.64 to 82.73	0.61 to 7.08	14.3 to 167	713.4 to 2239.6	146.27 to 535.55	30.7 to 70.7	49.22 to 291	4.09 to 9.09	55.06 to 105.06	67.04 to 198.02	68.95 to 262.69
ES15: Waste stage. Incineration	0.79 to 4.48	0 to 0.04	0.2 to 1.2	9.6 to 16.4	2.12 to 4.62	0.4 to 0.4	0.48 to 2.16	0.04 to 0.04	0.82 to 0.82	5.12 to 7.47	2.32 to 4.72
Total	66.03 to 384.2	14.8 to 118	41 to 330	10625 to 14910	2609 to 3749	285 to 365	622 to 1186	39 to 51	1214 to 1270	1366.04 to 1676.03	1488.85 to 2139.03

Table 94. Identified risks for workers during PVC compounding, PVC conversion and recycling activities (based on realistic worst-case approach)

Scenario	DOTE	DMTE	MMTE	DEHP*	EC 421-090-1	Sb_2O_3	Zn borates
ES1: Formulation (PVC compounding) and ES2: Article production (PVC conversion)	Covered by Authorisation**	No risk	No risk	Covered by Authorisation**	No risk	No risk	No risk
ES13: Waste stage. Recycling (Lower RMMs)	Risk	Risk	No risk	Risk	No risk	Risk	No risk
ES13: Waste stage. Recycling (Higher RMMs)	Risk	No risk	No risk	Risk	No risk	No risk	No risk

*The risk is based on a DNEL for which it is not known whether it is sufficiently protective for endocrine effects (see section B.6.6.4). For DEHP a minimisation of the worker exposures might be necessary.

**DOTE and DEHP are listed in Annex XIV

Further, a potential risk for consumers was also identified for benzoate EC 421-090-1 which is mainly coming from dermal exposure. However, this needs to be considered carefully since the RCR is also slightly above 1. In this case, the DNEL applied would need to be further evaluated according to industry comments.

Table 95. Identified potential* risks for consumers during article service life (based on realistic worst-case approach)

Scenario	DOTE	DMTE	MMTE	DEHP	EC 421-090-1	Sb_2O_3	Zn borates
ES6: Article service life. Use in flooring	N/A	N/A	N/A	N/A	Potential* risk	No risk	No risk
ES7: Article service life. Use in packaging (food and non-food)	Potential* risk	No risk	No risk	N/A	N/A	N/A	N/A
ES9: Article service life. Use in artificial leather	N/A	N/A	N/A	N/A	N/A	N/A	No risk
ES10: Article service life. Automotive interiors	Potential* risk	Potential* risk	Potential* risk	N/A	N/A	No risk	No risk

* Risk was identified in the default assessment based on the information submitted in CfE2, but based on the further information received, the concern may be removed (see text).

Risks by additive groups

The data above seems to suggest that, plasticisers should be prioritised for further regulatory risk management without delay considering that the environmental stock of plasticisers is likely to increase over time. This will result in a problem both for the human health and the environment. As mentioned in section B.4, more than 85 % of the plasticisers are used in PVC. Action is warranted at the latest if the non-threshold hazards described in sections 0 to B.5 are confirmed. However, their confirmation is not absolutely necessary in the current working approach for environmental risks.

Among plasticisers, priority should be given to ortho-phthalates, in particular medium chain ortho-phthalates. Based on the assessment of regulatory needs (ARN) for ortho-phthalates done by ECHA, medium chain ortho-phthalates (C7-C8) are likely to contain medium chain ortho-phthalates (C4-C6) which are all likely endocrine disruptors to the environment. The potential non-threshold hazards for long-chain ortho-phthalates are not yet clear and further analysis and data generation might be needed to confirm non-threshold hazards. Nevertheless, effects data are available supporting the overall case-by-case non-threshold risk approach as described above under 'Releases as proxy of risk', and confirmation of hazards at the level of CMR, STOT RE, PBT/vPVB and/or ED properties is not needed.

Trimellitates should also be considered with care, considering their potential for both ED and PBT/vPvB properties. Data generation is on-going to clarify those potential severe hazards.

With regard to flame retardants, according to the information provided in the calls for evidence, they are mainly used in other plastics than PVC. When used in PVC, inorganic flame retardants are the main choice. As described above, inorganic flame retardants potential hazards seem to be threshold-based and no substantial risk has been immediately identified.

