INVESTIGATION REPORT
ON
PVC AND PVC ADDITIVES

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY
P.O. BOX 400, FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

VERSION NUMBER: 1.0 (Final)

DATE: 22/11/2023

ABOUT THIS REPORT

The investigation report was initiated based on a request of the European Commission (EC, 2022).

This report consists of a main report which highlights the main findings of the investigation and Appendices with more detailed information and supporting analysis.

ECHA would like to thank the stakeholders that made contributions to the calls for evidence, and requests for information.

This version of the report has been reviewed for confidential information and any such information has been redacted.

VERSION HISTORY

Version	Changes	Date
1.0	Final version for publication	22/11/2023

CONTENT

TABLES

FIGURES

LIST OF ACRONYMS AND ABBREVIATIONS

Acronym / abbreviation	**Meaning**
ARN	Assessment of regulatory needs
BAT	Best Available Technique
BAT-AELs	BAT Associated Emissions Levels
BOEL	Binding occupational exposure limit
BREFs	BAT Reference documents
CCH	Compliance check
CfE	Call for evidence
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic, reprotoxic
CoRAP	Community rolling action plan
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
EVA	Ethylene vinyl acetate
GHG	Greenhouse gas
HBM4EU	Human biomonitoring for Europe
HCl	Hydrochloric acid
HDPE	High density polyethylene
IED	Industrial Emissions Directive

Acronym / abbreviation	**Meaning**
LCA	Lifecycle analysis
LDPE	Low density polyethylene
LVOC	Large volume organic chemicals
OC	Operational conditions
OEL	Occupational exposure limit
PBT	Persistent, bioaccumulative and toxic
PCDDs	polychlorinated dibenzodioxins
PCDFs	polychlorinated dibenzofurans
PE	Polyethylene
PET	Polyethylene terephthalate
PE-X	Crosslinked polyethylene
PLASI	Plastics additives initiative
PMT	Persistent, mobile and toxic
POP	Persistent organic pollutant
PP	Polypropylene
PS	Polystyrene
PU	Polyurethane
PVC	Polyvinyl chloride
PVDC	Polyvinylidene chloride
RAC	Risk assessment committee
REACH	Registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measures
RoHS	Restriction of (the use of certain) Hazardous Substances
RRM	Regulatory risk management
SEAC	Socio-economic analysis committee

Acronym / abbreviation	**Meaning**
SEv	Substance Evaluation
SVHC	Substance of very high concern
TPE	Thermoplastic elastomer
TWA	Time-weighted average
VCM	Vinyl chloride monomer
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile
WEEE	Waste from electrical and electronic equipment
WFD	Waste Framework Directive
WGC	Waste gas from chemicals

REPORT

1. Background

PVC and its additives have been under regulatory scrutiny in the past decade. Certain additives in PVC, such as cadmium- and lead-based stabilisers and certain phthalates, have been concluded to pose an unacceptable risk to human health and the environment and are now restricted under REACH. The PVC industry has also taken an active role by phasing out those substances even before the regulatory measures were implemented.

Nevertheless, there are growing concerns that the alternative substances used to replace the restricted additives may themselves pose risks. Furthermore, potential risks may also arise from the manufacturing of PVC. The possible impact on circular economy of legacy additives in PVC has also been raised recently.

Consequently, the Commission requested ECHA to collect information on the potential risk to human health and the environment posed by PVC additives and PVC itself, including an assessment of the socio-economic impacts of potential risk management measures (EC, 2022).

Three calls for evidence were organised to collect data for this investigation report (for details see Appendix E):

- Call for evidence 1 (CfE1): a targeted call for evidence towards key industry associations in the PVC supply chain during July-September 2022. The objective of the call was to identify the PVC additives currently used in the EU, their functions and typical concentrations, as well as whether they are used in soft or rigid PVC. Information about R&D activities on additives was also requested.

- Call for evidence 2 (CfE2): This call for evidence was run between 2 November 2022 and 6 January 2023. The request is located on ECHA's website: https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/71301/term. The objective of the call was to retrieve information on the volumes of PVC and prioritised additives (section 3.2) used per sector and use. Furthermore, end-of-life information (e.g. on recycling rates per use) and measured exposure information were requested.

- Call for evidence 3 (CfE3): This call for evidence was run between 1 February 2023 and 31 March 2023. The request is located on ECHA's website: https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/72201/term. The objective of the call was to retrieve information on 1) alternative substances to the currently used prioritised additives in PVC, and 2) additives used in alternative plastics to PVC.

Data collected via calls for evidence, literature, publicly available information and interactions with stakeholders were used to perform a risk screening (Appendices A and B) and impact assessment (Appendix C).

In addition, data were collected regarding the regulatory framework on plastics and PVC (Appendix D) and the impact of the regulatory actions on the use of legacy additives in PVC (Appendix F).

The result of this work is summarised in the sections below.

2. Overall conclusions

PVC is used in rigid and soft forms in various sectors and uses, including 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), other miscellaneous consumer articles and vehicles (automotive interiors and cables).

The annual sales volume of compounded PVC totalled 6.8 million tonnes in the EU in 2021. Approximately 70 % of PVC is used by the building and construction sector, and the largest individual uses are pipes, flooring, cables and window frames. Appendix A provides an overview of the PVC volumes and uses.

This investigation project focusses on a list of 63 PVC additives (aka ‘prioritised additives’, Table 21) out of ca. 470 PVC additives identified as currently in use (Table 20), which belong to three main classes of additives (heat stabilisers, plasticisers and flame retardants), and the impact assessment covers pipes, flooring, cables, window frames, packaging, toys, medical applications, and artificial leather applications, which use 70–85 % of the total volume of compounded PVC consumed annually in the EU.

This investigation identified risks to human health from some of the prioritised additives, via direct exposure based on conventional realistic worst-case quantitative risk assessment. Risks to the environment (incl. man via environment) were also found for all prioritised additives based on a pragmatic approach applied in absence of a more complete set of data. Risks due to microparticle exposures in the environment are also expected for PVC itself. However, this is not a PVC-specific issue but a general challenge for any plastics, which is also recognised in the EU Plastics strategy (EC, 2023c). The potential risks are described in further detail in section 3 and in Appendices A and B.

Alternative materials to PVC are available for all uses covered in the assessment, but the substitution of PVC with alternative materials generally entails substantial costs, as PVC is often the low-cost option. Availability of alternative materials may be an issue when the share of PVC products is large (building and construction sector), or certification/ authorisation is needed (medical applications).

Alternative additives, with a lower level or currently no identified concern, are available for plasticisers, heat stabilisers and flame retardants, but they may impact technical performance. Substitution of additives normally entails costs, although they are considerably lower compared to the costs of replacing PVC with alternative materials. Substitution to alternative additives may increase the import of additives, at least in the short term. The impacts of risk minimisation are described in detail in section 4 and Appendix C.

Based on the findings from the risk screening and impact assessment, the following recommendations for follow-up actions are drawn. These recommendations are complementary to each other and not ordered by any means.

Need for regulatory actions (further elaborated in section 5 together with other complementary measures) should be considered to address the identified risks from PVC additives and PVC microparticles:

- **Regulatory action is needed to minimise risks from plasticisers, and in particular ortho-phthalates** that (i) contain constituents which have already been confirmed as reprotoxic or endocrine disruptors, (ii) have data showing effects on reproductive and/or endocrine system (additivity of effects within this group is known and/or highly likely), and/or (iii) for which a direct read-across/grouping approach can be applied. The most suitable regulatory action seems to be a REACH restriction.

The need for regulatory action is based on the environmental (and man via environment) risks assessment which applied a non-threshold case-by-case risk approach. These substance groups are the main contributors to the total environmental exposure to prioritised additives. The additives are assumed to be very persistent when they are released within PVC microparticles. It is therefore preferable not to wait until each of these substances (or subgroups) have gone through the steps of CLH, SVHC or even data generation before a restriction would take place, as a significant amount of the substances would have been placed on the market, and then further accumulated in the environment before risk reduction would take place.

Alternative general-purpose plasticisers that have currently no concern could replace large volume medium-chain (e.g. DINP) and also long-chain ortho-phthalates (e.g. DIDP) for many uses with no significant impacts on performance. Medium-chain ortho-phthalates could also potentially be replaced with long chain ortho-phthalates of less concern, in some cases with no additional unit cost.

It is important to note that, although there has been a transition to use longer-chain ortho-phthalates in the EU, shorter-chain ortho-phthalates are still widely produced and used in other markets, e.g. China, India, and other parts of Asia, the Middle East, Africa and Latin America. Consequently, imported articles are likely to contain shorter-chain ortho-phthalates and could pose a risk.

Although in this investigation report the focus was on PVC, and plasticisers are mostly used in PVC (over 85 % of total volume) it is acknowledged that plasticisers are also used in other polymers to a lower extent. For other polymers the same environmental risk approach applies and therefore regulatory action may also be necessary (risks not quantified in this report).

- **Regulatory action is needed to reduce the risks from the organotin substances (other than 'MOTE with a concentration of DOTE below 0.3%').** The seemingly most suitable regulatory action is REACH restriction, combined possibly with other measures.

  Risks for workers at recycling plants were identified in this investigation, based on a realistic worst-case default estimation approach. All uses contribute to the risk.

  There are indications that MOTE has already been used to substitute DOTE, at least in packaging, with no significant impacts on performance or costs. Substituting organotin substances with mixed metal stabilisers would lower technical performance, and industry has stated that some PVC articles that use organotin substances could not be produced with these additives due to performance issues. Use of mixed metal stabilisers (Zn/Ca) would be more costly than organotin substances due to the larger quantity needed, but as the volumes are low, the additive costs are relatively limited. Main costs are likely related to R&D and reformulation.

  It is important to note that there has been a transition to using mainly Zn/Ca-based heat stabilisers in the EU and the use of organotin substances has been reduced to specific applications where transparency and/or higher stabilising performance is needed. However, they are widely used in other geographic locations and specifically in North America, where they are used for almost all rigid PVC applications. Consequently, imported articles containing organotin substances (other than MOTE with a concentration of DOTE below 0.3%) may be placed on the market, and contribute also to releases and exposures during recycling and landfilling.

- **Regulatory action is necessary to ensure minimisation of the releases of PVC microparticles and prioritised PVC additives.** This can be done by implementing and improving on-site emission minimisation technologies for PVC microparticle releases, especially at recycling sites and landfills. Despite of data gaps, end-of-life (recycling and landfills) can be considered the main contributor to the overall releases of prioritised PVC additives. Recycling plants are a significant source of PVC microparticles. There is sufficient evidence to consider action at the EU level. The socio-economic impacts of implementing emission minimisation technologies were not assessed in this investigation report, apart from regulatory measures that would affect the volume of recycled PVC. This is further elaborated under section 6.

- **Flame-retardants** also contribute significantly to the overall releases of the prioritised additives. Flame-retardants are used in high amounts and high concentrations also in other plastics than PVC. In order to ensure a sufficiently wide angle, **follow-up as proposed in ECHA's strategy on flame retardants is recommended**.

Data and assessment gaps are presented in Appendices B and C and priorities for data gathering and assessment follow-up steps in section 6. Those data gaps could be addressed by e.g. data generation, using the European Partnership for the Assessment of Risks from Chemicals (PARC), founding, industry initiatives.

3. Summary of risks

3.1. Risks from PVC polymer

Risks from the uncompounded PVC resin itself, i.e. from PVC without considering the additives, were assessed covering also the production of PVC and the end of life.

The identified main sources of potential risk are: 1) the starting materials, EDC and VCM, which are released during the production of PVC, 2) the generation of PCDD/Fs during the production and during the incineration of PVC waste, 3) exposure of workers to PVC dust, and 4) PVC microparticle releases to the environment.

3.1.1. Starting materials in the production of PVC

PVC is produced by polymerisation of vinyl chloride monomer (VCM) which is almost exclusively produced by cracking 1,2-dichloroethane (EDC). EDC is manufactured from the chlorination/oxychlorination of ethylene (more details in Appendix A.1.1).

Workers

EDC and VCM are classified as carcinogens (Carc. 1B and Carc. 1A respectively) and the exposure to these substances is predominantly occupational exposure for which there are the following Binding Occupational Exposure Limits (BOELs) set in the EU: 2 ppm or 8.2 mg/m^3 (8h TWA) for EDC, and 1 ppm or 2.6 mg/m^3 (8h TWA) for VCM.

Both EDC and VCM are produced in closed systems that are highly automated and monitoring is conducted to assess the effectiveness of the operational conditions and risk management measures in place. This also applies to PVC manufacturing plants. Thus, the data collected by the European Council of Vinyl Manufacturers (ECVM) in two recent periods, namely 2013-2015/6 and 2017/8-2021, shows measurements below the EU BOELs (Appendix A.2.3.3). ECVM represents the seven leading European PVC resin manufacturers accounting for 85 % of the PVC resin manufactured in EU.

In addition, 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 reduce VCM exposure.

This information seems then to indicate that the operational conditions and risk management measures implemented in the VCM/PVC industry are adequate and effective to control the risk for workers from EDC and VCM.

Environment

Reductions of EDC and VCM emissions from PVC production facilities have been driven by voluntary initiatives of the PVC industry to optimize the manufacturing process and by regulatory requirements. 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). BAT Associated Emissions Levels (BAT-AELs) are especially relevant because permitting authorities must set a maximum to 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).

In this regard, three BREFs are relevant for the EDC/VCM/PVC manufacturing chain: the Large Volume Organic Chemicals (LVOC) BREF, the Polymers BREF and the Waste Gas from Chemicals (WGC) BREF. In addition, the EDC/VCM/PVC manufacturing chain is also regulated by BREFs covering all industries like e.g. the Common Waste Water (CWW) BREF. These BREFs set forth BAT-AELs for, among others, EDC, VCM, PCDD/Fs, HCl and PVC dust.

A third-party verification of compliance with the criteria set on the ECVM charter done in 2022 showed that the overall compliance with the emission limits seems to be now at ~90 % and most of the 10 % non-compliance seem to correspond to failures to respect guidelines (e.g. monitoring frequency) rather than excessive emissions or exposures (CfE2, #1601). The aggregated emissions to air and water from 2000 until 2021 have been reduced by 67 % for EDC and 65 % for VCM, respectively.

This information seems then to indicate that the operational conditions and risk management measures implemented in the VCM/PVC industry are adequate and effective to control the risk for workers from EDC and VCM.

PVC articles

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 the use of PVC for food packaging and PVC used in 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 to sample at least once 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 ~90 %. In addition, measured data indicates very low residual content of EDC and VCM in articles manufactured with PVC (Svensson, 1994).

However, it should be mentioned that the presence of residual content of EDC and most in particular VCM is highly dependent on the manufacturing process in place and consequently company dependent. Thus, in the recent ECHA's investigation report on the potential presence of CMR 1A or 1B substances in childcare articles it was identified that in a few cases VCM was measured in PVC childcare articles (outside the EU only and mostly from one manufacturer) at concentrations above 1000 mg/kg (ECHA, 2023a).

This information seems then to indicate that the levels of residual ECD/VCM in PVC articles seem to be appropriately controlled in Europe.

3.1.2. PCDD/Fs

PCDDs and PCDFs are families of organic compounds that are known persistent organic pollutants (POPs) listed under the Stockholm convention on Persistent Organic Pollutants. PCDD/Fs can be generated during the oxychlorination of ethylene in the production of EDC, as well as during the thermal oxidation of chlorinated production residues during incineration.

Similar to EDC and VCM, BAT-AELs for PCDD/Fs are set in the relevant BREFs for the EDC/VCM/PVC manufacturing chain. BAT-AELs are also set in the Waste Incineration BREF. Therefore, those BAT-AELs limit the amount of dioxin that is emitted to the environment.

Further, and as mentioned before, a third-party verification of compliance with the criteria set on the ECVM charter showed an overall compliance of ~90 % for the members of ECVM which represent 85 % of the total PVC resin manufactured in EU.

National emissions reported to the Convention on Long-range Transboundary Air Pollution obtained from the European Environment Agency (EEA) suggest that the emissions of PCDD/Fs have been declining over the years (although it is not possible to determine the fraction corresponding to the PVC industry).

Whilst PVC is a source for generation of PCDD/Fs during incineration, its significance for the overall PCDD/Fs generation in those activities is not clear. Other sources of chlorine are available in municipal waste and thus impacting the PCDD/Fs generation. This is apparent when looking at the above-mentioned national emissions reported to the Convention on Long-range Transboundary Air Pollution obtained from the European Environment Agency (EEA). Further, the PCDD/Fs generation does not seem proportional to the amount of chlorine present but rather the production of PCDD/Fs in incinerations processes is strongly linked to furnace types, their operating conditions and the type and efficiency of air pollution control systems.

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 what share would correspond to PVC waste. From a regulatory point of view, the Industrial Emission Directive contains specific provisions on the emission of all harmful pollutants from waste incineration plants (Commission Implementing Decision (EU) 2019/2010), including chlorine and PCDD/Fs for which BAT-AELs are available (Appendix A.2.3.1).

3.1.3. PVC dust

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

PVC resin is not classified as a possible carcinogen, and it is considered a polymer of low concern by the OECD although this classification does not consider the whole life cycle of the polymer (OECD, 2009). 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). However, 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 the dust itself.

The effect of the size of the PVC dust particles needs further 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 dust via inhalation. Further, a difference is expected between exposure to uncompounded PVC resin dust and compounded PVC dust due to the migration and leaching of additives from the PVC microparticles (Zhang et al., 2020). In this regard, soft PVC needs higher concentrations of additives compared to alternative plastics.

Conventional warnings related to generic dust properties are used also for PVC dust based on several safety data sheets available publicly.

Currently, PVC dust does not have an EU BOEL. However, there are occupational limits for PVC dust in place in several countries in EU Member States 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 EU Member States 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 or below the level of detection (0.1 mg/m^3).

This information seems then to indicate that the operational conditions and risk management measures implemented in the VCM/PVC industry are adequate and effective to control the risk from PVC dust in industrial settings.

3.1.4. PVC microparticle releases to the environment

See section 3.5.

3.2. Risks from current PVC additives

A list of additives currently used in PVC was compiled using the initial list of substances provided in Annex 2.2 to the report “The use of PVC in the context of a non-toxic environment” and a targeted call for evidence (CfE1) with the key industry associations of the PVC supply chain. The result was a list with ~470 substances (Annex 1 to this report and Appendix B) (EU, 2022).

In the following, these 470 substances were prioritised for further work in this investigation report considering the following aspects: hazard scoring (severe hazards only), and release potential (Appendix B).

As a result, substances belonging to the group of heat stabilisers, plasticisers and flame retardants with high and medium scores were further assessed, and a subset of substances having a (potential) hazard as CMR 1A or 1B, STOT RE 1, ED and/or PBT/vPvB was identified. A small extension to the core selection criteria was made with the aim of considering the additives in the context of groups of structurally related substances. For the substances with high and medium scores, groups of substances were identified (e.g. terephthalates). Substances belonging to those groups were also considered, even when not scoring high or medium (e.g. DOTP).

This prioritisation resulted in a total of 63 substances (Annex 1 to this report) belonging to several substance groups and covered under Appendices B.3, B.4 and B.5 and shown in Table 1, Table 2 and Table 3. The rest of substances identified to be in use in PVC as heat stabilisers, plasticisers and flame retardants are considered of low/no concern for now.

Although all prioritised substances were initially identified as currently being used in PVC in the CfE1, from the information provided in subsequent calls for evidence (CfE2 and CfE3) no uses in PVC were explicitly identified for many of those substances or the substances are not registered under REACH. Further assessment was only performed for those substances that are registered under REACH, and for which uses in PVC were explicitly identified.

Table 1. Prioritised heat stabilisers

Group	Chemical name	EC No	CAS No	Aggregated tonnage (REACH)	Leading (potential) hazard	Identified uses in PVC
Organotin substances	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DOTE**)	239-622-4	15571-58-1	1000-10000	Repr. 1B (H360D), STOT RE 1 (H372, immune system)	Pipe fittings, Window frames, Packaging (food and non-food), Automotive parts, Medical packaging (blister packs)
	2,2-dioctyl-1,3,2-oxathiastannolan-5-one (**DOTTG**)	239-581-2	15535-79-2	0	Reprotoxicity (developmental)	Pipe fittings, Window frames
	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**MOTE**)	248-227-6	27107-89-7	1000-10000	-	Pipe fittings, Window frames, Packaging (food and non-food), Automotive parts, Medical packaging (blister packs)
	dioctyltin dilaurate (**DOTDL**)	222-883-3	3648-18-8	100-1000	Repr. 1B (H360D), STOT RE 1 (H372, immune system)	No identified uses
	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DMTE**)	260-829-0	57583-35-4	1000-10000	STOT RE 1 (H372, nervous system), Repr. 2 (H361D)	Pipe fittings, Window profiles, Packaging (food and non-food), Automotive parts, Medical packaging (blister packs)
	Ethyl 9,9-dioctyl-4,7,11-trioxo-3,8,10-trioxa-9-stannatetradeca-5,12-dien-14-oate (**DOT-MalEt**)	268-500-3	68109-88-6	100-1000	Repr. 2 (H361D)	Pipe fittings, Window frames
	DioctylTin di(2ethylhexylmercaptopropionate)	261-645-3	59185-95-4	10-100	Reprotoxicity (developmental)	No identified uses
	2-ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**DBTE**)	234-186-1	10584-98-2	10-100	STOT RE 1 (H372, thymus), Reprotoxicity (developmental)	No identified uses
	2-ethylhexyl 14-ethyl-6,6-dioctyl-4,8,11-trioxo-5,7,12-trioxa-6-stannaoctadeca-2,9-dienoate	233-117-2	10039-33-5	10-100	STOT RE 1 (H372, thymus), Repr. 2 (H361D)	No identified uses
	2-ethylhexyl 10-ethyl-4-[[2-[(2-	260-828-5	57583-34-3	1000-10000	Repr. 2	Pipe fittings, Window frames, Packaging

Group	Chemical name	EC No	CAS No	Aggregated tonnage (REACH)	Leading (potential) hazard	Identified uses in PVC
	ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (**MMTE**)				(H361D)	(food and non-food), Automotive parts, Medical packaging (blister packs)
Mono-, di- and triphenylphosphite derivatives	Isodecyl diphenyl phosphite	247-777-4	26544-23-0	0	-	Window frames
	Tris(nonylphenyl) phosphite	247-759-6	26523-78-4	0	Reprotoxicity, ED (hydrolysis products), PBT	No identified uses
	Triphenyl phosphite	202-908-4	101-02-0	100-1000	Neurotoxicity	No identified uses
	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	700-485-5	939402-02-5	1000-10000	Reprotoxicity, ED, (hydrolysis products), PBT	No identified uses
	Diisodecyl phenyl phosphite	247-098-3	25550-98-5	0	-	Potential use in window frames
	2-ethylhexyl diphenyl phosphite	239-716-5	15647-08-2	0	-	No identified uses
	Diisotridecyl phenyl phosphite	267-466-7	67874-37-7	0	-	Potential use in window frames
Phenyl 1,3-diones	1,3-diphenylpropane-1,3-dione	204-398-9	120-46-7	1000-10000	-	Flooring, Toys, Automotive parts
	Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione	915-316-2		1000-10000	Reprotoxicity	Window frames
Others	barium 4-dodecylphenolate	300-141-0	93922-04-4	10-100	Reprotoxicity, ED, PBT	No identified uses
	Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated	800-029-6	1290049-56-7	100-1000	STOT RE 1	No identified uses

Table 2. Prioritised plasticisers

Group	Subgroup	Chemical name	EC No	CAS No	Aggregated tonnage (REACH)	Leading (potential) hazard	Identified uses
Ortho-phthalates	Short chain (C3)	Diisobutyl phthalate (**DIBP**)	201-553-2	84-69-5	>1	Repr. 1B, ED (HH, ENV)	No identified uses
		Diallyl phthalate (**DAP**)	205-016-3	131-17-9	100-1000	Repro, ED (HH, ENV)	No identified uses
	Medium chain (C4-C6)	Dibutyl phthalate (**DBP**)	201-557-4	84-74-2	>1000	Repr. 1B, ED (HH, ENV), PBT	No identified uses
		Benzyl butyl phthalate (**BBP**)	201-622-7	85-68-7	1-10	Repr. 1B, ED (HH, ENV), PBT	No identified uses
		Bis(2-ethylhexyl) phthalate (**DEHP**)	204-211-0	117-81-7	10000-100000	Repr. 1B, ED (HH, ENV), PBT	Medical applications
		1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (**DIHP**)	276-158-1	71888-89-6	NO	Repr. 1B, ED (HH, ENV), PBT	No identified uses
	Medium chain (C7-C8)	Di-''isononyl'' phthalate (**DINP**)	249-079-5	28553-12-0	100000-1000000	Reprotoxicity, ED (HH based on constituents, ENV), PBT	Flooring, Cables, Packaging (food and non-food), Artificial leather, Automotive
		Bis(2-propylheptyl) phthalate (**DPHP**)	258-469-4	53306-54-0	100000-1000000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Packaging, Artificial leather, Automotive
		1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (**D79P**)	271-082-5	68515-40-2	0	Reprotoxicity, ED (ENV), PBT	No identified uses
		1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (**D711P**)	271-084-6	68515-42-4	0	Repr. 1B, ED (ENV), PBT	No identified uses
		1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (**DINP**)	271-090-9	68515-48-0	10000-100000	Reprotoxicity, ED (HH based on constituents, ENV), PBT	Flooring, Cables, Packaging (food and non-food), Artificial leather, Automotive
	Long chain (C9-C18)	Diundecyl phthalate (**DUP**)	222-884-9	3648-20-2	100-1000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Packaging, Artificial leather, Automotive
		Diisotridecyl phthalate (**DITDP**)	248-368-3	27253-26-5	0	Reprotoxicity, ED (HH, ENV), PBT	No identified uses
		1,2-Benzenedicarboxylic acid,	271-085-1	68515-43-5	1000-10000	Repro, ED (HH,	Cables, Packaging, Artificial

Group	Subgroup	Chemical name	EC No	CAS No	Aggregated tonnage (REACH)	Leading (potential) hazard	Identified uses
		di-C9-11-branched and linear alkyl esters (**D911P**)				ENV), PBT	leather, Automotive
		1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (**D1114P**)	271-089-3	68515-47-9	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Packaging, Artificial leather, Automotive
		1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (**DIDP**)	271-091-4	68515-49-1	100000-1000000	Reprotoxicity, ED (HH, ENV), PBT	Flooring, Cables, Packaging (food and non-food), Artificial leather, Automotive
		1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters (**D1618P**)	290-580-3	90193-76-3	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Artificial leather
		1,2-benzenedicarboxylic acid, di-C10-12-branched alkyl esters (**D1012P**)	700-989-5	#N/A	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather
		bis(decyl and/or dodecyl) benzene-1,2-dicarboxylate (**DDP/DDDP**)	931-251-2	#N/A	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather
Terephthalates		Dibutyl terephthalate (**DBTP**)	217-803-9	1962-75-0	1000-10000	ED	Flooring, Artificial leather, Automotive
		Bis(2-ethylhexyl) terephthalate (**DOTP or DEHTP**)	229-176-9	6422-86-2	100000-1000000	-	Flooring, Cables, Packaging (food and non-food), Toys, Artificial leather, Automotive, Medical applications
Trimellitates		1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters (**T911TM**)	304-780-6	94279-36-4	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather, Automotive
		1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters (**T810TM**)	290-754-9	90218-76-1	10000-100000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather, Automotive
		Trioctyl benzene-1,2,4-tricarboxylate (**TOTM**)	201-877-4	89-04-3	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather, Automotive, Medical applications
		Triisononyl benzene-1,2,4-tricarboxylate (**TINTM**)	258-847-9	53894-23-8	100-1000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather, Automotive
		Triisodecyl benzene-1,2,4-tricarboxylate	253-138-0	36631-30-8	1000-10000	Reprotoxicity, ED (HH, ENV), PBT	Cables, Artificial leather, Automotive

Group	Subgroup	Chemical name	EC No	CAS No	Aggregated tonnage (REACH)	Leading (potential) hazard	Identified uses
		(**TIDTM**)					
Benzoates		Nonylbenzoate, branched and linear	447-010-5	670241-72-2	100-1000	Repro 1B	No identified uses
		Benzoic acid, C9-11, C10-rich, branched alkyl esters	421-090-1	131298-44-7	1000-10000	Repro 1B	Flooring

Table 3. Prioritised flame retardants

Group	Chemical name	EC No	CAS No	Aggregated tonnage (REACH)	Leading (potential) hazard	Identified uses
Organophosphates	Trixylyl phosphate	246-677-8	25155-23-1	100-1 000	**Repr. 1B**, ED	Cables
	Phenol, isopropylated, phosphate (3:1)	273-066-3	68937-41-7	1 000-10 000	Reprotoxicity, ED, PBT	Cables
	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	945-730-9	-	1 000-10 000	Reprotoxicity, ED	Cables
	Tris(methylphenyl)phosphat	809-930-9	1330-78-5	1 000-10 000	Reprotoxicity, ED	Cables
	tert-butylphenyldiphenyl phosphate (**tBuTPP**)	939-505-4		100-1 000	Reprotoxicity, ED	Cables
	Diphenyl tolyl phosphate	247-693-8	26444-49-5	0	Reprotoxicity, ED	Cables
	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate	700-990-0	-	1 000-10 000	Reprotoxicity, ED	Cables
	Tris(2-ethylhexyl) phosphate	201-116-6	78-42-2	1 000-10 000	ED (HH,ENV)	Cables
Inorganic	Diantimony trioxide	215-175-0	1309-64-4	>10 000	Carc.2 (TBD if Carc. 1)	Sealants in window frames, Flooring, Cables, Automotive
	Dimolybdenum trizinc nonaoxide	245-322-4	22914-58-5	1-10	-	No identified uses
	Zinc borate	215-566-6	1332-07-6	10-100	Reprotoxicity	Flooring, Cables, Automotive
	Hexaboron dizinc undecaoxide	235-804-2	12767-90-7	1 000-10 000	Reprotoxicity	Sealants in window frames, Cables, Artificial leather, Automotive
Halogenated	Paraffin waxes and Hydrocarbon waxes, chloro (**LCCP**)	264-150-0	63449-39-8	10 000-100 000	PBT	No identified uses
	Bis(2-ethylhexyl) tetrabromophthalate	247-426-5	26040-51-7	100-1 000	PBT	No identified uses

3.2.1. Hazard assessment

The dynamics of leaching from PVC and the further fate after leaching of the additives can be very complex (Appendix B). The working assumption for this report is, nevertheless, that the fate of the additives can be assumed to be the same as of PVC microparticles in the environment for those additives releases which occur bound in PVC microparticles and thus rendered as vP (Appendix A). Accumulation of PVC and additives contained therein can be expected in the environment in the similar manner as for vP substances. However, it is acknowledged that experimental or estimated leaching data are needed for PVC microplastics released and present in the environment. Such data are not available for the substances in focus of this report.

A further concern of PVC is co-exposure to several additives (Appendix B.6.12). This is especially the case for the environmental exposures. Risks due to co-exposures were not quantified. A quantification of environmental risks (incl. man via environment) due to co-exposures is likely not possible to carry out for the prioritised additives within a reasonable timeframe. Considering the multitude of the prioritised additives and the nature of their effects including confirmed severe hazards (very toxic threshold and non-threshold), it is likely that only a part of the risks from co-exposures might become quantified within the next years. For some of the risks, no quantification 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 dozens of prioritised additives, their accumulation in the environment would continue.

It is noted that direct co-exposures of workers (especially at recycling sites) and consumers also clearly occur due to PVC uses, but they were not further identified. Partially similar challenges apply to their assessment as described above.

Many of the additives focused on this project have already confirmed threshold or non-threshold severe toxicity, as listed in the following subsections. Part of the prioritised additives are suspected to have such severe toxicity, and the confirmation is pending further data and/or assessment. For all prioritised additives, data show hazardous effects. The effects, regardless of whether indicating severe toxicity or not, in combination with the above two elements of very high persistence and complex co-exposures, give rise to a concern which should be considered as non-threshold.

In summary, the concern related to the PVC additives should be considered as of non-threshold character because:

- the additives released within PVC microparticles are expected to behave in the environment as very persistent substances because they are bound in the PVC microparticle matrix,

- the use of additives in PVC induces direct human and environmental co-exposures. Synergistic or additive effects cannot be excluded,

- the leading effects of the prioritised additives are severe, many of which are non-threshold (see following subsections) and/or

- substances for which the lead effect has been so far suspected based on screening information (and pending confirmation) data on further effects are largely available to support the hazard profile (need full assessment in the follow-up).

More information about the assessments of regulatory needs for those substances and the data generation needs are available in Appendices B.3, B.4 and B.5 and they are summarised in sections 3.2.1.1, 3.2.1.2 and 3.2.1.3 below.

3.2.1.1. Heat stabilisers

General information about heat stabilisers can be found in Appendix B.3. 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 prioritised for further work (low hazard for now at the time of writing).

Ca/Zn heat stabilisers systems represent ~94 % of the total stabilisers used in the EU and the rest corresponds to organotin substances.

<u>Organotin substances</u>

Organotin substances have been widely used in PVC applications, but currently their use in Europe has been reduced to specific applications where transparency and/or higher stabilising performance is needed. However, they are widely used in other geographic locations and specifically in North America, where they are used for almost all rigid PVC applications.

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 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 1). An assessment of regulatory needs for this group of substances is currently ongoing 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.

Also, recent concerns for potential endocrine disrupting properties are also currently under assessment.

<u>Phenyl 1,3-diones</u>

These substances seem to be used as co-stabilisers with colour-improving properties with Ca/Zn heat stabilisers systems. From the information received in the different calls for evidence uses in PVC were identified only for window frames, flooring, toys and automotive parts. However, since they are used together with Ca/Zn heat stabilisers systems, phenyl-1,3-diones might be used in more PVC applications.

Although the two substances prioritised in this group were initially identified as potential PBT in an assessment done in ECHA, this was later clarified not to be the case. Data generation has been requested to clarify potential reproductive toxicity for substance EC 915-316-2.

Other

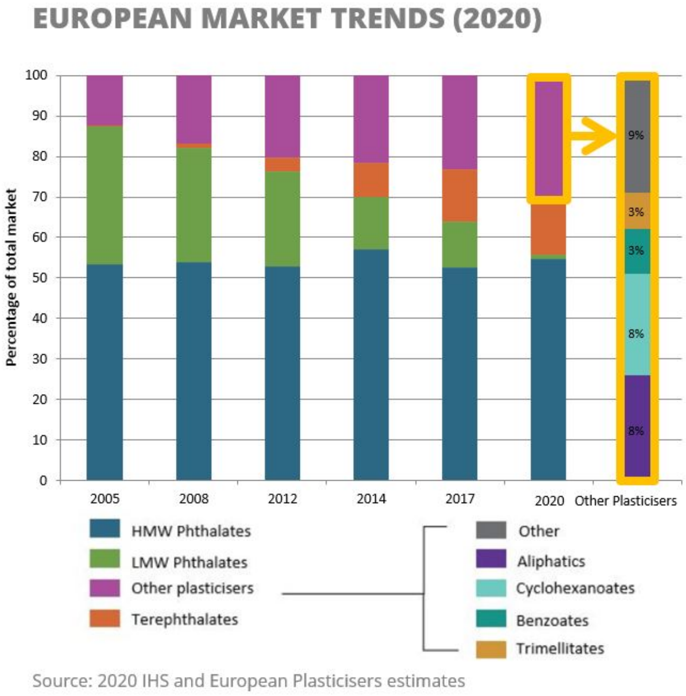
Other substances belonging to the heat stabilisers group were initially identified as being in use in PVC (Table 1). However, based on the information provided during the different calls for evidence no uses were finally identified. In addition, several of the phenylphosphites are also not registered under REACH. Therefore, no risk screening has been performed for those substances. However, other information sources identify phenylphosphites to be used in combination with Zn/Ca heat stabilisers (Appendix B).

3.2.1.2. Plasticisers

More general information about plasticisers in PVC can be found in Appendix B.4.

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.

Over 85 % of all plasticisers consumed in Europe are used in flexible PVC applications (European Plasticisers, 2023). 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.



Source: 2020 IHS and European Plasticisers estimates

Figure 1. Distribution of most common plasticisers in the European market

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, included in

Annex XIV and subject to restriction (entries 30 and 51), to higher molecular weight phthalates. Today, the most used ortho-phthalates are DINP, DPHP and DIDP (DINP and DIDP are subject to restriction, entry 52). It is noted that outside of the EU, low molecular weight phthalates continue to account for approximately 35 % of the global consumption as they are widely produced and used in China, India, and other parts of Asia, the Middle East, Africa and Latin America (CfE2,#1601). Figure 1 above shows the distribution in the European market of the most common plasticisers.

A total of 28 substances used as plasticisers were prioritised for further assessment. They can be grouped into the following groups: ortho-phthalates, terephthalates, trimellitates and benzoates (Table 2).

Ortho-phthalates

Even though ortho-phthalates 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 sub-grouped based on the alkyl backbone length (not the total carbon range) of the alkyl substituent. Thus, following the assessment of regulatory needs performed for ortho-phthalates,[1] the following subgrouping was considered in this investigation report: 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).

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)

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 due to several regulatory actions following the identification of several of those substances as SVHC. As a consequence, none of the short-chain ortho-phthalates and the medium-chain ortho-phthalates have been identified in any use in PVC with the exception of DEHP in medical applications.

In the assessment of regulatory needs (ARN) for ortho-phthalates done by ECHA[1] it is indicated that medium-chain (C7-C8) ortho-phthalates (DINP and DPDP) are likely not or not as potent reproductive toxicants as the ortho-phthalates with shorter backbone alkyl chains. Nevertheless, EFSA in an update of the risk assessment for five phthalates[2]

---

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

[2] Update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate (DIDP) for use in food contact materials https://doi.org/10.2903/j.efsa.2019.5838

concluded that small or transient reproductive effects might be able to contribute to the reprotoxic effects of other phthalates after combined exposure. However, endocrine disrupting properties cannot be excluded due to: 1) potential presence of constituents with shorter backbone alkyl chain, 2) unclear covering of this endpoint in the toxicological studies available for DINP and identified effects on the thyroid observed in toxicological studies available for DPHP. Both DINP and DPDP are currently subject of dossier evaluation.

For long-chain (C9-C18) ortho-phthalates, in the ARN for 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 shorter chain ortho-phthalates. However, no firm conclusion was able to be drawn because adequate data was only available for a few substances and the substance identity data for these UVCB substances indicates that they might contain constituents similar to medium-chain (C4-C6) ortho-phthalates. In this case, several substances are currently subject of dossier evaluation to clarify those concerns.