Organophosphates have been also identified as to be used in PVC, in particular in cables and in the automotive sector. As described in ECHA's Regulatory Strategy on Flame Retardants (ECHA, 2023c), organophosphates are of concern. This concern, however, is not only restricted to PVC but also to especially other more flammable materials. The Regulatory Strategy on Flame Retardants indicates that it will be revised in 2025 based on the current data generation for these substances and based on the findings of this project.

With regard to organotin substances used as heat stabiliser, a potential risk has been identified specially for DMTE, and to a lower extent for DOTE, in the current situation even if the potential non-threshold hazards are not confirmed. Considering the current harmonised classification as neurotoxicant (STOT RE 1 (nervous system)) this could be prioritised for further regulatory action. Further information is needed in particular from automotive sector but also related to the identified risks to workers to verify and, if relevant, refine the exposure estimates.

B.7. Concern banding to use in the impact assessment

In order to facilitate the impact assessment, a preliminary risk banding for the substances was done. Considering that for all of the substances, there is a non-threshold potential hazard (very high persistency, ED and/or PBT/vPvB), a preliminary banding for the purpose of the impact assessment was carried out based on the hazard and more specifically on the certainty of the (potential) hazard. It is highlighted that only the lead effects, which represent the most severe hazards of the substance are included, other effects are not taken into account.

Table 96. Concern banding to be used in the impact analysis

Function	High concern	Medium concern	Low concern	Currently no identified regulatory concern
Heat	Organotins (DOTE,	Organotins (DOTTG,		MOTE

Function	**High concern**	**Medium concern**	**Low concern**	**Currently no identified regulatory concern**
stabilisers	DOTDL, DMTE)	DOT-MalEt, MMTE) Phenyl 1,3-diones		
Plasticisers	DEHP	Medium chain (C7-C8) ortho-phthalates Terephthalates (DBTP) Trimellitates Benzoates	Long chain (C9-C18) ortho-phthalates	DOTP
Flame retardants		Organophosphates Zinc borates	Diantimony trioxide	Zinc molybdate

The high concern band includes all those substances used in PVC for which there is a harmonised classification as CMR 1A or 1B and/or STOT RE 1 or that have been identified as an SVHC for ED and/or PBT/vPvB hazards. The medium concern band includes substances for which a hazard or potential hazard has been identified (see sections 0, B.4 and B.5). The low concern band is for those substances for which the potential for the hazards listed above is less clear than for those in the medium risk band (see sections B.4 and B.5). The currently no identified risk band is for those substances for which none of the hazards listed above have been identified.

B.8. Key uncertainties, assumptions, and data gaps

Key uncertainties in the risk assessment of PVC and PVC additives are presented in Table 97.

Table 97. Main uncertainties and analysis or data gaps related to the risk assessment

Relevant section of the assessment	Identified uncertainties					
	No.	Description of uncertainty	Specific information on uncertainty	Input	Metho-dology	Analysis gap[32]
Section A.2.2. Hazard assessment	1	Uncertainty regarding epidemiological and toxicological data on the effects of PVC dust via inhalation	No systematic evaluation for epidemiological and toxicological data on the effects of PVC dust via inhalation was performed. Nevertheless, several relevant articles were identified in Section A.2.2.			X
Section A.2.3. Release and exposure assessment	2	Uncertainty regarding PVC particle accumulation in the receiving environmental compartments	No systematic review of measured data of PVC particle accumulation in the receiving environmental compartments was done. Nevertheless, several relevant articles were identified in Section A.2.3 and a link was made to the work performed by ECHA (2020) on intentionally added microplastics.			X
Section A.2.3. Release and	3	Uncertainty regarding PVC microparticle	No information on direct measured releases of PVC microparticles. Limited applicability of the available default release estimation approaches to plastic microparticles Fate of PVC microparticles	X	X	

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[32] Analysis gap means that an assumption/conclusion was made for the purpose of the investigation based on the available data and assessments, including the expert judgement, but that for the purpose of, e.g., an Annex XIV restriction proposaldossier, a more detailed evaluation/assessment would need to be written. However, it is likely that the more detailed work would not significantly change the assumptions and conclusions of this report.