Therefore, although it is acknowledged that medium-chain (C7-C8) and long-chain (C9-C18) are still subject of further evaluation in ECHA, for the purpose of this investigation report it is considered as if medium-chain (C7-C8) are likely going to display ED properties and less likely for long-chain (C9-C18).

In addition, a potential for PBT/vPvB properties was also identified for medium-chain (C7-C8) ortho-phthalates since they screen as potentially bioaccumulative based on the values for $\log K_{OW}$. Although they are identified by the registrants as readily biodegradable, flaws in the available data cannot fully support this conclusion. As mentioned above, both DINP and DPDP are currently subject of dossier evaluation also in this regard.

Terephthalates

According to the assessment of regulatory needs (ARN) for terephthalates done by ECHA,[3] potential thyroid toxicity is assumed for DBTP, a C4 linear constituent, and therefore potential ED concern based on the effects seen for substance EC 946-149-3 (C4-C6 mixed terephthalate). In this case, hypertrophy of follicular epithelium in thyroid glands is seen in both sexes at 300 and 1000 mg/kg bw/day. This substance is currently subject of dossier evaluation.

For DOTP no hazards of potential hazards were identified.

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

Therefore, although it is acknowledged that substance EC 946-149-3 (C4-C6 mixed terephthalate), and consequently also DBTP, is still subject of further evaluation in ECHA, for the purpose of this investigation report it is considered as if they are likely to display ED properties.

Trimellitates

---

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

Based on the assessment of regulatory needs (ARN) for trimellitates done by ECHA[3] no firm conclusion or potential reproductive toxicity and ED properties can be made for this group of substances based on the available data and further data will be needed. Nevertheless, some of the data available raises a concern about potential ED properties.

Several substances belonging to this group are currently subject of dossier evaluation to clarify this concern.

As mentioned before, although these substances are still subject to further evaluation in ECHA, for the purpose of this investigation report it is considered as if they are likely to display ED properties.

Similarly, the available data for these substances does not allow to conclude on PBT/vPvB properties either and this hazard is also under consideration in dossier evaluation.

Benzoates

Based on the available information,[4] both benzoates (EC 421-090-1 and 447-010-5) were identified as potential reprotoxicants. This 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).

This assessment also concludes that they are unlikely to display PBT/vPvB properties.

Both substances EC 421-090-1 and 447-010-5 are currently subject of dossier evaluation to clarify the concerns.

3.2.1.3. Flame retardants

More general information about flame retardants in PVC can be found in Appendix B.5.

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, the use of flame retardants in PVC is quite limited, especially in the case of rigid PVC, compared to other commodity plastics like e.g. polyolefins, stryrenics and acrylics (ECHA, 2023b). 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 more 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 soft 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 in the compounded PVC 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

---

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

(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 considering the intrinsic flame resistance of PVC (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 when using PVC.

Among the substances identified as being in used in PVC, several flame retardants were identified. A total of 12 substances used as flame retardants were prioritised for further assessment. They can be grouped into the following groups: organophosphates, inorganics and halogenated flame retardants (Table 3).

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. Nevertheless, most of the organophosphates identified to be used in PVC are triphenylphosphate derivatives. Only one trialkylphosphate derivative was identified: Tris-(2-ethylhexyl) phosphate (EC 201-116-6).

All triphenylphosphate derivatives have been identified as potential reprotoxicants and endocrine disruptors for both human health and environment[5] and data generation is on-going to clarify those concerns.

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 from o-methyl/cresyl isomers (Nordic Expert Group, 2010), therefore all substances containing TOCP (tri-o-cresylphosphate, EC 201-103-5) as constituent or impurity may be neurotoxic.

In general, substances in this group are unlikely to meet the PBT/vPvB criteria based on the data available.

Although it is acknowledged that these substances are still subject of further evaluation, for the purpose of this investigation report it is considered as if they are likely to display ED properties.

Inorganics

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. 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

---

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

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.

This assessment is based on the assessments of regulatory needs (ARN) for inorganic borates[6], molybdenum simple compounds[7] and the assessment of DE CA in the CoRAP justification document and Substance Evaluation decision for Diantimony Trioxide.[8]

A general hazard concern for reproductive toxicity was identified for a group of inorganic borates (containing boric acid and salts based on alkali metals, alkaline earth metals or ammonium counter ions). 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.

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 carcinomas 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 further data that is expected during the second half of 2023.

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

---

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

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

[8] 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 to conclude on reproductive toxicity and that further data may be needed. However, no potential human health hazard was identified to date.

Halogenated flame retardants

Even though halogenated flame retardants were identified as flame retardants currently used in PVC and Table 3 shows the two substances prioritised for assessment in this report (LCCP and bis(2-ethylhexyl) tetrabromophthalate), 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 provided is not concrete and 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 which seems to contradict the information received in previous projects, from which it can be concluded that halogenated flame retardants are used in soft PVC (ECHA, 2022).

Therefore, considering the lack of information, no further assessment was performed for those substances.

Nevertheless, it should be mentioned that, as highlighted in ECHA's Regulatory Strategy for Flame Retardants, 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) (ECHA, 2023b). These are expected to be addressed in the 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 ECHA's Regulatory Strategy for Flame Retardants is the general concern identified for aromatic brominated flame retardants due to their known or potential PBT/vPvB properties (ECHA, 2023b). 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.

3.2.2. Exposure assessment

The exposure assessment and risk screening for prioritised additives (Appendices B.3, B.4 and B.5) were 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.

The assessments of regulatory needs (ARN) published on ECHA website[9] were 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 were also be considered when appropriate

---

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

for those substances that are classified for human health threshold hazards, i.e. Repro. 1 or STOT RE 1, or when the only potential hazard identified is Repro. 1 or STOT RE 1.

Exposure scenarios were identified covering the PVC compounding (formulation), the PVC article production (conversion), the article service life for the uses of PVC assessed in this investigation report, the professional uses for building and construction products and the waste stage covering recycling, landfilling and incineration.

- ES1: Formulation (PVC compounding)
- 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 2.

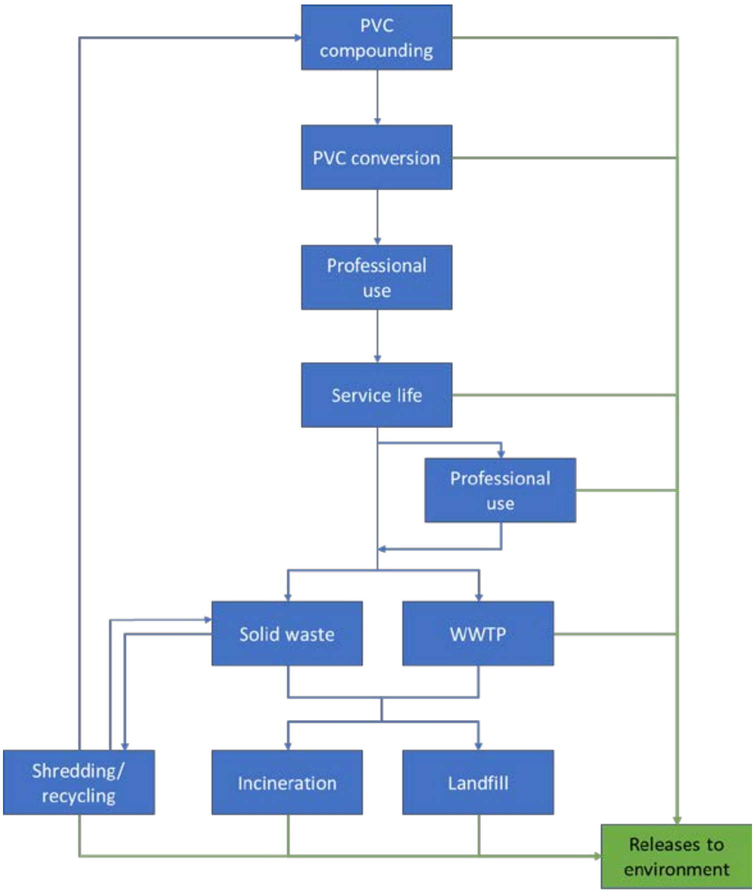


Figure 2. Generic sequence of exposure scenarios

The assumptions and strategy for release and exposure estimations are described in Appendices B.6.2 and B.6.3 respectively. The key input parameters for the estimation of release are described in Appendices B.6.2.1 to B.6.2.5. The volumes per use for the substances, which is the basis for the release estimation, are provided in Appendices B.6.4.2 to B.6.11.2.

ECHA has received data on migration for some substances (e.g. organotin substances used as heat stabilisers in rigid PVC or ortho-phthalates (DEHP, DINP, DIDP)), especially from testing required by other legislation (Drinking Water Directive, Food Contact Materials legislation). This testing shows very low migration and compliance with the relevant legislation. However, the transfer of those results to the releases / exposure estimation is not straightforward. The following are some reasons behind that:

- If you consider all possible uses, releases to environment are subject to different conditions (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 higher molecular weight ortho-phthalates (e.g. DINP, DIDP), they have been nevertheless detected in human biomonitoring data (HBM4EU, 2022). The recent results of the HBM4EU (HBM4EU, 2023) initiative suggest widespread human exposure to these compounds simultaneously and specially infants/children who seem to carry a higher body burden 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.

3.2.3. Risk characterisation

3.2.3.1. Releases as proxy of risk

A concern of non-threshold nature was identified considering:

- the very persistent properties of PVC microparticles and therefore of the additives contained within,
- the fact that currently is not possible to estimate environmental exposures of individual additives in combination with the co-exposure of the environment (including man via environment) to several additives simultaneously from (and within) the PVC matrix, and
- the available effects data on the prioritised additives.

Releases of prioritised additives within the PVC microparticles are likely causing an ongoing increase of the environmental levels. Environmental levels for the additives contained within the PVC microparticles are difficult to reverse once they are reached.

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 to the environment and man via environment. Consequently, the application of REACH Annex I, para 0.10 and hence a case-by-case environmental risk assessment is recommended as a general approach. For further details, see Appendix B.6.13.

3.2.3.2. Environmental risk (total releases)

The releases per environmental compartment per group of prioritised additives, per function and the total releases are reported in Appendix B.6.13. 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 (e.g. to be presented by molar weight), as no comparison to a no-effect level is carried out. A similar approach for aggregating releases of multiple substances has been taken in various restriction dossiers on poly- and perfluorinated substances (PFASs).

The main contributors to the overall estimated releases of the prioritised additives are plasticisers (79 %), followed by flame retardants (19 %) and heat stabilisers (2 %). This is a consequence of the high absolute use volumes of particularly plasticisers, as well as of the higher overall concentrations of additives needed for soft PVC applications (prioritised flame retardants are also mainly used in soft PVC). Although this analysis was carried out only for the prioritised additives, a similar picture is likely to emerge if all the additives were considered based on the typical compounding recipes for PVC.

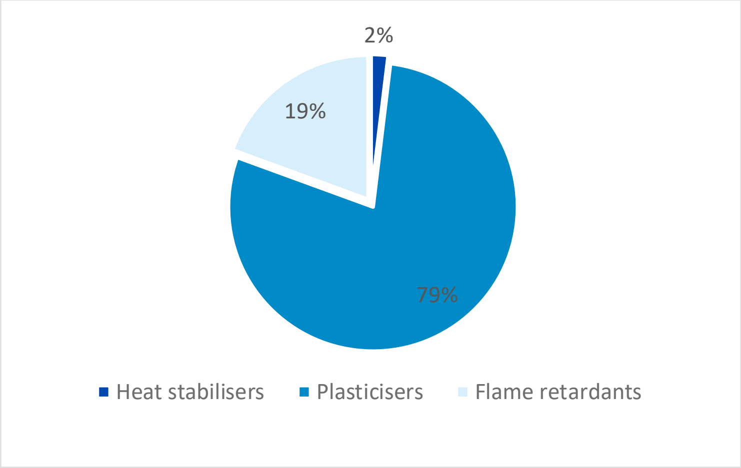


Figure 3. Contribution to the overall estimated releases per additive type

Since plasticisers are mainly used in PVC (over 85 % according to the European Plasticisers), higher risks to the environment can be expected to emanate from soft PVC when compared to alternative materials in this regard.

From the prioritised plasticisers in this report, ortho-phthalates are the major contributors to the overall releases (Appendix B.6.13). More specifically, medium chain (C7-C8) ortho-phthalates (DIDP and DINP) account for 49 % of the total releases followed by long-chain (C9-C18) ortho-phthalates with 12 % of the total releases.

Consequently, the main uses contributing to the overall release of the prioritised additives are soft PVC applications. Four uses account for 97 % of the total overall estimated releases for the prioritised additives: cables (67 %), flooring (15 %), artificial leather (8 %) and automotive interiors (7 %). It is noted that the relevance of roofing material (a soft PVC end-use) for the release estimation was only understood after the CfE2. Those releases were not estimated in this report.

Of the PVC lifecycle steps, the major contributors to the overall estimated releases are the ES12 (Professional use. Handling of plastic articles), which covers installation and removal of building and construction products, ES13 (Waste stage. Recycling) and ES14 (Waste stage. Landfilling) with an overall of ~45 %, ~31 % and ~11 % of the total estimated releases, respectively. Releases from the service life of articles have a low contribution to the overall picture.

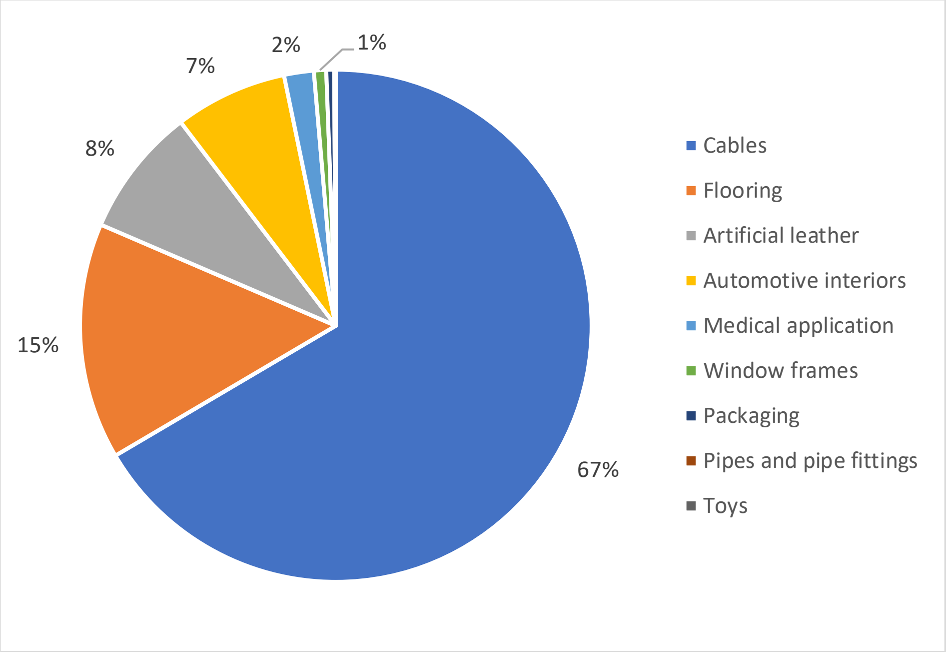


Figure 4. Contribution to the overall estimated releases per use

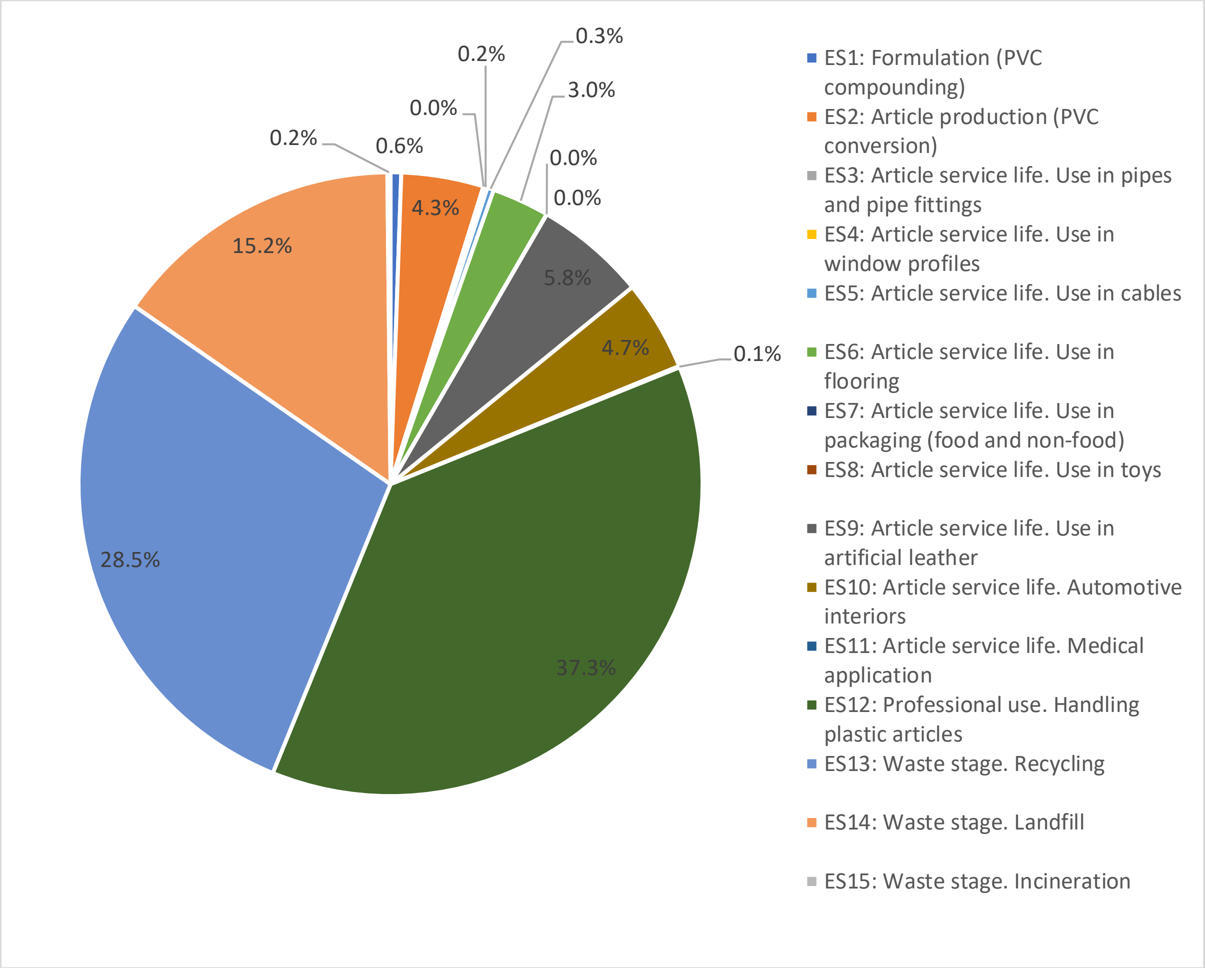


Figure 5. Contribution to the overall estimated releases per lifecycle exposure scenario

Due to the non-threshold nature of the risk (Section 3.2.3.1), minimisation of the releases of additives should be the focus of regulatory and/or voluntary actions. The releases of additives are strongly linked to the releases of PVC microparticles and release minimisation may be expected to be most effective when minimisation of both the additives and microparticles is targeted. However, this needs further assessment. Minimisation potential of the releases from the key life-cycle steps as listed above need further information (data gap).

This investigation did not analyse a 20-year baseline horizon as is usual in restriction proposals, but a plausible baseline horizon can still be discussed qualitatively. If neither the current total annual use volumes of PVC and prioritised additives (and in their allocation to the various uses) nor the annual volumes of PVC and additives routed to recycling, landfilling and incineration change, an increase of the overall volume of PVC and additives circulating in the economy can be expected. It is then likely that the volumes of landfilled and incinerated PVC would also increase.

The increase of the total volumes of PVC and additives circulating in the economy results generally in an increase of annual releases[10]. Considering that the released PVC and the additives released in the PVC microparticles are very persistent in the environment, the total stock of PVC and additives in the environment will steadily increase unless the releases are minimised.

In the alternative baseline scenario, the PVC volume in the economy (and in landfills) remains at the current level and hence the annual releases remain approximately at the current level. This results in an increase of the environmental stock due to the high persistence of the PVC and additives therein. The current trends in the use of PVC (see Appendix A and C) and the societal aim to increase recycling rates as well as the voluntary substitution trends complicate the baseline forecast significantly. Increases in the recycling rate do not directly reduce the releases and may even have a contrary effect (see section C.13.3 of Appendix C) in case that no site-specific release minimisation at recycling/landfilling stage is carried out or no containment is possible. It would therefore be necessary to investigate the mass balance of various baseline scenarios.

3.2.3.3. Risks to workers and consumers

With regard to the human exposure data and subsequent risk characterisation, the results described in Appendices B.6.4.4, B.6.5.4, B.6.6.4, B.6.7.4, B.6.8.4, B.6.9.4 and B.6.10.4 are collected in Table 4 and Table 5.

Results obtained with the default realistic worst case exposure assessment methodology suggest that there are risks from DOTE and DEHP for workers exposed at recycling facilities. For DMTE and Diantimony trioxide, risk to workers is likely in recycling facilities with lower levels of operational conditions and risk management measures in place. For MMTE and Zn borates, no potential risks were identified. Further refinement of exposure estimation (e.g. considering actual OCs and RMMs implemented in recycling facilities) and

---

[10] The release estimates of additives are highly dependent on the additive volumes. Hence, in this simplistic baseline scenario one consequence would be that the releases of prioritised additives would increase. Only if the environmental releases would be not higher than the annual virgin PVC and additives volumes added to the economy (plus the volume removed by incineration), and the total PVC use volume is not increasing, there is no increase of releases.

DNEL derivation (in most cases the DNELs derived by the registrants were used) may be needed.

Considering the structural similarity of the prioritised organotin substances and their toxicological profile (section 3.2.1.1), an additive effect in case of co-exposure may be possible. Co-exposure occurs in those worker exposure settings most relevant at recycling facilities. Thus, the potential risks identified for some of the additives (DOTE, DMTE) could be extended to organotin substances in general. A similar logic may be applicable to DEHP and ortho-phthalates, in particular medium-chain (C7-C8) ortho-phthalates (section 3.2.1.2). Especially for workers at recycling facilities, potential risks related to further co-exposure may be relevant and warrant further attention. Further, since organotin substances are widely used in almost all rigid PVC applications in other geographic locations (specifically in North America), they are to be found in imported articles and consequently in the PVC waste stream.

For consumers during article service life, risks from organotin substances in automotive interiors were initially identified with the realistic worst-case approach. However, the result may be an overestimation. Organotin substances in the automotive sector were identified in monofilament profiles (CfE2,#1601). In the absence of further information, it was assumed that those were used only in automotive interiors. 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, a risk was identified for consumer uses of packaging based on the realistic worst-case approach, but further information needs to be sought and considered carefully since the combined RCR is only slightly higher than 1. The exposure results might be 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 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 the plasticiser 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.

It is noted that this investigation project was not able to screen potential threshold risks related to exposure to other substances than those mentioned above, because no DNELs were available for other prioritised additives (several reasons apply). Hence the identified risks to workers and consumers give only an indication of the whole spectrum of potential risks. This is a data/analysis gap.

No quantification of risks from co-exposures was attempted in this project, but the 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 (both soft-PVC uses) cannot be excluded.

Table 4. Identified potential risks for workers during PVC compounding and conversion and at recycling facilities (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[1]	No risk	No risk	Covered by Authorisation[1]	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

[1] DOTE and DEHP are listed in Annex XIV

Table 5. 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

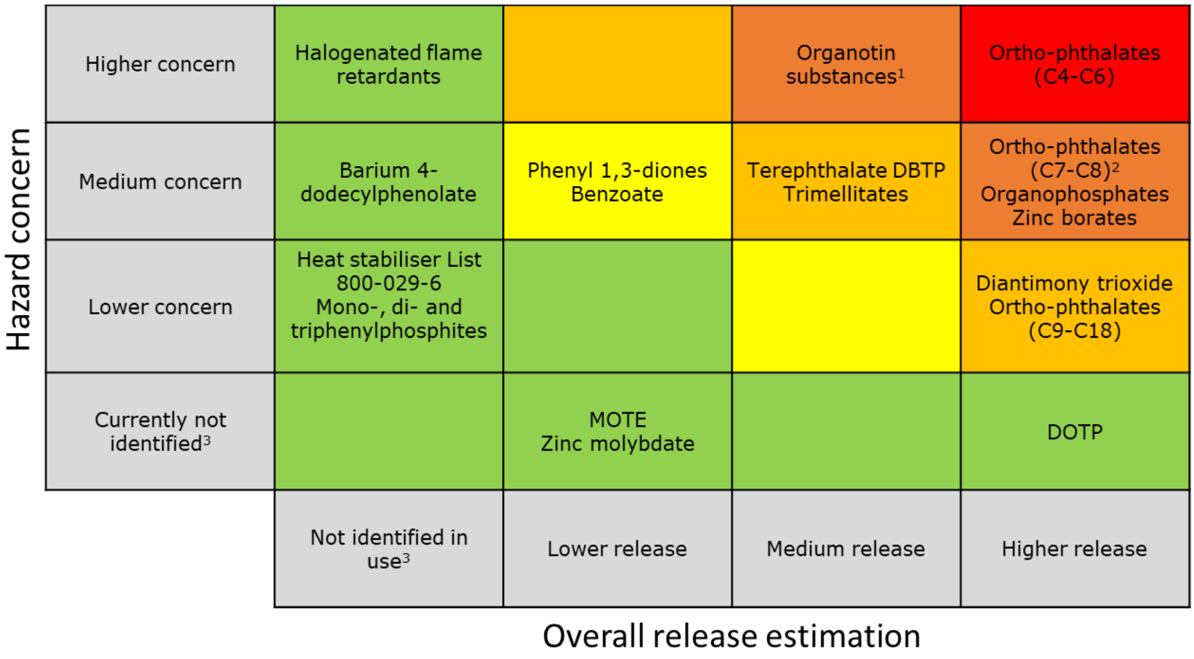
* Risk was identified in the default assessment based on the information submitted in CfE2, but based on the further information received, the concern may be removed (see text).

This investigation project did not analyse a 20-year baseline horizon, which is a standard assumption in restriction proposals, but a plausible baseline can be discussed qualitatively. Considering the current trends in the use of PVC (see Appendix A and C) and the societal aim to increase recycling (section 3.4), an increase in PVC waste and recycled PVC is expected. This will likely result in an increase in exposure to the prioritised additives of workers in recycling facilities. Further, the relative proportions between rigid and soft PVC in the waste and recycling (e.g. if recycling of soft PVC increases compared to that of rigid PVC) may also result in an increase in the concentration of certain additives entering the recycling plant. Finally, an increase in the PVC that is to be recycled may also result in an increase of workers exposed to the relevant additives.

The overall concentrations of additives in articles may or may not remain constant and therefore also the development of consumer exposures needs further exploration.

3.2.3.4. Risk matrix

Considering the overall risk approach (non-threshold concern) there is no quantitative method available to understand the differences between the substances with regard to the prediction of the timing and scale of effects in the baseline situation (when no action is taken). However, a simplified risk matrix approach is proposed based on the lead effects of the substances listed in the hazard assessment (section 3.2.1) and the overall release estimation (section 3.2.3.2 and Appendix B.6.13). The risk matrix may support the prioritisation of the substance groups from the point of view of potential further regulatory work.



Higher concern	Halogenated flame retardants		Organotin substances[1]	Ortho-phthalates (C4-C6)
Medium concern	Barium 4-dodecylphenolate	Phenyl 1,3-diones Benzoate	Terephthalate DBTP Trimellitates	Ortho-phthalates (C7-C8)[2] Organophosphates Zinc borates
Lower concern	Heat stabiliser List 800-029-6 Mono-, di- and triphenylphosphites			Diantimony trioxide Ortho-phthalates (C9-C18)
Currently not identified[3]		MOTE Zinc molybdate		DOTP
	Not identified in use[3]	Lower release	Medium release	Higher release

Overall release estimation

[1] All organotin substances have been put together except for MOTE.

[2] Medium-chain (C7-C8) ortho-phthalates may contain medium-chain (C4-C6) ortho-phthalates and/or display additive effects after combined exposure with them. Therefore, they could be considered together.

[3] No release estimation was done for substances for substances for which no hazard was identified for now or for which no use in PVC was identified. MOTE, Zinc molybdate and DOTP were in the release banding based on the volumes used for the substances.

Figure 6. Risk matrix considering potential hazard and overall release estimation

Medium-chain ortho-phthalates (both C4-C6 and C7-C8) are assigned the highest priority followed by organotin substances, organophosphates and zinc borates. It should be noted that the halogenated flame retardants (section 3.2.1.3) are not prioritised considering the lack of specific information for PVC and because they are addressed under the flame retardants strategy.

3.3. Legacy additives in PVC and alternative materials

ECHA identified for this investigation project also the additives which are already heavily regulated and/or not used anymore in PVC. A literature search and analysis of the results was carried out for ~50 substances (Appendix F) to roughly screen the current status of use and exposures and the impact of the existing regulatory measures to volumes, concentrations in products and to human exposure. The results can be found in Appendix F. It is noted that lead compounds were excluded from the project due to the restriction decision recently adopted under REACH.

The analysis of the legacy additives in alternative plastics may be limited as only legacy additives used in PVC were looked at, whereas alternative plastics may be relevant for some additional legacy additives which are not relevant for PVC.

The main findings can be summarised as follows:

1. The import and volume statistics, as well as product and exposure concentration information, indicate that the regulatory measures seem to have had an impact. From all included legacy additives, it was only possible to identify from the data an apparent correlation between the risk management of the substances and levels in humans for the regulated phthalates and cadmium. For other legacy substances other exposure sources than PVC may be more or equally relevant and no strong link between their regulated use in PVC and the observed reductions in imports, volumes and concentrations could be made.

2. At the EU level, current legacy additives do not normally cause a challenge for recyclability. However, there are some exceptions and a concentration limit may have a severe impact on the recyclability, or technical consequences. The recyclers may choose to ensure compliance with a concentration limit by mixing waste sources (e.g. cadmium, see Appendix F) in order to ensure recyclability. In this case the volume of a legacy additive present in the economy by the time of the restriction and further recycled after the restriction is only gradually reduced over time after several recycling loops via releases and incineration.

3. For alternative plastics, the situation with current legacy additives is similar to PVC with the exception of HBCD which was never used in PVC but in other plastics. However, concentrations of legacy additives in products at end of service life may be expected to be higher for especially soft PVC compared to its alternative plastics.

4. For the next steps on PVC and its additives, it is important to differentiate the specific conditions depending on whether the driver is a risk to human health due to direct exposure or risk to the environment (or man via environment). Due to the fact that the major contributors to the overall additive releases from PVC lifecycle are recycling, professional handling (in construction sector) and landfilling, the key action for reducing environmental releases (beside site specific release reduction management) is to reduce the overall volume of the substance at these life-cycle stages, and in particular in recycling and landfilling. Whether such a volume reduction or full containment is reached by specific concentration limits or by other means (e.g. contained closed-loop recycling, cf. lead in PVC) needs to be further explored. Substitution of a substance in new products would only have a partial influence on the environmental releases over time due to the long lifetime of PVC products. A significant fraction of the additive volume becomes a legacy volume as a consequence of substitution as it still remains in the circular economy or ends up in landfills. A mass balance of PVC over (20 years of) time was not estimated in this project (a data gap) for the current PVC legacy additives but would be vital to carry out in the planning of a potential REACH restriction or other type of substitution to understand the level of effectiveness of a substitution in particular from the viewpoint of the (new) legacy additives volumes after substitution. A concentration limit of a substance in the product/waste/recyclate as a specific instrument of a restriction has a direct role in reducing the risks of workers and consumers, but whether it is effective for reducing (or minimising) risks to the

environment needs to be clarified. This question is particularly important to address for soft PVC, which contains several additives in total concentrations which are generally higher than in alternative plastics.

3.4. Recycling of PVC

Several major applications of PVC are in 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 (CfE2, #1601) (VinylPlus, 2017). However, the amount of PVC waste is expected to increase over the years.

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, the main source of PVC waste (around 83 % or 2.4 million tonnes per year), consists of products that have been discarded at the end of their life. In the post-consumer waste materials are likely not homogeneous and the additives concentrations and profiles are less known.

The majority of the post-consumer waste comes from the building and construction industry (44 %), packaging (20 %), electric and electronic equipment (8 %), automotive industry (4 %) and the rest from several other sectors. 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 the production, and waste production is closely coupled with consumption. For other products with longer lifetimes the situation is different.

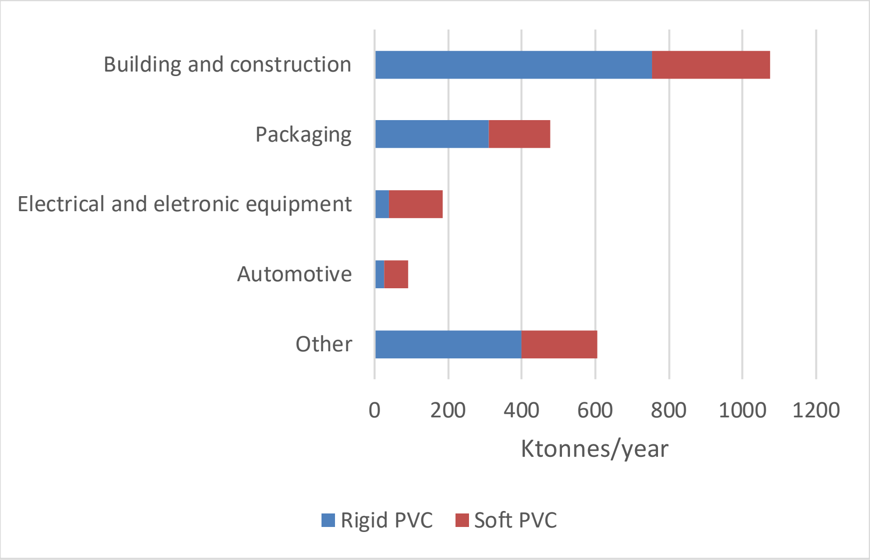


Figure 7. PVC post-consumer waste per sector

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

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). Figure 8 shows that the total volume of recycled PVC from pre-consumer waste is always higher than the total volume of recycled PVC from post-consumer waste, with the notable exception of cables for which the volume of recycled PVC from post-consumer waste far exceeds the volume of recycled PVC 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. It should be further noted that under its VinylPlus 2030 commitment, the organisation aims to recycle 900 000 tonnes/year by 2025 and 1 000 000 tonnes/year by 2030.

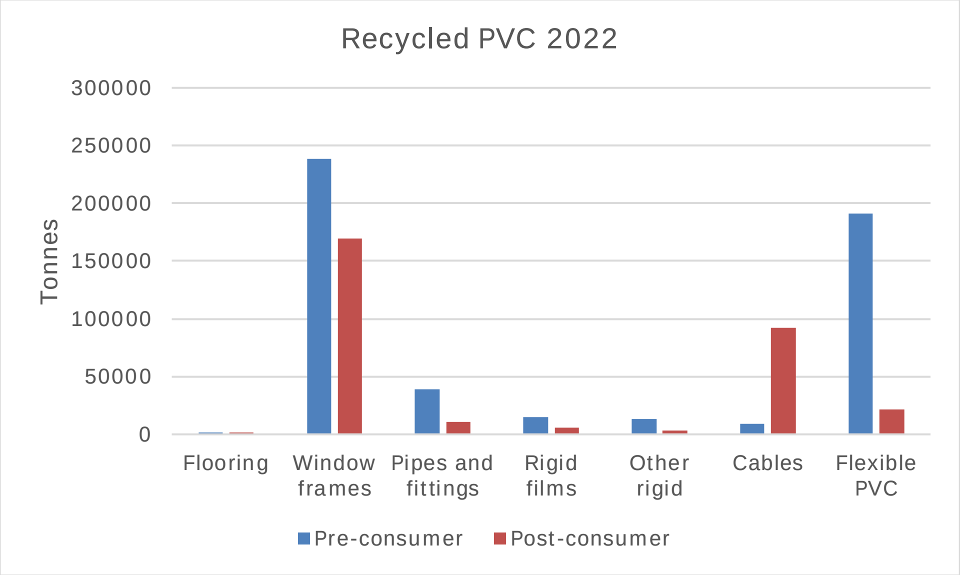
The economic incentives and technical needs for collecting, sorting and processing make recycling more difficult in some waste streams than in others. An example of non-recovery post-consumer waste are PVC water pipes that remain in the ground after replacement. An example to the contrary are cables, for which the economic incentive to recover the metal seems to drive the recycling of PVC. However, the rate of recycling does also depend on technical needs like collecting, sorting and processing. For PVC used in cables, the rate of recycling is not the same across different sectors. Thus, according to the data provided by VinylPlus, while the rate of recycling in building and construction (~50 %) and for electric and electronic equipment (~60 %)[11] is substantial, this is not the case for the automotive sector (~11 %).

If economic profitability (usually associated to scaling and the availability of enough adequately sourced PVC waste) cannot be achieved, the recycling of PVC will not take place unless there are legal obligations or voluntary measures to enforce or promote it. In this regard, the on-going work by the PVC industry to improve recycling of PVC should be noted.

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).

---

[11] This rate seems to contradict the information received from plastic recyclers which suggests that PVC in electrical and electronic equipment mostly ends up in the heavy fraction of the shredder light fraction which is subsequently incinerated.



Source: VinylPlus Progress Report (VinylPlus, 2023)

Figure 8. Contribution of specific product types to recycling volumes of PVC in 2022

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

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

For PVC, as well as for other plastics, there is a potential for release of microparticles that might be formed during handling, conveying and/or processing of PVC articles. One of the most common means of generation is via abrasion, but also when articles are cut or shredded, which are common activities in the recycling processes (see the next section on the microparticle releases).

In addition, and for soft PVC in particular, higher additive concentrations are expected in compounded PVC compared to other plastics (albeit exceptions may apply) and therefore, additive releases carried by the PVC microparticle releases can also be expected to be proportionally higher than for those of other plastics. This is especially relevant for workers in recycling facilities where combined exposure to multiple PVC additives is likely.

More information about waste management of PVC/PVC articles can be found in Appendix A.1.3.