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis gap[32]**
exposure assessment		releases and fate	can be expected to be, slightly different from other microparticles but the differences would need further elaboration. No PVC specific models for environmental fate of microparticles are available and fate of plastic microparticles is generally very complex. Research data and models on deformation and degradation PVC microparticles into smaller size as well as physicochemical changes on the particle surface in the environment would be of added value to understand the dynamics between accumulation and transport of PVC in the environment and release of additives from PVC microparticles.			
Section A.2.3. Release and exposure assessment	4	Uncertainty regarding PVC microparticle releases	Further information on the releases of microparticles to air and waste water from recycling plants would be necessary in order to be able to estimate the releases. Further information on the technologies to reduce releases at recycling sites would be also necessary.	X	X	X
Section A.2.3. Release and exposure assessment	5	Relevance of PVC particle releases compared to releases from other plastics	Although risks have been identified at screening level to occur due to the releases of microparticles from the various uses and life-cycle steps of PVC, it is noted that similar risks can also be expected from the releases of microparticles due to the use of other plastics. These risks are mainly not PVC specific. No data gathering neither comparative analysis between PVC and other plastics was made with regard to their shares for the contribution of microparticle pollution.	X	X	X
Sections B1, B.3.X, B.4.X and B.5.X	6	Uncertainty on the substances identified as to be used in PVC	Although the list of substances currently used as additives in PVC was compiled together with relevant Industry industry stakeholders, it is possible that the list is not complete. In particular, when assessing the substances in groups many substances could be potentially used in PVC considering structural	X		

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis gap[32]**
			similarities and several substances identified as to be used in PVC do not currently have active registrants under REACH.			
Section B.2.2	7	Uncertainty on the substances prioritised	Substances identified as pigments have not been prioritised based on the low potential for migration following the results from the plastics initiative (PLASI). It is possible that some of the substances identified as pigments are in fact dyes with higher solubility in water and/or organic solvents and thus with higher migration potential. This has not been assessed.	X		X
Sections B.3.X.2.1, B.4.X.2.1 and B.5.X.2.1 Physicochemical properties	8	Uncertainty regarding the physicochemical properties	Physicochemical and degradation properties of the substances obtained from ECHA dissemination portal have not been evaluated before using them for release and exposure estimation.	X		X
Sections B.3.X.2.3, B.4.X.2.3 and B.5.X.2.3 Human health hazard assessment	9	Uncertainty regarding the (potential) hazards identified for the substances	Potential hazards were identified for the substances prioritised in Section B.2. For most of the substances, data generation is still needed to clarify those hazards. For several substances DNELs from registrants' CSRs were used for the quantitative risk assessment. Those DNELs need to be evaluated/verified by ECHA.	X		X
Sections B.3.X.2.4, B.4.X.2.4	10	Uncertainty regarding the potential hazards	Potential hazards were identified for the substances prioritised in Section B.2. For most of the substances, data generation is still	X		

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis gap**[32]
and B.5.X.2.4 PBT/vPvB assessment		identified for the substances	needed to clarify those hazards.			
Sections B.3.5, B.4.6 and B.5.4 Additives in other plastics	11	Uncertainty regarding the presence of the prioritised additives in alternative materials	Little information was received regarding the presence of the prioritised additives in alternative materials.	X		
Sections B.6.X.2 Tonnage used in the EU	12	Uncertainty regarding the additive volumes per use	Except for flooring, there was no specific information about volumes of specific substances per use. Estimations were done based on the available information. In some cases, it might be an overestimation and in other cases an underestimation. Further explanations are available in the different B.6.X.2 sections.	X		
Sections B.6.X.3	13	Uncertainty regarding the estimated releases	Several assumptions have been made for estimating releases to the environment. Most critical ones have been discussed and a sensitivity analysis has been made to evaluate the impact of such hypothesis on the final release estimation; here below we describe the assumptions considered as “critical” and the outcome of the sensitivity analysis performed: • <u>Direct releases to soil</u>: release estimation is largely based on OECD ESD for plastics, in particular for use scenarios covering the article service life. The ESD does include emission factors based on (no) contact with water, however it disregards possible direct releases to soil; on contrary,	X		X

Relevant section of the assessment	Identified uncertainties					
	No.	Description of uncertainty	Specific information on uncertainty	Input	Metho-dology	Analysis gap[32]
			ERC release factors from R16 Guidance (also based on OECD ESD emission factors), assume an equal emission to soil as for the water; this might constitute an overestimation of the total releases, since the fraction potentially migrating (or abraded) from the water does go to wastewater via sewage collection or directly to soil (e.g. for outdoor use), but not to both. We have therefore removed all direct releases to soil (i.e. set release factor to soil equal to 0) except for landfill and professional uses (not based on OECD): the analysis showed a decrease of the total releases around 20% for most of the substances, with peaks of 40% for some substance. • Biodegradation in STP: another element investigated is the removal mechanism of PVC additives in the municipal STP; as mentioned, this is estimated via the partitioning and degradation simulated by Simpletreat; however, it is likely that the PVC additives are partially included in plastic particulate, and as such not available for biodegradation or emission to air. We have therefore made a simulation assuming an arbitrary partitioning of 90% to sludge and 10% to water from the STP, setting to 0 the fraction biodegraded or emitted to air; the outcome of the estimation showed a minimal impact on the total releases, with increases lower than 5% for most of substances, with few ones up to 10%. It is then concluded that the simulation by Simpletreat is still valid and does not impact significantly to the release estimation.			