3.5. About the role of microparticle releases

PVC microparticle releases have a role as the main carrier of PVC additives releases. Most of the PVC additive releases to the environment occur in particle form (see Appendix B). The activities with the highest dust/microparticle formation potential contribute the most to the estimated additive releases. The largest contributors to the environmental releases of (prioritised) additives (section see 3.2.3.2 and Appendix B) can, in absence of more detailed information and approaches, and relying on the default exposure assessment approaches of OECD and ECHA, be assumed to reflect well the most significant contributors to the PVC microparticle environmental releases as well.

PVC uses can be expected to cause environmental releases of PVC microparticles in all life-cycle steps (see Appendix A). Although no attempt was made in this project to estimate such releases, an estimate was derived for the releases to the aquatic environment from recycling plants based on a recent study (see Appendix A for details). Although the estimate (7 750 tonnes per year) covers member facilities of VinylPlus only, it is an indication of significant PVC microparticle releases. Furthermore, the scarce measured environmental data provides evidence of PVC microparticle exposures in the environment. Due to the lack of specific effects studies for PVC based on ECHA (2020) data (no data search carried out in this project), specific observed effects of microparticle exposures cannot be directly attributed to PVC but generically to any plastic microparticles. Despite of the data gaps, it can be inferred that PVC uses cause same risks as caused by the releases of intentionally added synthetic plastic microparticles, for which a restriction has been recently adopted (EC, 2023b).

As discussed in section 3.2, the additives are considered as very persistent when released in particle form. Minimization of the PVC microparticle releases to the environment, in particular from the soft PVC, is needed due to the non-threshold nature of the risk from (prioritised) PVC additives. 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.

To summarise, reduction (minimisation) of PVC microparticle releases to the environment is needed as:

1. PVC microparticle releases function as the main carrier for (the prioritised) PVC additive releases,

2. the additive releases carried by the PVC microparticle releases can be expected to be proportionally higher from PVC than from other plastics due to the higher additive concentrations usually needed (exceptions may apply),

3. PVC microparticles contribute to a proportionally higher additives co-exposure than other plastics (and other alternative materials),

4. PVC microparticles render the additives very persistent, and

5. PVC microparticles cause a risk themselves in analogy to the restricted intentionally added plastic microparticles.

Particularly point 2 and 3 are specific to PVC, whereas the other points can be expected to apply similarly to other plastics. The link between the estimated additives releases and PVC microparticle releases needs to be understood more in detail in order to identify the most effective emission reduction measures, considering that the recycling rates are increasing as a result of EU policy on plastics (data and assessment gap).

4. Impacts of risk mitigation

PVC is used in various sectors and uses, each having their specific functionality requirements, alternatives, substitution possibilities and impacts. The impact assessment covers both alternative materials to PVC and alternatives to prioritised substances used as additives in PVC, which include some plasticisers, heat stabilisers and flame retardants (see Appendix B).[12]

The impacts were assessed by use, covering pipes, cables, flooring, window frames, packaging, medical packaging (blister packs), toys, medical applications and artificial leather.[13]

The main focus of the impact assessment is on the costs of substituting PVC with alternative materials or substituting certain additives in PVC with other substances. In addition, the impacts of no-recycling of PVC were assessed. The costs of other potential risk management options, such as product modifications or emission abatement at the end-of-pipe, were not assessed.

In the absence of a quantitative risk assessment, human health and environmental benefits were not monetised. Benefits from the substitution of PVC and prioritised additives, as well as from technological emission reduction measures, are described qualitatively. Foreseen follow-up work related to the impact assessment is described in Appendix C. This includes a proposal for an approach for calculating the release reduction potential of different risk management measures, taking into account the damage potential of the additives based on their level of concern.

The geographic scope of the impact assessment is the European Union as of 2020 (EU27). The assessment could also apply to the EEA states. However, because of a lack of data for Iceland, Liechtenstein and Norway, impacts in these countries were not assessed.

All cost estimates are expressed in 2022 prices, with inflation adjustment based on the Eurostat consumer price index (Eurostat, 2023). Annual costs are presented whenever possible. The discount rate used in the calculation of net present value of lifetime costs is 3 % (EC, 2023a).

4.1. Substitution of additives

This section describes the impacts from replacing prioritised additives used in PVC with alternatives. The assessment was made separately for the three groups of additives and their uses.

For all of the prioritised additives, there is a non-threshold potential hazard (very high persistency, ED and/or PBT/vPvB) for which release/exposure should be minimised. In order to facilitate the impact assessment, additives were categorised based on the assessed level of concern to four categories: high, medium, low and currently no identified

---

[12] Additives were prioritised for further analysis in the report based on their hazard scoring and release potential. Several substances currently used were excluded, because they were undergoing the final stages of regulatory decision process towards regulatory risk management.

[13] Roofing, wallpapers and other (miscellaneous consumer items) have not been covered in the analysis due to lack of data.

concern (Table 6). This concern banding was done based on hazard properties and (un)certainty of a (potential) hazard. This allows calculating the costs of moving from additives of higher concern to those of lower concern, or to additives with no identified concern.

Table 6. Concern banding for the prioritised additives used in PVC

Function	High concern	Medium concern	Low concern	Currently no identified regulatory concern
Heat stabilisers	Organotins (DOTE, DOTDL, DMTE)	Organotins (DOTTG, DOT-MalEt, MMTE) Phenyl 1,3-diones		MOTE[*]
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

[*] MOTE with a concentration of DOTE below 0.3%

Substitution costs were estimated for reducing the quantity of the prioritised additives, based on the price difference between a prioritised additive and an alternative additive of lower concern. The costs are a proxy of the consumer surplus losses to be expected from the substitution. When available, additional one-off costs related to either R&D or machinery were estimated.

Supply chain impacts include producer surplus losses for the EU producers of additives. They were estimated when the currently used additive is (mainly) produced in the EU, while the alternative additive is (mainly) imported. The assessment follows the SEAC approach for cases where alternatives are generally available in the EU (SEAC, 2021) and assumes a 10 % profit margin, 20-year assessment period, and a discount rate of 3 %.

Considering that the hazards in PVC additives are mainly non-threshold and most of them lack a dedicated dose-response function that would link exposure to expected health outcomes, a PBT approach should be applied (SEAC 2023). The impact assessment for PBT (and other persistent) substances consists of calculating the cost per kg or tonne of releases avoided (so-called cost-effectiveness). The cost-effectiveness of release reductions of prioritised additives was not quantified in the impact assessment of this investigation report (see Appendix C for reasons why that was not feasible).

The main gap of the impact assessment relates to the supply chain impacts on manufacturers of the chemicals and raw materials (additive producers, suppliers of chemicals etc.), and the possible employment impacts.

4.1.1. Benefits of additives substitution in reducing risks

The environmental benefits, and hence risk reduction, from substituting prioritised additives can currently be quantified only in terms of release reduction. The difference of the (eco)toxicity profiles between a prioritised additive and its alternative can be considered qualitatively. This results from the risk assessment approach taken for the environmental risks ('PBT-like' concern, see Appendix B).

Substitution of prioritised PVC additives may be expected to gradually reduce their volume in the circular economy and may hence be expected to also reduce their releases. This project did not quantify how much the substitution of the prioritised additives would reduce additive releases. The magnitude of the release reduction is uncertain. It is mainly dependent on the relationships between the remaining volume of the substituted additive in the circular economy, the applications in which recycled PVC is used, as well as the volume of PVC annually landfilled, recycled and incinerated. Releases may also change in case the substitution changes the volumes going to recycling, landfilling and incineration.

As a result of substituting prioritised additives, negative impacts on human health (via indirect exposure) and the environment might be prevented or they would appear further in the future. The benefit can be described qualitatively in a similar manner as in the recent restrictions of PBT/vPvB and PBT-like substances, but may be less pronounced, due to e.g. the expected increase in the recycling of PVC. In case substitution would be complemented with other technical release prevention/reduction measures, reduction of recycling (of those products containing prioritised additives), and increase of incineration (of those products containing prioritised additives), the benefits would likely be more pronounced. However, mass balance modelling would be necessary to better estimate the outcomes.

The benefits of substituting specific additives for which there are risks to human health from the direct exposure of workers and/or consumers can be explicitly identified. The substitution would gradually lead to a control of risks related to the known toxicity endpoint(s) (e.g. neurotoxicity, reproductive toxicity). However, risks due to the prevailing co-exposures were not quantified (see qualitative discussion in Appendix B). Thus, the benefits of substituting individual additives may be underestimated by the conventional risk assessment approach applied in this project. Benefits could be higher if also additional prioritised additives for which no risk was identified individually (or no assessment was made) were substituted. Such additional benefits can, however, only be understood by carrying out a risk assessment addressing the most relevant co-exposures.

4.1.2. Plasticisers

Plasticisers are needed in soft PVC uses, e.g. pipes (flexible tubes), cables, flooring, soft packaging, toys and artificial leather. Of the prioritised additives, medium chain ortho-phthalates (DEHP, DINP, DPHP, D810P), long chain ortho-phthalates (DIDP, DUP, D911P, D114P, DDP and DDDP, D1012P), terephthalates (DOTP, DBTP), trimellitates (TOTM, T810TM, T911TM, TINTM, TIDTM) and triphenylphosphate derivatives (tBuTPP) are used.

The main alternative plasticiser is DOTP, which is included in the list of prioritised additives but has currently no identified concern. Also DINCH, which is not in the list of prioritised additives, could be a potential alternative, but its availability is lower than DOTP. Thus, the analysis mainly focuses on replacing prioritised additives with identified concern with DOTP.

DOTP could replace DINP (medium concern) and DIDP (low concern) in standard cables, flooring, packaging and artificial leather. DOTP has already been gradually replacing DINP in the EU, e.g. in flooring (ERFMI, e-mail, 1.6.2023, Bywall & Cederlund 2020).

Based on information from the industry, DINP is replaceable with DOTP with no considerable impacts on performance (CfE3, #1708, VinylPlus). The main cost would be in terms of the possible price difference between the two plasticisers (CfE3, #1708, VinylPlus). The availability of DOTP in the world market has pushed down the prices to be comparable to DINP (Chemorbis, 2022a), and DOTP has been on average €50/tonne more expensive than DINP and DIDP (Chemorbis, 2022b).

In all medical applications, DEHP can be replaced by the other non-regulated alternatives (DOTP, DINCH, TOTM and BTHC) (CfE3, #1708, VinylPlus). DOTP has already replaced DEHP in most medical applications, but DEHP remains to be used in specific applications, including blood bags (CfE3, #1708, VinylPlus). DOTP is on average €580/tonne more expensive than DEHP (ECHA, 2006, Intratec, 2023, Maag et al., 2010).

Other medium chain ortho-phthalates (medium concern) and trimellitates (medium concern) could potentially be replaced with long chain ortho-phthalates (low concern). For example, DPHP could be replaced with DIDP or DUP in cables that require a high temperature resistance. The prices of DPHP and DIDP are assumed to be equal, and thus the costs from this replacement would mainly entail reformulation costs. The other long chain ortho-phthalates, such as DUP, are assumed to be twice as expensive as DIDP, based on anecdotal evidence. Trimellitates are assumed to have the same price as long chain ortho-phthalates.

The main supply chain impacts would take place as a result of replacing plasticisers produced mainly in the EU with substances that are largely imported. Many medium and low concern plasticisers are mostly produced in the EU, except for DUP (100 % imported) and DBTP (90 % imported). DINP and DIDP are almost entirely produced in the EU (0.2–2.4 % imported), and also DEHP is largely manufactured in the EU (9 % imported).

DOTP is primarily imported (67 %), mainly from South Korea, US, China and Turkey (Chemorbis 2023; CfE3, #1708, VinylPlus). Thus, moving from the other plasticisers to DOTP would mean profit losses for EU plasticiser producers, at least in the short term. If DOTP manufacturing capacity would increase in the EU, the profit losses would be reduced or eliminated.

The profit impacts can be estimated based on the purchase prices and sales volumes of the plasticisers to be replaced (DINP, DIDP and DEHP) and the profit margins. If DOTP capacity building would take place in the EU, the profit losses incurred by producers of other additives would eventually be compensated by increases in the profit of DOTP producers.

In addition to costs related to additive prices and profit losses to EU plasticiser producers, there may be (one-off) reformulation costs for article manufacturers. Estimates vary between €0.25–5 million per company, depending on the sector and use. Table 7 summarises the costs of moving to plasticisers of lower concern.

Table 7. Costs to EU companies of moving to plasticisers of lower concern

Use	**Additive(s) to be replaced**	**Alternative additive(s)**	**Additional additive costs per year (million €)**	**Supply chain impacts: producer profit losses (million €)**	**Other costs**
Cables	DINP (standard cables)	DOTP	2	1	Reformulation costs to cable providers: €0.3 million per company, ~€120 million
	Medium chain ortho-phthalates and trimellitates (high temperature rating cables)	Long chain ortho-phthalates	14	None	
Flooring	DINP	DOTP	1.4	0.5	Reformulation already largely taken place
Soft packaging	DINP DIDP	DOTP	0.13	0.05	NA
	DEHP	DOTP	1.0–5.9	0.08	

Medical applications	TOTM		DOTP?	NA	NA	R&D activities, logistics, the additive itself, and manufacturing costs, ~€0.25 million per company
Toys	No plasticisers with identified concern used in EU production)			None	None	NA
Artificial leather	DINP	DIDP	DOTP	0.5–2.8	0.7	NA
	DPHP		DIDP	None	NA	NA
	D810P		Long chain ortho-phthalates	0.8–5.0	NA	NA
	Trimellitates		Long chain ortho-phthalates	None	NA	NA
	Medium chain ortho-phthalates	Long chain ortho-phthalates	DINCH	None	NA	R&D costs up to €5 million per company
			Mesamoll	9-56	NA	NA
Total (million €)				**29–87**	**2.3**	**NA**

Notes: NA = not available. Colours correspond to concern categories, defined based on the (potential) hazard and its certainty: red = high concern, orange = medium concern, yellow = low concern, green = currently no identified regulatory concern.

4.1.3. Heat stabilisers

Over 90 % of the heat stabilisers used in the EU are mixed metal stabilisers, mostly Zn/Ca carboxylates, which have currently no identified concern. Of the prioritised heat stabilisers, organotins (mainly DOTE, DMTE, MOTE and MMTE) and phenyl 1,3-diones are used. About 6 % of the total stabiliser consumption in the EU are organotins.

Organotins are used specifically for their performance-enhancing properties (CfE3, #1708, VinylPlus). Organotins contribute to the long-term heat stability and durability of the product and provide colour retention and transparency (CfE3, #1708, VinylPlus). They are suitable for high-demanding process conditions and provide a good processability with high throughput (CfE3, #1708, VinylPlus). Organotins are used in specific applications including pipes, window frames, rigid packaging and medical packaging (blister packs), but also (potentially to a small extent) in flooring.

Although mixed metal stabilisers (mainly Zn/Ca) are already largely used, they have a lower performance in terms of long-term heat stability and durability than organotins (CfE3, #1708, VinylPlus). Thus, substituting organotins with mixed metal stabilisers has impacts on the performance. Industry has indicated that without organotins, some products could no longer be produced, including window frames as well as pressure fittings and valves in pipes, at least not without a suitable transitional period (CfE3, #1708, VinylPlus; CfE3, #1652, TEPPFA).

The use of MOTE and MMTE would be of lower concern than DOTE and DMTE, but there is contradictory information on their interchangeability. According to industry information, DOTE has already been substituted by MOTE to the extent possible, and it is not possible to fully replace DOTE with MOTE and DMTE with MMTE, as different organotins bring specific technical performance properties and hence cannot simply replace each other (CfE3, #1708, VinylPlus). However, this may not be the case for packaging. In pharmaceutical packaging, DOTE has already been replaced with MOTE, and there are indications that DOTE and MOTE are easily exchangeable in all packaging (pharmaceutical packaging representative, personal communication, 29/09/2023). Similarly, there has been a major move away from DOTE to MOTE in food packaging since 2018 (VinylPlus, email communication, 09/10/2023). Thus, it appears that specifically in packaging, MOTE can replace DOTE without any major consequences on performance or costs. For the other uses where organotins are needed, i.e. pressure pipes, fittings and valves as well as window frames, it is unclear to what extent MOTE could replace DOTE. A more complete analysis of replacing DOTE will be possible when information is available from REACH applications for authorisation on the technical performance and costs of alternatives for DOTE, which should start in Q3 of 2023 given the latest application date for that substance.

As no alternative additives to organotins with similar performance are currently available, eliminating their use would require replacing them with lower-performing additives, such as mixed metal stabilisers, developing novel additives that perform similarly, or replacing PVC with alternative materials (see section 4.2 for cost estimates)

The costs of replacing organotins with mixed metal stabilisers were estimated, recognising that the latter do not provide the same performance. The price of organotin additives is on average €9 000–12 000/tonne, while Zn/Ca stabilisers cost €5 000–7 000/tonne (ESPA, email communication, 18/05/2023). However, a 1–3 times larger quantity of the Zn/Ca stabiliser is needed (ESPA, email communication, 18/05/2023). Assuming the average price and taking into account the larger quantity of Zn/Ca stabiliser needed, using a mixed metal stabiliser would be approximately €1 500/tonne more expensive than using organotins.

In addition to increased costs, lower heat stability with mixed metal stabilisers may also reduce the processing time window for converters, increasing downtime and generating more scrap, as well as increasing the energy consumption in manufacturing, leading to increased risk of damage to machinery and eventually reducing the recyclability of PVC (CfE3, #1625, Swish Building Products; #1675, BENVIC SAS).

Stabilisers are relatively small volume products (e.g. compared with plasticisers) and often made in batch reactors (CfE3, #1708, VinylPlus). Thus, the total replacement costs are not as high as for plasticisers (CfE3, #1708, VinylPlus). However, the development of new stabilisers is expected to incur significant costs, including R&D costs associated with the adjustment for formulations and testing of key properties for compounders, evaluation of formulations and alignment with application requirements for converters, conformity with norms or quality labels either for the compounders or converters, as well as investments to build new plants and machinery (CfE3, #1657, BENVIC SAS, #1708, VinylPlus). Precise cost estimates of developing novel heat stabilisers to replace organotins are not available, but earlier substitution costs could give potential indication of their magnitude. For example, costs of replacing lead-based stabilisers over a period of 15 years were of the order of €100–250 million (CfE3, #1708, VinylPlus). Additionally, reformulation, R&D and requalification cost at converters may be significant, reaching up to €5 million for a single company (CfE3, #1708, VinylPlus).

The main impacts on the supply chain of chemical would occur from replacing additives of concern with ones of lower concern. Of the organotins, DOTE and MOTE are mainly manufactured in the EU (DOTE 80 %, MOTE 65 %), as is ‘reaction mass of 1-

phenyloctadecane-1,3-dione and phenylicosane-1,3-dione' (72 %). Almost all DMTE and DOT-MalEt is imported (6–7 % manufactured in the EU) and MMTE is fully imported.

Import of Zn/Ca stabilisers to the EU is negligible, except from Turkey (ESPA, email communication, 18/05/2023). Considering that Zn/Ca stabilisers are largely produced in the EU, no significant negative supply chain impacts in the EU are expected from replacing organotins with Zn/Ca stabilisers. Table 8 summarises the costs of moving to heat stabilisers of lower concern.

Table 8. Costs to EU companies of moving to heat stabilisers with lower concern

Use	**Additive(s) to be replaced**			**Alternative additive(s)**	**Additional additive costs per year (million €)**	**Supply chain impacts: producer profit losses (million €)**	**Other costs**
Pipes	DOTE DMTE	MMTE DOTTG	MOTE	Zn/Ca stabilisers	0.2	None	Reformulation costs; over €10 million per product range (number of product ranges unknown)
Flooring	DOTE	Phenyl 1,3-diones	MOTE	Zn/Ca stabilisers	NA	NA	NA
Window frames	DOTE DMTE	MMTE DOT-MalEt DOTTG Phenyl 1,3-diones	MOTE	Zn/Ca stabilisers	0.9	None	Reformulation, R&D and requalification costs for converters up to €5 million per company
Rigid packaging	DOTE DMTE	MMTE	MOTE	Zn/Ca stabilisers (MOTE, no cost information available)	2.1	None	Reformulation, R&D and requalification costs for converters up to €5 million per company
Blister packs	DOTE DMTE	MMTE DOTTG	MOTE	Zn/Ca stabilisers (MOTE, no cost information available)	2.2	None	Reformulation, R&D and requalification costs for converters up to €5 million per company
Toys	Phenyl 1,3-diones			Zn/Ca stabilisers	NA	NA	NA
Total (million €)					**5.4**	**NA**	**NA**

Notes: NA = not available. Colours correspond to concern categories, defined based on the (potential) hazard and its certainty: red = high concern, orange = medium concern, yellow = low concern, green = currently no identified regulatory concern.

4.1.4. Flame retardants

Limited information is available regarding the prioritised flame retardants used in PVC and their potential alternatives. Of the prioritised flame retardants, diantimony trioxide (ATO) and borates are used in cables and artificial leather in automotive interiors, and in low quantities in flooring. In addition, phosphates are used in cables.

Diantimony trioxide (ATO), an inorganic synergist to enhance the flame retardancy of halogens such as chlorine, is one of the most commonly used flame retardants in PVC (e.g. CfE3, #1653; #1683; #1704; #1708).

Zinc stannate, magnesium dihydrate and aluminium trihydrate have been mentioned as potential alternative flame retardants (CfE3, #1708, VinylPlus; #1620, anonymous). New low toxicity flame retardants and smoke suppressants are under market development, but the exact chemistry is proprietary and undergoing patent filing (VinylPlus, email communication, 16/05/2023).

There are indications that the prioritised flame retardants currently used could not be easily replaced due to negative impacts on flame retardancy, increased additive costs and issues with zinc availability (CfE3, #1697, EURATEX). However, many of the flame retardants used in cables could potentially be replaced by ATO (a move from high or medium concern to low concern), and ATO could possibly be replaced by zinc stannate, magnesium dihydrate or aluminium trihydrate (a move from low to currently no identified concern) (CfE3, #1620; #1704; #1708; Vinylplus, email communication, 16/05/2023). At present, there is no information on the costs and other impacts of such substitution.

4.2. Substitution of the material

This section describes the impacts of substituting PVC with alternative materials. The costs of substituting PVC with alternative materials were monetised, at least partly, for all uses covered in the impact assessment.

For some uses (pipes, cables, flooring, window frames), article lifetime costs were assessed, including the purchase, installation, replacement, maintenance and dismantling costs. These uses have a long lifetime, often decades. The lifetime costs are expressed as net present value over the lifetime of the material that has the longest lifetime in each use. This allows considering the difference in lifetimes of the various materials quantitatively. The lifetime costs of a representative article were multiplied with the annual quantity of PVC articles placed on the market in the EU. The resulting figure represents the annual cost of substituting PVC with an alternative material in that specific use, or the annual change in the consumer surplus for the end-users of the affected articles.

For some uses (packaging, medical packaging (blister packs), medical applications, toys, artificial leather), assessment of lifetime costs was not possible due to lack of information. For these, the costs include the difference in the price of the materials for the total annual sales volume of PVC in the use, as well as some discussion on possible additional costs of substitution. The cost estimates for these uses can be considered as providing supporting information but are not deemed sufficient for a proper assessment of substitution costs.

Producer surplus losses were estimated for the producers of PVC articles using SEAC's approach to assessing changes in the producer surplus for cases where alternatives are generally available in the EU (SEAC 2021) and assuming a 10 % profit margin, 20-year assessment period and a discount rate of 3 % (SEAC, 2021).

Investment cost estimates are reported for some uses. However, the profit losses and the one-off costs related to new machinery cannot be aggregated due to double-counting issues as both approximate the same loss in producer surplus impact.

Supply chain impacts were not quantified due to lack of data. The main exclusions are the supply chain impacts for the manufacturers of the chemicals (PVC producers, compounders, additive producers etc.) and the raw materials, and the possible employment impacts on the entire supply chain, starting from the raw material supply all the way to the production of the PVC articles.

Circular economy aspects and wider environmental impacts of PVC and alternative materials were assessed based on life cycle analysis (LCA) data and literature. Where possible, these wider impacts were quantified, and for climate change impacts also monetised, to assess the costs to society. A more rigorous quantitative approach was applied for flooring to give an example of a proposed approach in the follow-up-work for uses such as pipes, cables and window frames that have good LCA data availability.

There is no quantitative comparison of human health and environmental risks between PVC and alternative materials. A qualitative comparison can be found in Appendix A.

4.2.1. Benefits of material substitution in reducing risks

As pointed out in section 3 and Appendices A and B, substitution of PVC with other plastics would be expected to have a two-fold effect. Firstly, particularly for substituting soft PVC, it can be expected that the releases of priority additives and hence environmental risks are reduced, as the alternative plastics generally contain less and partly other additives (it is noted however that the safety of additives not used in PVC was not mapped in this project). Secondly, a minor effect on the risks directly related to the plastic microparticle releases can be expected, but it is not known whether that has an overall positive (risk reduction) or negative impact (risk increase). The factors that determine whether the substitution would result in a reduction or increase of risk are mainly related to differences in the rate of recycling and landfilling of PVC and the alternative plastics. For a reliable estimation, the difference of the microparticle releases of a plastic alternative and PVC would need to be assessed.

4.2.2. Pipes

PVC is used in many piping applications, which can be narrowed down into three broad applications: potable/drinking water, sewage, and industry.

These categories account for more than 95 % of the total use of PVC in pipes. For potable/drinking water and sewage, there are many alternative materials that the water service provider or other end-users can choose to use. According to industry, there is evidence that alternatives are widely used, but it is possible that there can be niche uses where PVC would be hard to replace with an alternative.

The annual volume of PVC pipes in 2017 for potable/drinking water was 254 000 tonnes, for sewage 682 000 tonnes and for industry 88 000 tonnes. Sub-applications that are not covered by the three categories had an annual volume of around 80 000 in total. (CfE2, #1596, TEPPFA.)

The impact assessment was performed by converting the tonnages into a functional unit of a DN200[14] PVC pipe. The annual tonnage in the EU translates into 20 000 – 34 000 km of potable/drinking water pipes, 54 000 – 91 000 km sewage pipes, and 7 000 – 12 000 km industrial pipes. Potable/drinking water and sewage pipes are fully covered in the socioeconomic analysis. More details related to the industry pipes are discussed in the section dealing with prioritised additives, their substitutability and associated costs. Other, smaller uses are not covered by the analysis.

For all three pipe applications, many different materials or combination of materials (i.e. internal, or external coating) are used. The choice of the material of the pipes is not only based on performance requirements since all listed materials under each application are technically feasible. For a more detailed overview of the use of different materials, ECHA asked APE (Aqua Publica Europea) to conduct a market study of EU water companies (regional & municipal). A total of 10 companies sent responses to the market study. Based on the stakeholder responses, there are large differences between EU countries with regard to which materials are favoured (APE, market study, 2023).

PVC is not the most commonly used material for potable/drinking water. The main alternatives to PVC in this pipe category are PE and ductile iron. PVC is also used as a water service pipe within buildings, where the main alternative is PP. In the economic assessment, it was estimated that 70 % of PVC is replaced with PE, 20 % with ductile iron and 10 % with PE. PVC is the cheapest pipe material for potable/drinking water, with PE pipes being at least 20 % and ductile iron pipes 90 % more expensive.

While the difference in the purchase cost is high, the purchase cost itself is a minor cost component in comparison to the installation costs (5-10 % of the total cost), and thus the price of the pipe itself is not a deciding factor when choosing the material.

PVC is also the cheapest available material for sewage systems based on the market study. For small diameter sewage pipes, common alternatives to PVC are PP, PE and stoneware. In regions where different piping materials are used within the sewage infrastructure, PVC is mainly used for gravity non-pressurised systems. PE is 30-100 % more expensive (gravity pipes), and stoneware is 190-400 % more expensive compared to PVC. It is also likely that stoneware is more expensive to install. The main alternative for gravity pipes, PP, is around 0-20 % more expensive compared to PVC. (Pipelife, personal communication, 2023). For large diameter sewage pipes, PVC is used to a lesser extent. The main materials are concrete, stoneware and PP.

Based on the information, it is expected that the main alternative for PVC sewage pipes are PP (75 % replacement) and PE (25 % replacement).

All the materials listed as alternatives for pipes fulfil the key characteristics. However, there are differences in their performance, e.g. with regards to the ease of detecting leaks, flow capacity and lifetime. The largest use for PVC is in the category of small diameter pipes in gravity sewage pipes. PVC is easier to install than PE pipes since it does not need to be welded and has a smoother surface than PE pipes making it less likely for the pipe to get stuck (APE, 2023; HSY, personal communication, 2022 & 2023). PE can also be used as a gravity sewage pipe but will need a protective tube to keep its shape.

---

[14] DN stands for *Diametre nominel* which denotes the inside diameter (in millimeters) of a pipe. DN200 pipe has an inside diameter of 200mm.

PP pipes do not require welding and have a smooth surface and are therefore the main alternative for PVC sewage pipes as well as PVC pipes that are used in buildings.

Table 9. Impacts of replacing PVC with alternative materials in pipes

Pipes	
(Main) Alternatives	Potable/drinking water: PE, Ductile Iron, Carbon Steel, PP Sewage: PP, PE, (Concrete and Stoneware) Industry: PE (medium and high density), PE-X, polyamide/nylon, stainless steel, copper, ductile iron, aluminium, PP
Economic impacts	The total cost of replacing PVC pipes for potable/drinking water and sewage would be in the magnitude of €520 million per year in the EU. Industry is not included in the calculation. However, it represents only 3-4 % of the total PVC tonnage in the use. In addition, some of the alternatives might be slightly more expensive to install.
Supply chain impacts	Pipe manufacturers would have to invest at least €840 million for new machinery if they were to switch producing only alternative materials (ECHA Market survey 2023, TEPPFA).
Life cycle impacts	If PVC pipes are replaced with alternative material pipes, the CO_2 emissions would decrease. This is attributable to lower CO_2 emissions of PP compared to PVC. With the social cost of carbon approach, the value of the decrease would be around €120 million per year. However, in total, based on the current evidence, it cannot be concluded if PVC performs better or worse than other materials.

4.2.3. Cables

A cable is an assembly of one or more wires to transmit electrical power or data. The conductor of the cable is most often copper or aluminium. The next layer in a typical cable is the insulation, which protects the wire(s). Insulation is made out of non-conducting material, such as plastic or rubber. The most common material used for insulation is PVC. The top of the cable is called the jacket or the sheath of the cable. Again, the same material choices apply, the most common ones being PVC and polyolefins. For many cables, there is also a layer called armour between the insulation and the jacket, most often made of steel (Aupetit, 2021).

Cables are used in many sectors. The main sectors are buildings and construction, electrical and electronic equipment (EEE), and vehicles (in which the automotive sector is the main sub-sector). Approximately 466 000 tonnes of compounded PVC are used to produce cables annually in the EU. This figure includes the cables used in the building and construction sector, in EEE, and in vehicles (mainly cars). (CfE2, #1564, Europacable). However, Europacable (CfE2, #1564, Europacable) points out that this does not include imported cables, and the actual tonnage of PVC in cables placed on the EU market may be significantly higher. However, more cars are exported from the EU than imported to the EU (ACEA, 2022), partially balancing this mismatch.

In the cables placed on the EU market, PVC has the highest market share of around 35-40 %. PE (including low/medium/high density PE and PE-X) cables have a market share of around 33-38 %, low smoke zero halogen/halogen-free flame-retardant (LS0H/HFFR "halogen free cables" – main resins polyolefins mixed with EVA) have a market share of around 18 % and others, such as silicone rubber cables, represent the remaining market share (PVC4Cables websites, 2023).

Mainly due to a stricter fire safety requirement for buildings materials the overall market share of PVC cables has decreased significantly (from around 65 % in 2000 to around 35 % in 2023) (Aupetit, 2021; Sarti and Piana, 2022).

The economic impacts of substitution are calculated for the end-users of the cables, who pay the purchase of the cable, either in the price of the cable itself, or as a component in a more complex product. In the case of cables, evaluation of the costs for use and maintenance are not relevant as cables do not need ordinary maintenance and the costs of use (for example in the form of loss of electric power) are not significant if cables are correctly installed.

The functional unit used in the assessment is a standard 3 x 1.5 mm cable for the building and construction sector; a standard GTP cable for the vehicle sector; for EEE, we are only able to assess the costs based on the material costs. It is assumed that the main alternative would be halogen-free cables for the building and construction sector (10-15 % more expensive), PE-X for the vehicles (10-20 % more expensive) and TPE for EEE (152 % more expensive).

Table 10. Impacts of replacing PVC with alternative materials in cables

Cables	
(Main) Alternatives	Building and construction: Halogen-free cables, PE Vehicles: PE-X EEE: TPE
Economic impacts	If total volume of PVC would be replaced with the main alternatives, the cost would be at minimum €384 million per year. However, it is likely that there would be large R&D costs for both the cable manufacturers and the manufacturers of EEE and vehicles.
Supply chain impacts	One-off costs related to machinery could then amount to €4-8 billion. While an average lifespan of a 40 years is indicated for such machinery (CfE3, #1656, Fenerazione ANIE), on average, the current machinery has a remaining lifespan of 20 years. The annualised costs would then be around €270 – 540 million.
Life cycle impacts	Only one relevant study was identified. In the study, PE outperformed PVC in all but one of the assessed impact categories. On the other hand, PVC outperformed PET in all other impact categories with the exception of acidification. The ranking of materials for the total (standardised across impact categories) environmental impacts was quite clear, as PE was the favoured material, PVC the second, and PET performed the worst. As PE is one of the main alternatives to PVC, there would likely be fewer negative impacts for the environment following the substitution.

	However, with the current knowledge, there is not enough evidence to calculate the environmental impacts of switching from PVC to alternative cable materials.

4.2.4. Flooring

PVC is used as a material in flooring. There are different types of PVC flooring. Homogenous PVC flooring refers to floor covering with one or more layers of the same composition and colour, either as sheets or tiles. Heterogenous PVC flooring consists of an added wear layer (or a foam layer), and are available as sheets, tiles or planks. Tiles and planks can be sold as Luxury Vinyl Tiles. PVC flooring is in the market segment of resilient flooring (with linoleum, other polymers, rubber and cork), which consist of materials that can withstand heavy use, are easy to maintain, hygienic, and comfortable underfoot. However, products within the resilient market segment also compete with other products in the flooring market in general.

In 2021, an estimate of 773 000 tonnes of compounded PVC was imported and used for flooring (60 % imported, 40 % EU production) in the EU. The tonnage equates to roughly 200 million square meters of flooring (ERFMI, e-mail, 02.06.2023). PVC has a market share of 91 % of the resilient flooring market, but in the overall flooring market, the market share of PVC is lower than 10 %.

Given that many alternative materials exist PVC represents a small share of the overall flooring market, and an alternative can be found for every use. Therefore, ECHA does not see the technical feasibility of the alternatives as a significant problem for substitution. However, PVC tends to be less costly compared to alternative materials. The low cost is the result of low material cost, ease of installation and ease of maintenance, and better durability compared to some materials (i.e. carpet and laminate).

The economic impacts (reported in Table 11) of substitution were calculated for the end-user of the flooring. Material cost, installation cost, maintenance, and lifetime are included in the assessment. The cost of substitution is calculated both for the resilient flooring materials and the flooring materials in general.

Table 11. Impacts of replacing PVC with alternative materials in flooring

Flooring	
Alternatives	Other polymers, linoleum, rubber, ceramics, carpet, laminate, wood
Economic impacts	If the total volume of PVC would be replaced with the cheapest alternative polymer, the total cost would be in minimum €2.4 billion per year. If PVC is replaced with other resilient flooring materials according to their market shares in the market segment, the total cost would be in minimum €10 billion per year and calculated with the mean prices €15 billion per year. If PVC is replaced with other flooring materials according to their market shares in the EU flooring market, the total cost would be in minimum €13 billion per year and calculated with the mean prices €39 billion per year. The minimum figure is probably more likely, since alternatives such as wood and laminate are very costly in heave use due to the need for multiple replacements during the lifecycle of 60 years, and materials such as carpet, linoleum and ceramics are thus more likely alternatives for PVC.

Supply chain impacts	The annual profit losses would be around €22 million.
Life cycle impacts	In total, quantitative results show that there would be negative impacts for the environment, if PVC would be replaced with the currently used alternatives in their current market shares. If other alternatives would be instead of carpet, such as ceramics or linoleum, negative environmental impacts would be reduced or even reversed in most impact categories.

4.2.5. Window frames

PVC is a common material for window frames, alongside wood, aluminium and aluminium-clad wood. Approximately 0.3–1.9 million tonnes of compounded PVC are used for window frames annually in the EU, which is approximately half of the rigid PVC used in the building and construction sector (CfE2, #1601, VinylPlus; #1587, EuPC).

The impact assessment has been performed using the standard window (1.82 m^2) as the unit, and all cost information has been converted into costs per standard window unit.

In total 56.6–78.5 million windows are sold in the EU27 annually (Ceresana, 2020, Fenster and Fassade, 2017, Fenster and Fassade, 2023). The market shares of the frame materials in the EU27 in 2015 were PVC 50.1 %, aluminium 21.5 %, wood 22.0 %, and aluminium-clad wood 6.4 % (VFF 2017). The market share of fiberglass is below 1 % in Europe (ECHA market survey 2023, EPPA).[15]

General performance properties for window frames include durability, waterproofing, resistance to pressure and warping, resistance to fire, energy efficiency (good thermal performance), light weight, low maintenance and ease of cleaning.

All window frame materials have relatively similar technical performance, and there seem to be no critical differences in the technical performance of the different materials when they are properly treated and maintained. Wood requires surface treatment to achieve weather resistance and more frequent maintenance than the other materials and can also be somewhat less resistant to pressure and warping and heavier than the other materials (ECHA market survey 2023, EPPA, VinylPlus).

The economic impacts are estimated based on purchase, installation, maintenance and dismantling costs of window frames (Marangoni and Garbarino, 2011). The purchase cost of aluminium, wood and aluminium-clad wood frames is higher than PVC. Maintenance costs are higher for wood frames compared to the other materials, as they require more frequent treatment. Installation and dismantling costs are the same across the materials.

All alternative materials (wood, aluminium and aluminium-clad wood) are commercially available (EC 2022). PVC windows have the shortest lifetime (25-30 years) and aluminium the longest (45 years), with wood and aluminium-clad wood somewhere in between (e.g.

---

[15] Fiberglass has been excluded from the analysis due to its small market share in Europe and lack of lifetime cost information.

Asif et al. (2005), Carlisle and Friedlander (2016)). Table 12 presents the impacts of replacing PVC with alternative materials in window frames.