Relevant section of the assessment	Identified uncertainties					
	No.	Description of uncertainty	Specific information on uncertainty	Input	Metho-dology	Analysis gap[32]
			• It is pivotal for the further risk management strategy to acquire further information on the representative site RMMs in particular from professional handling of articles, recycling sites and landfilling. This would be relevant for understanding whether releases from these life-cycle steps can be minimised as all end-uses contribute to these releases. Potentially also refinement of the release estimates per end-use could bring some added value for the impact assessment. Also the question whether all or only a part of the recycling sites are covered by the IED needs further clarification. • Releases from soft PVC roofing were not estimated in this project as they were scoped out in the initial stage of the project. The use is, however, very relevant with regard to expected releases based on the volume information provided in CfE2. This end-use will need to be included in the follow-up steps. • Mass balance scenarios of PVC additives for over 20 years in case a substitution is implemented. The environmental releases from professional handling, recycling and landfilling depend on the volume of additives (and PVC) handled in these life-cycle steps. It is vital to estimate the mass balance and several release scenarios to understand the level of effectiveness of substitution in view of that a large volume remains in circular economy or is landfilled after a substitution takes place.			

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis gap**[32]
Sections B.6.X.3	14	Uncertainty regarding the estimated exposure	No information about migration of additives from PVC microparticles. Measured data on environmental and human levels of the prioritised additives was not compiled in this project.	X	X	
Sections B.6.X.3	15	Uncertainty regarding the exposure estimates	Site specific RMMs are necessary to produce more reliable exposure estimates, especially in PVC compounding, PVC conversion and at recycling facilities. Exposure values for PVC compounding and conversion were taken from the registration dossiers of the lead registrants of the substances. In relation to relatively high concentration and high risk simulated for the exposure to heat stabilizers in automotive interiors from emission to internal air, we need to underline that these values should be taken with care, since estimated by screening Tier I model (ECETOC TRA Consumer v.3.1) that might overestimate exposure, especially for inhalation route. On the other hand, the high exposure estimates for DMTE and MMTE are supported by relatively high vapour pressure (around 1 Pa, from registration dossier) which is the main driver for air emission. We therefore suggest filling this gap via dedicated measurements in a car for indoor air for these compounds. Also the worker exposure scenarios would need further information in relation to organotin additives to verify and potentially refine the risks now identified.	X	X	
Sections B.6.X.4	16	Uncertainty regarding the derivation of DNELs	Unless otherwise noted, DNELs used for risk characterisation were derive by the registrants in their registration dossiers. However, no assessment of the DNELs derived by the registrants was done. This might result in an underestimation of risk in those cases.	X		X

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis gap**[32]
Sections B.6.4 to B.6.11	17	Man via the environment not addressed	Man via the environment was not assessed quantitatively. Most of the prioritised substances that are currently used in PVC are non-hazardous for now. For the individual additives likelihood of risks due to man via environment is low. For co-exposure this route seems highly relevant for assessment. There is, however, no methodology for carrying out a qualitative or quantitative analysis for risks from co-exposure for man via environment.	X	X	X
Sections B.6.4 to B.6.11	18	Contribution to exposure from other sources than PVC were not identified quantitatively	Exposure to the prioritised additives is for several additives not only caused by the PVC but also other (plastic and non-plastic) sources are relevant. This project did not attempt to identify the contribution of other sources quantitatively.	X		X
Section B.6.12	19	Lack of a quantitative risk assessment of co-exposures	A quantitative risk assessment of co-exposures was not attempted in detail in this project except of summing up of the total releases of all prioritised additives. Hazards for several additives are still to be clarified by testing. In addition, mode of action information (for human health effects) is lacking for many of the prioritised substances.		X	
Section B.6.13	20	Contribution from professional use (handling plastics) to release	Further clarification of emission reduction mesures is needed.	X		

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