Table 12. Impacts of replacing PVC with alternative materials in window frames

Window frames	
Alternatives	Wood, aluminium and aluminium-clad wood
Economic impacts	The annual cost of replacing the total volume of PVC in window frames would be €1877–2026 million for aluminium-clad wood, €2979–4138 million for aluminium and €4084–5672 million for wood. With substitution taking place according to the current market shares of the alternative materials, the annual cost would be approximately €3322–4614 million.
Supply chain impacts	Due to the large market share of PVC window frames, substituting all PVC frames with alternative materials could be challenging in the short term. It is likely that the companies making PVC window frames cannot easily switch to aluminium or wood, as they require different skills. Import of PVC, wooden and aluminium window frames to the EU is limited (3–9 % of total consumption). Thus, no significant impacts on EU producers are expected.
Life cycle impacts	Production, use and end-of-life stages are important for determining the broader environmental impacts of window frames. The use phase is particularly relevant, as the lifetime of windows is quite long and has an influence on the energy demand of buildings via heat loss (Saadatian et al., 2021b, Souviron et al., 2019). Existing studies allow no conclusion on the preferable window frame material throughout all life cycle stages and impact categories. Some studies find PVC to have larger environmental impacts than other materials (Owsianiak et al., 2018, Souviron et al., 2019), while others consider the impacts of aluminium to be the highest and wood lowest, with PVC in the middle (Saadatian et al., 2021a, Saadatian et al., 2021b).

4.2.6. Packaging

PVC is used in both rigid and soft food and non-food packaging, including rigid food packs and trays, shrink foils and films, cling films, closures, labels, transparent gift films and blister packs[16]. More than 400 000 tonnes of compounded PVC are used in food and non-food packaging across the EU each year (ECVM 2023b), mainly for rigid applications.

Performance criteria for packaging include durability, transparency, barrier protection, temperature resistance and in some cases flexibility (ECHA market survey 2023). There are various alternative materials to PVC in packaging, including both plastics and other types of materials. There appear to be no critical differences between the lifetime or performance of PVC and the alternative materials in packaging. Table 13 presents the

---

[16] Use of PVC in blister packs in medical packaging is presented in Section 4.2.7.

available information on the impacts of replacing PVC with alternative materials in packaging (excluding blister packs).

Table 13. Impacts of replacing PVC with alternative materials in packaging

Packaging (excluding blister packs)	
Alternatives	PET, HDPE/LDPE/LLDPE, PP, BOPP, PS, PA, BOPA, PCTFE, EVOH (only in combination with PVC/other materials), PVDC (only in combination with PVC/ other materials), bioplastics, aluminium, paper, ceramics, glass
Economic impacts	Only costs of the materials have been estimated (no other costs). Material costs are lower per tonne for some and higher for some materials compared to PVC. The difference in material costs ranges from €-450 to €1 500 million per year, depending on the alternative.
Supply chain impacts	Annual profit losses to the PVC packaging producers would be around €3–8 million.
Life cycle impacts	Main life cycle impacts of packaging come from the production, feedstock (raw material supply) and transportation phases (Baitz et al., 2004). Overall, plastics appear rather preferable for non-reusable packaging in terms of impacts over the total life cycle, but there is no consensus which plastic is overall the most favourable (Baitz et al. 2004). It is not possible to compare the CO_2 emissions between packaging materials, due to lack of data.

4.2.7. Medical packaging: blister packs

Rigid PVC is the dominant materials for the base film of blister packs (Sphera 2022), which are largely used for pharmaceutical (medicine) and nutraceutical (such as dietary supplements and functional foods) purposes, but also for packaging other individual products. The volume of compounded PVC in blister packs is 47 000 – 284 000 tonnes/year.

Overall performance criteria for PVC in packaging include durability, transparency, barrier protection and in some cases flexibility (ECHA market survey 2023). Pharmaceutical blister packs are primary packaging, meaning that they come into direct contact with the product and affect shelf-life. For pharmaceutical blister packs, barrier protection (in particular water barrier) is the most critical factor, as it ensures drug stability and affects shelf-life (ECHA market survey 2023, Flexible Packaging Europe, anonymous).

Alternative materials to PVC in blister packs include other plastics and aluminium. It appears that the alternative materials perform as well as or better than PVC in most of the aspects, but there are differences in barrier protection and transparency. Table 14 presents the available information on the impacts of replacing PVC with alternative materials in blister packs.

Table 14. Impacts of replacing PVC with alternative materials in blister packs

Blister packs	
Alternatives	Aluminium, PET, PP, BOPP, COC/PO (only in combination with PVC/other materials), PCTFE, EVOH (only in combination with PVC/other materials), PVDC

	(only in combination with PVC/ other materials)
Economic impacts	Only costs of the materials have been estimated (no other costs). Material costs are lower per tonne for some plastics and higher for some compared to PVC. Aluminium is more expensive than PVC. The difference in material costs ranges from €-250 to €1 300 million per year, depending on the alternative.
Supply chain impacts	Annual profit losses to the PVC blister pack producers would be around €1–7 million.
Life cycle impacts	No conclusion on the preferable material throughout the entire life cycle and all potential alternative materials. PVC is preferable to aluminium and to the combination of PVC/PVDC or OPA/aluminium/PVC as the base film material for lice cycle stages from resource extraction to the factory gate (Bassani et al., 2022, Raju et al., 2016). It is not possible to compare the CO_2 emissions between blister pack materials, due to lack of data.

4.2.8. Toys

Both soft and rigid PVC is used in various toys including dolls, bath ducks, snorkels, inflatable beach toys, balls and paddling pools, rubber boats and rafts, modelling clay, trampolines, building blocks, and toy figures ((Baitz et al., 2004, Sphera, 2022), CfE3). PVC appears to be used the most in inflatable toys, boats and rafts (Baitz et al. 2004, Sphera 2022).

The manufacture of toys and childcare articles has largely moved outside the EU, mainly to China (CfE2, #1601, VinylPlus; (Eurostat, 2022)).The share of PVC of the plastics used in toys and childcare articles in the EU is small, with total volume estimated to be 6 000–36 000 tonnes per year (CfE2, #1601, VinylPlus).

Performance criteria for toys include flexibility, water resistance, high strength to weight ratio, durability, resistance to flexing, ease of decorating and moulding possibilities. Various alternative materials are available. There appear to be no evident differences in other properties, but PVC is superior in the ease of painting, decorating and gluing. Table 15 presents the available information on the impacts of replacing PVC with alternative materials in toys.

Table 15. Impacts of replacing PVC with alternative materials in toys

Toys	
Alternatives	PP, PE, TPE, EVA, PU, PS, silicone, rubber, wood
Economic impacts	Only costs of the materials have been estimated (no other costs). Material costs are lower per tonne for some and higher for some materials compared to PVC. The difference in material costs ranges from €-1 to €100 million per year, depending on the alternative.
Supply chain impacts	Annual profit losses to the PVC packaging producers would be around €0.1–0.9 million.

Life cycle impacts	Comparison of life cycle impacts, including CO_2 emissions, of PVC and alternative materials for toys is not possible due to lack of comparable data.

4.2.9. Medical applications

PVC is the single most commonly used polymer in medical devices in Europe (Global-Market-Insights, 2021). It is particularly important in medical bags (blood, intra-venous (IV), dialysis and urine), and used also in sterile disposable tubing, catheters and cannulas; connectors; medical bags; oxygen and anaesthetic masks; and exam and surgical gloves (CfE2, #1588, EFPIA; CfE2, #1600, VinylPlus Deutschland e.V.; CfE2, #1601 VinylPlus). Most of these applications are soft PVC.

Overall performance criteria in medical applications include biocompatibility, elasticity and flexibility (with good tensile strength), safe storage of contents, heat resistance, chemical resistance, water resistance, sterilizability, transparency, surface properties (abrasion resistance, surface friction), dimension control, kink resistance and recovery, solvent bondability, printability, manufacturability (cutting, welding, bonding and moulding) and avoidance of latex allergies (ECHA market survey 2023; CfE3, #1629, MedTech Europe; CfE3, #1693).

Several alternatives to soft PVC in medical applications are on the market or in development, but publicly available research on their performance and properties is sparse (Sphera 2022). No single alternative material would not be suitable to replace PVC in all medical uses, and there may be challenges in finding suitable alternatives to PVC for some uses (CfE2, #1611, MedTech Europe; CfE3, #1628, MedTech Europe). Table 16 presents the available information on the impacts of replacing PVC with alternative materials in medical applications.

Table 16. Impacts of replacing PVC with alternative materials in medical applications

Medical applications	
Alternatives	PU, EVA, PP, PE, PET, EAA, PS, ABS, SBS, TPE, rubber latex, PE and PO blends, PU and PE blends, non-phtalate/non-DEHP plasticised PVC
Economic impacts	Economic impacts of substitution include possible changes in material costs, investment costs and costs related to testing, validation and approval of the new material for medical applications. No information on lifetime costs or costs of final products is available. Material costs are lower per tonne for some and higher for some materials compared to PVC. The difference in material costs ranges from €-50 to €870 million per year, depending on the alternative. Reformulation or material changes could cost around €650 000–€900 000 per project/product.
Supply chain impacts	Considering the extensive use of PVC in medical applications, in particular medical bags, supply issues for alternative materials and products are possible. Annual profit losses to the PVC packaging producers would be around €1–4 million.
Life cycle impacts	Comparison of life cycle impacts, including CO_2 emissions, of PVC and alternative materials for medical applications is not possible due to lack of comparable data.

4.2.10. Artificial leather

Artificial (synthetic) leather consists normally of polyester textiles coated with PVC or PU (Meyer et al., 2021). Soft PVC is commonly used in artificial leather both in clothing (e.g. jackets, pants, bags and shoes) and automotive interiors (e.g. panel skins, seat upholstery, door panels and trim parts). The compounded PVC volume is 47 000–281 000 tonnes/year in clothing and 21 000–127 000 tonnes/year in automotive uses (CfE2, #1601, VinylPlus; #1587, EuPC).

The main functionalities required from artificial leather include durability, water resistance, flame resistance, UV radiation resistance, cold resistance, insulation, comfort, aesthetic factors, lightweight, staining, and cleanability (ECHA market survey 2023; Bywall and Cederlund (2020); CfE3, #1697, EURATEX).

Several alternatives are available that either replace artificial leather altogether or only the PVC component in artificial leather. PVC artificial leather is less durable and comfortable in terms of breathability and flexibility than leather, but it provides a better water and staining resistance and cleanability. Compared to PU artificial leather, PVC is more durable, has a higher weather resistance, and has a lower risk of staining, but is less comfortable (less breathable and flexible). PU leather is thought to resemble real leather better, as it wrinkles and remains soft throughout its life. Table 17 presents the available information on the impacts of replacing PVC with alternative materials in medical applications.

Table 17. Impacts of replacing PVC artificial leather with alternative materials

Artificial leather	
Alternatives	leather, cotton, silk, wool, latex, polyester, PA, PU artificial leather, bio-based artificial leather
Economic impacts	Economic impacts of substitution include possible changes in material costs and investment costs. No information on lifetime costs or costs of final products is available. Material costs are lower per tonne for some and higher for some materials compared to PVC. The difference in material costs ranges from €-130 to €1300 million per year for clothing and €-60 to €600 million per year for automotive interiors, depending on the alternative.
Supply chain impacts	Annual profit losses to the PVC packaging producers would be around €1–7 million in clothing and €1–3 million in automotive interiors.
Life cycle impacts	Comparison of life cycle impacts, including CO_2 emissions, of PVC and alternative materials for artificial leather is not possible due to lack of comparable data.

4.2.11. Summary of substitution costs

Table 18 summarises the costs of replacing PVC with alternative materials in the production of new articles for the sectors and uses covered in the impact assessment.

Table 18. Summary of the costs of replacing PVC with alternative materials

Sector	Use	Sub-use	Total costs (€ million per year)
Building and construction	Pipes and fittings	Potable water/ Drinking water	530
		Sewage	
		Industry	NA
	Cables	Building and construction cables	100–580
		Vehicle cables	
		EEE cables	
	Flooring	Homogenous and heterogeneous PVC flooring	2 400–39 000
	Window frames	-	2 000–2 200
Medical applications	Medical applications (blood and infusion bags, medical devices, gloves and medical tubing)	-	1–880*
Plastic products	Packaging	Rigid food and non-food packaging	4–2 800*
		Soft food and non-food packaging	
		Blister packs	
	Toys	-	1–110*
Textiles, leather and fur	Clothing	Artificial leather (not car) / Bags, luggage	1–1 300*
Vehicles	Automotive (interior)	Artificial leather, foamed films	1–600*

*Notes: NA = not available. * No lifetime costs assessed, only material costs and producer surplus losses.*

4.3. Technical release minimisation measures and applicability

As described in sections 3.2.3.2 and 3.2.3.3, the lifecycle major contributors to the overall estimated releases are the professional handling in the construction sector (~45 %) and activities in recycling facilities (~31 %). In addition, potential risk to workers in recycling facilities was also identified for some substances: organotin substances, DEHP (that could be extended to medium-chain ortho-phthalates due to additive effects in a scenario of combined exposure) and diantimony trioxide.

Recycling plants are a common life-cycle stage for almost all of the PVC uses (with few exceptions). Although the various PVC uses/life-cycle stages may have specificities related to the additives used, all types of PVC are channelled via recycling plants and hence those function as the mixing point of release/exposures for practically all PVC additives. Furthermore, recycling plants can be expected to be the most significant common source of releases of PVC microparticles where generally all uses contribute to the releases.

Despite the data gaps identified, there seems to be sufficient evidence to identify the lifecycle steps above as the main contributors to the overall estimated releases of prioritised PVC additives and by extension to the overall release of PVC microparticles. Plastic microparticle releases is not an issue that only applies to PVC but to other plastics as well and it is expected to be a significant contributor to the overall releases of other plastics microparticles from the same lifecycle steps as well. However, PVC, and in particular soft PVC, requires in total more additives (in the number of additives, functions and their concentration in PVC) than other plastics and microparticle releases function as the main carrier of the PVC additives releases.

Implementation and/or improvement of on-site emission minimisation technologies can be expected to reduce the risks related to the prioritised PVC additives and the PVC microparticles. Likewise, the implementation and/or improvement of risk management measures on-site could also be expected to reduce the occupational risks for workers. More detailed information on the measures and their costs has not been gathered for this report. Some cost estimates for best available techniques for waste treatment are available (Pinasseau et al., 2018), but additional work is needed to assess the socio-economic impacts of emission minimisation by technical measures.

It should be considered that recycling of PVC is expected to increase because of both voluntary efforts in the PVC industry and the objectives set in different regulations, e.g. the waste framework directive, packaging and packaging waste directive and sector-specific regulations (see Appendix D). Further, although 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 in case of plasticisers and from organotin substances to Ca/Zn chemistries in the case of heat stabilisers, this is not completely the case outside the EU and import of articles containing those substances is still possible.

The benefits from the reduction in the release of additives brought about by technological means is the attenuation or prevention of the increase of the environmental exposures (including man via environment exposures) of the PVC additives. This benefit can be expected to be proportionally higher especially for the release reduction of PVC at recycling plants than for the release reduction of an equal volume of other recycled plastics. The emergence of the known (or potential) severe long-term effects from the prioritised additives is delayed or prevented. Furthermore, the likelihood of synergistic and/or cumulative effects caused by the whole spectrum of additives arriving at (and released from) the recycling stage are attenuated in the environment (and for man via environment). This means the prevention/attenuation of effects related to human health (reproduction, immunological effects, neurotoxic effects, effects on endocrine system, other) and of population effects in nature (endocrine effects, chronic other effects).

To conclude, release reduction by technological means (especially at recycling plants) is considered beneficial for the attenuation/prevention of long-term effects of the prioritised PVC additives. However, benefits would also encompass the less known and even less predictable effects of PVC additives at large, as well as reduce a variety of co-exposures. Risks caused by microparticles exposure in the environment would be reduced. Thus, positive benefits are expected from technical exposure and release reduction of PVC microparticles on environmental species and human health (e.g. in the prevention of reproduction toxic, neurotoxic and immunotoxic (and potentially also carcinogenic) effects in a long term.

4.4. Life-cycle considerations of risk reduction measures

4.4.1. Upstream supply chain

Chlorine and ethylene are the two main inputs for the production of PVC. Chlorine is produced by electrolysis of brine, also called the chlor-alkali process. The main outputs of the chlor-alkali process are chlorine, caustic soda and hydrogen. Around 32 % of chlorine is used for the production of PVC (Euro Chlor, 2023). Ethylene is used in a wider scale (for example, to produce polyethylene).

Approximately 99.5 % of all caustic soda is produced by the chlor-alkali process. Caustic soda is an important material for many industries, including for example paper & pulp, alumina and chemical industry. Stakeholders have commented that if there would be a restriction that would decrease/cease the use of PVC, and thus have a large impact on the demand for chlorine, there would also be wider impacts for the chlor-alkali chain affecting the supply of caustic soda: there would be a significant decrease in the demand for chlorine. This would then also impact the market of the other outputs of the chlor-alkali process, most importantly caustic soda (CfE3, #1643, Vinyl Environmental Council).

At least the following impacts would occur if a restriction would alter the production of PVC:

- If there is a decrease in the demand of chlorine (e.g. 30 %, the share of total chlorine used for PVC), the market price of chlorine would decrease. The demand function for chlorine is unknown, particularly in the case of large-scale changes in the demand. It is not known if the market price of chlorine would stay positive (due to the possible disposal cost), or if the industry would need other ways to treat the excess chlorine. In the case of smaller changes in the demand of chlorine from the PVC industry, the main impact would be a lower price of chlorine.

- If the price of chlorine decreases, this would make the chlor-alkali process less profitable and would increase the price of caustic soda as well, since caustic soda is produced 99.5 % out of this process.

4.4.2. Impacts of non-recycling of PVC

In a scenario where the recycling of PVC would cease or decrease, there would be socio-economic impacts for the end-users of the products made of PVC recyclate, profit losses for the recyclers, increased cost of EoL treatment of PVC, likely employment impacts, and substantial increases of GHG-emissions and other environmental impacts from the increased production of virgin PVC. Such a scenario could take place either as an indirect impact of a more general risk management measure, for example a strict limit value of one of the prioritised additives, or directly from a risk management measure targeting emissions at the recycling sites. On the benefit-side, a shift from recycling to incineration and burning could decrease the environmental emissions, particularly for soft PVC.

To analyse these impacts further, ECHA has drafted a hypothetical scenario where recycling of PVC would come to a full stop. The assessment has been implemented separately for rigid and soft PVC since there is a large difference in terms of the use volumes of the prioritised additives between these types of PVC. The impacts are assumed to be linear to the extent the recycling would be reduced, and thus a, say, 20 % decrease in recycling would result in 20 % of the quantified impacts.

The amount of recycled post-consumer waste was around 310 000 tonnes in 2022, with 120 000 tonnes being soft and 190 000 tonne rigid PVC waste. The total amount of post-consumer waste of PVC is around 2 500 000 tonnes per year, and thus around 12 % is recycled. Stakeholders expect progress in the future to increase the share of PVC waste that is recycled with technological development (mechanical & chemical recycling) and social innovation (“designed for recycling”, market incentives for collection) (VinylPlus, 2023).

Most of the post-consumer recyclate comes from applications where PVC articles can easily be separated from other articles, the waste stream is homogenous and easily recyclable. These types of articles are window frames, which are easily separated during demolition work. Similarly, cables and (above-ground) pipes can be easily obtained in the demolition phase. Due to digging and cleaning costs, underground pipes are typically left in the ground after the lifecycle. For the cables, there are high economic incentives for recycling so that the conductor material (e.g. copper) can be recovered.

Most of the rigid PVC recyclate is obtained from window frames. Out of the quantified impact categories, the monetised impacts are largest for the increase of GHG emissions related to the need for virgin PVC. The total annual cost from stopping the recycling of rigid PVC would be around €210-400 million, plus possible capacity problems for incineration plants and employment impacts for the recyclers. The environmental and health benefits of ceasing recycling of rigid PVC (for the workers) are expected to be substantially lower.

Most of the soft PVC recyclate is from cables. Soft PVC recyclate is not used for the same use after recycling, but, for example, for different types of road furniture or agricultural items. Out of the quantified impact categories, the monetised impacts are largest for the increase of GHG emissions. The total annual cost from stopping the recycling of soft PVC would be around €125 million, plus possible capacity problems for incineration plants and employment impacts for the recyclers.

The benefits from non-recycling of soft PVC are higher than for the rigid PVC, despite of the lower volume of soft PVC rerouted from recycling to incineration and landfilling. This is because soft PVC contains more additives than rigid PVC that are present in significantly higher concentrations than heat stabilisers used in rigid PVC. For human health, this scenario results in some benefits as the worker exposure at recycling sites reduces to zero for plasticisers and flame retardants. Overall, it seems that the benefit (linked to the risk reduction) of stopping the recycling of soft PVC is higher compared to non-recycling of rigid PVC. More detailed information is available in Appendix C.

For the challenges in the recycling related to substitution see also section 3.3.

5. Regulatory options

As described in section 3, three main potential risks were identified for PVC and PVC additives and are related to:

- environmental risk from release of PVC microparticles,
- environmental risk from release of prioritised additives, mainly bound to PVC microparticles, for this investigation report, and
- potential risk to workers, especially in recycling facilities, by (combined) exposure to organotin substances (except MOTE with a concentration of DOTE below 0.3%) and medium-chain (C4-C6 and C7-C8) ortho-phthalates.

Regulatory alternatives to address the risks above are discussed in the sections below. The regulatory alternatives discussed are not exclusive and can be used in combination.

5.1. Regulatory measures to reduce PVC microparticles releases

The main justification to propose emission reduction by technological means is that the environmental risks identified in sections 3.2.3.2 and 3.1.4 are mainly linked to PVC microparticle releases.

The lifecycle major contributors to the overall estimated releases of the prioritised PVC additives are the professional handling in the construction sector (~45 %) and the end-of-life, in recycling facilities (~31 %) and landfills (~11 %). In addition, PVC waste and recycling of PVC is expected to increase, which both induce further releases from recycling sites and landfills unless improvement of the site release reduction measures are implemented.

Table 19 shows an overview of the current legislation/initiatives by activity and the options to address by technological means the risks identified above.

Table 19. Overview of regulatory options for emission reduction of PVC microparticles

Activity	Concern	Current legislation/initiatives	Gaps	Need for (further) regulation and options
Waste treatment	Microparticle releases during the treatment operation	IED: WT BREF and BAT conclusion on waste treatment (dust emission controls) Stricter level of control in some MS OELs for dust OELs for PVC dust at national level in several MS	Operation outside the scope of the BAT conclusions Emission requirements in BAT conclusions not specifically targeted at reducing microparticles Emissions to water	Tackle installations outside the scope of BAT conclusions and consider more specific measures for microparticles.
Recycling of plastics (pellet polymer production)	Spillage of pellets during production	National regulations in place in few countries (e.g. France) OELs for dust	Environmental releases of PVC microparticles not covered on an EU wide level, however,	Microplastic initiative: proposal of a regulation on preventing plastic pellets losses would

Activity	Concern	Current legislation/initiatives	Gaps	Need for (further) regulation and options
		OELs for PVC dust at national level in several MS Voluntary limits for PVC dust used by industry	new regulation proposed	reduce releases, however, dust via shredding does not seem to be directly covered
Landfills	Microparticle releases via air and landfill effluent and leachate	Landfill directive: • Requirements to minimise landfilling • Treatment requirements. Ban and restriction of landfilling of plastic waste of waste in several MS IED revision: IED extension to landfills Water legislation	Emissions of microparticles to water and to air	Addressing microplastics in water legislation (currently monitoring as a first step proposed)

Technological means to achieve release minimisation could be introduced via the Industrial Emissions directive, in particular via the WT BREF, by extending the scope of the BAT conclusions. Currently, only installations exceeding a specific waste tonnage per day depending on the type of waste are in scope.

Plastic microparticles pollution is already in the focus and the Microplastics initiative[17] aims at addressing various sources of plastic microparticles pollution. A proposal for a regulation on preventing plastic pellet losses was published in October 2023 (EC, 2023d). While pellets loss is an issue in the plastic production at several steps of the PVC life-cycle, it is not clear whether the technical measures to be implemented at ‘installations’ to comply with the proposed regulation to decrease pellets spills would also , to some extent, reduce other PVC microparticle releases, e.g. those formed during the shredding steps in the recycling plants or during industrial processes handling PVC in both pelletised and other form of PVC. Many of the PVC life-cycle steps do not handle pellets but other forms of PVC and induce thereby PVC microparticle releases as described in Appendix A. Furthermore, many of the life-cycle steps of PVC (e.g. professional handling of plastic articles) take place in a wide dispersive manner, not in installations, which are the subject of the requirements of the proposed regulation. Similar applies to expected releases of microparticles from other plastics. A need for broader regulatory risk management instrument to reduce the microparticle releases should be therefore further investigated.

The impacts of emission minimisation technologies were not assessed in this investigation report. It is unclear if the implementation of technological means would be feasible and/or effective for the professional handling in the construction sector (e.g. installation and removal, debris). A follow-up activity is necessary to gather information at more detailed level on the different recycling sites, the measures in place, their feasibility and costs. No such information was provided in CfE2.

---

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

Regulatory options to reduce releases of PVC microparticles from landfills would be linked to the landfill directive and therefore inter alia to the classification of the relevant waste streams.

5.2. Restriction of PVC additives

Restriction under REACH is one of the legislative instruments which can promote or ensure substitution of substances and define other measures to support risk reduction related to the manufacture and use of substances.

In the context of PVC, it is technically possible to define individual PVC additives, additive groups and the PVC itself as restriction targets. There is also an overarching, common environmental risk caused by all prioritised substances and the respective PVC uses based on the working approach taken (see section 3.2.3 for details). No further quantitative rationale of selecting additive groups and uses for a potential restriction(s) can be derived from the risk approach applied directly. A pragmatic approach as proposed in section 3.2.3.4 can be used to select the priority substance groups. The benefits of substitution have been generally described in section 4.1.1 (for PVC additives) and section 4.2.1 (for PVC itself). However, it is highlighted that it is necessary to carry out further work for especially informing on whether substitution of the identified substance groups in the highest concern and release category in section 3.2.3 would entail a sufficient level of effectiveness in reducing/minimising the risk and/or whether certain uses only should be targeted from the point of view of the combination of the impact and effectiveness.

As discussed in section 3.3, restriction does not have necessarily direct significant impact on releases as there would further be releases from articles in use, recycling, recycled PVC uses and landfills. A more immediate impact could be achieved in a scenario in which recycling of PVC comes to a full stop (see section 4.4). A qualitative assessment of the impact of such a scenario was carried out separately for rigid and soft PVC (Appendix C). Overall, it seems that the benefit (risk reduction) of stopping the recycling of soft PVC is higher compared to non-recycling of rigid PVC. It is noted, that ECHA is aware of the objective of the Plastics Strategy and its more recent downstream strategies to increase recycling rates in the EU (see Appendix D) and notes that the non-recycling scenario is provided for comparison only.

When considering which PVC uses contribute the most to the environmental risk found for prioritised additives, it appears that cables (a soft PVC use) stand out as a single contributor to the prioritised additives releases. As discussed in section 4.2, substitution of PVC with alternative materials in cables would be less costly than in other uses and hence for minimising risks of additives a restriction of PVC in cables seems worthwhile further assessment.

In addition, restriction may work as an instrument to reduce the risks to workers, especially in recycling facilities (worker exposure at recycling step is not covered by Authorisation under REACH), which have been identified for some organotin substances (DOTE and DMTE), DEHP and diantimony trioxide. As explained in section 3.2.3.3, it may be warranted to expand the substitution to all prioritised organotin substances (except MOTE with a concentration of DOTE below 0.3%) and to all medium-chain (C4-C6 and C7-C8) ortho-phthalates.

Considering the risk prioritisation matrix shown in Figure 6 and the risks to workers identified in recycling facilities, substitution (hand-in-hand with regulatory activities to reduce releases by technological measures) may be warranted for medium-chain (C4-C6 and C7-C8) ortho-phthalates and organotin substances. Nevertheless, it is acknowledged that there are other groups of substances that are used in high volumes and for which it should be clarified whether substitution would also be necessary like zinc borates, organophosphates and trimellitates.

Organotin substances and medium-chain ortho-phthalates have very different use profiles. While for organotin substances the stabilisation of PVC is by far the largest use of the substances (only a small fraction is used as catalysts), medium-chain (C4-C6 and C7-C8) ortho-phthalates are also used in other applications with other functions as well. Nevertheless, 85 % of the total volume of plasticisers are used in PVC according to the European Plasticisers. In addition, while organotin substances are only used in very specific rigid PVC applications (food and non-food packaging in particular), medium-chain ortho-phthalates are used more transversally in soft PVC applications. Nevertheless, as described in section 3.2.3.2, soft PVC in cables is the main contributor to additive releases (67 % of the overall estimated releases) and the main source of the soft PVC that is recycled, accounting for 81 % of the total recycled post-consumer soft PVC waste (Figure 8).

Although this investigation report has been focused on PVC, it is acknowledged that ortho-phthalates are used in other polymers in which they are also contained as additives and where the same risk approach would be applicable. We have not quantified the releases from those sources and it will be relevant to estimate them at a later point but considering that at least 85 % of the volume of plasticisers is used in PVC, a PVC-specific restriction can be expected to be sufficiently effective. Due to the very high persistence and ongoing accumulation of the additives in the environment it is important to act on risks when identified without delay. Acting on these additives on PVC would be the first step followed by, where necessary (based on the results of similar risk screening as presented here) regulatory action on these additives in other polymers.

Therefore, although specific actions could be considered for specific applications related to those groups of substances, for ortho-phthalates in particular substituting efforts should be considered in a wider context and considering all the uses of the substances and not only PVC, which is subject to this investigation report.

In addition, as explained in section 4.1.2 and 4.1.3, substitution of the prioritised additives as mentioned above might be possible for most of the uses and the economic impact does not seem to be prohibitively high.

Although an emission reduction by technological means (section 5.1) would address some of the main contributors to the overall estimated releases and thus mitigate the environmental risk, it will not address the entire lifecycle of the PVC articles.

Restriction under REACH is a regulatory instrument that would enable substitution of specific PVC additives groups in all relevant uses of PVC across several sectors. It is unlikely that another legislation determining restrictions could cover in one process the necessary number of substances and/or substance groups and all relevant uses in practically one assessment. Furthermore, the risk concept on the environmental risk as presented in this report is not a novelty under the REACH restriction process but similar PBT-like risks have been assessed for intentionally added microplastics, PFHxA and PFASs in fire-fighting foams.

Sector and product specific legislation such as the Directive 2000/53/EU on end-of-life vehicles, the RoHS Directive (Directive 2011/65/EU) or the Construction Product Regulation (Regulation (EU) No 305/2011) would cover individual sectors only and hence could not cover in one evaluation and legislative process all the sectors contributing to the environmental and worker risks of PVC uses. The Ecodesign Directive 2009/125/EC and the proposed Ecodesign for Sustainable Products Regulation (ESPR) could also be used as a basis to address the presence of additives hampering recycling. Considering the number of sectors and uses of the prioritised additives and of those additives with highest priority for regulatory action, regulating the same substance groups under the various sector legislations may result in a cumbersome process compared to proposing a restriction under REACH.

When considering the Drinking Water Directive (Directive (EU) 2020/2184) and Food Contact Materials legislation as well as the Medical Device Regulation, these do not address environmental risks as presented in this report but cover only the exposure (by leaching/volatilisation/migration) from the actual products during use, not over the lifecycle of the material. Furthermore, for some PVC uses no sector specific legislation is available.

5.3. Other and complementary regulatory options

Although there are several sector/product-specific regulations (Appendix D) that could be used to partially address the main potential risks identified above, the diverse number of uses of PVC suggests that a more holistic approach would be necessary. Some of the concerns e.g. growing production and plastic pollutions are in the focus of policy and regulatory initiatives and could also more broadly addressed by approaches tackling plastic materials as a whole (see Appendix D).

In addition to regulatory measures to reduce PVC microparticles releases and the restriction of use and placing on the market of some additives, other complementary measures could be used. Concerns related to the waste lifecycle stage and recycling could be addressed by waste legislations. To ensure the proper treatment of specific PVC waste streams it could be considered to add some PVC containing waste types to the list of waste. The definition of end-of-waste criteria for PVC could include requirements such as threshold values for certain additives for the materials ceasing to be waste.

Stricter measures to prevent releases of PVC microparticles could be required in the future to meet requirement under water protection legislation. Addressing microplastics pollution is envisaged in the revision of the water directives (Water Framework Directive, EQSD and Groundwater Directive) and monitoring microplastics pollution is considered for surface and groundwater. However, setting an actual EQS would only be foreseen as a second step after more information is available.

Setting occupational exposure limits for PVC dust and hazardous PVC additives could also be considered as a (complimentary) regulatory measure. Setting limits on the exposure to PVC dust and hazardous PVC additives will help employers to identify operational conditions and risk management measures to protect workers' health at work. This would be particularly relevant to address the potential risk identified at recycling facilities. In addition, this could also impact the emissions to the environment but not address it completely.

Other complementary measures to address the listed concerns could be for example measures under the Ecodesign Directive/Ecodesign for Sustainable Products Regulation (ESPR), or setting incentives through procurement schemes or product labelling schemes (e.g. EU Ecolabels).

6. Assessment and data gathering follow-up priorities

Based on the findings from the risk screening and impact assessment, several recommendations were identified (section 0) and regulatory options were explored (section 5). However, further work and data needs were also identified to support the recommendations drawn.

From the point of view of the risk screening, the following have been identified:

- Measured and estimated release of additives from PVC microparticles in the environment and in workplaces.
- Measured and estimated releases of PVC microparticles (including approach development, where necessary). Comparison with other plastics and relative contribution to microplastic pollution.
- Risk assessment of direct human exposure for co-exposure (especially recycling plants).
- Mass balance of PVC and (prioritised) additives in circular economy over a 20-year timespan considering selected end-of-life, recycling rate and substitution scenarios. Corresponding temporal development of releases and environmental stock.
- Further information on 'miscellaneous consumer articles' and a consequent risk assessment (not assessed in this project due to lack of data although the share of the total volume is high).
- Risk assessment of alternative additives (in case regulatory action on certain additives as mentioned in section 0 is taken forward as a follow-up activity).
- Risk assessment of alternative materials (in case PVC substitution as mentioned in section 0 taken forward as a follow-up activity).

For the impact assessment, the following priorities have been identified:

- Data to conduct impact assessment for some uses
  - building and construction: roofing, wallpaper, other profiles and sheets.
  - clothing: other uses than artificial leather.
  - vehicles: other uses than artificial leather, e.g. automotive parts.
  - miscellaneous consumer articles.
- Estimation of impacts of other risk reduction measures than substitution, in particular technical emission reduction solutions
- Improved data on full/lifetime substitution costs for some uses (packaging, medical packaging (blister packs), medical applications, toys and artificial leather).
- Cost-effectiveness analysis for prioritised additives and PVC alternative materials in terms of costs per avoided releases, taking into consideration the damage potential of additives.

- Quantifying the benefits of potential restriction options based on prioritisation scoring/concern banding.

APPENDICES

The appendices are available as separate files:

Appendix A and B: Use overview and risk screening

Appendix C: Impact Assessment

Appendix D: Regulatory Framework

Appendix E: Stakeholders Engagement

Appendix F: Legacy additives

ANNEX 1

List of PVC additives currently in used compiled in CfE1 (Table 20) and list of PVC additives in focus for the investigation report prioritised as explained in section 3.2 of this report and Appendix B.2 (Table 21).

Table 20. List of PVC additives currently in use compiled in CfE1

EC/List No.	CAS No.	Substance name	Main function	Other function
200-313-4	57-11-4	Stearic Acid	Lubricant	n.a.
201-039-8	77-58-7	Dibutyltin dilaurate	Heat Stabiliser	n.a.
201-067-0	77-90-7	Tributyl O-acetylcitrate	Plasticiser	n.a.
201-070-7	77-93-0	Triethyl citrate	Plasticiser	n.a.
201-071-2	77-94-1	Tributyl citrate	Plasticiser	n.a.
201-116-6	78-42-2	Tris-(2-ethylhexyl) phosphate	Flame retardant	Plasticiser
201-286-1	80-51-3	4,4'-oxydi(benzenesulphonohydrazide)	Blowing agent	n.a.
201-297-1	80-62-6	Methyl methacrylate	co-monomer	n.a.
201-344-6	81-33-4	Perylene-3,4:9,10-tetracarboxydiimide	Pigment	n.a.
201-346-7	81-39-0	3-methyl-6-(p-toluidino)-3H-dibenz[f,ij]isoquinoline-2,7-dione	Pigment	n.a.
201-353-5	81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone	Pigment	n.a.
201-375-5	81-77-6	6,15-dihydroanthrazine-5,9,14,18-tetrone	Pigment	n.a.
201-398-0	82-16-6	1,8-bis[(4-methylphenyl)amino]anthraquinone	Pigment	n.a.
201-553-2	84-69-5	Diisobutyl phthalate	Plasticiser	n.a.
201-557-4	84-74-2	Dibutyl phthalate	Plasticiser	n.a.
201-618-5	85-60-9	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	Antioxidant	n.a.
201-622-7	85-68-7	Benzyl butyl phthalate	Plasticiser	n.a.
201-877-4	89-04-3	Trioctyl benzene-1,2,4-tricarboxylate	Plasticiser	n.a.
202-319-2	94-28-0	2,2'-ethylenedioxydiethyl bis(2-ethylhexanoate)	Plasticiser	n.a.
202-908-4	101-02-0	Triphenyl phosphite	Heat Stabiliser	Flame Retardant
203-051-9	102-76-1	Triacetin	Secondary Bioplasticiser	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
203-090-1	103-23-1	Bis(2-ethylhexyl) adipate	Plasticiser	n.a.
203-091-7	103-24-2	Bis(2-ethylhexyl) azelate	Plasticiser	n.a.
203-234-3	104-76-7	2-ethylhexan-1-ol	Solvent	n.a.
203-350-4	105-99-7	Dibutyl adipate	Plasticiser	n.a.
203-366-1	106-14-9	12 hydroxystearic acid	Heat Stabiliser	Lubricant
203-431-4	106-79-6	Dimethyl sebacate	Plasticiser	n.a.
203-672-5	109-43-3	Dibutyl sebacate	Plasticiser	n.a.
203-755-6	110-30-5	N,N'-ethylenedi(stearamide)	Lubricant	n.a.
203-757-7	110-33-8	Dihexyl adipate	Plasticiser	n.a.
203-953-2	112-27-6	2,2'-(ethylenedioxy)diethanol	Solvent	n.a.
203-961-6	112-34-5	2-(2-butoxyethoxy)-ethanol	Heat stabiliser	n.a.
203-982-0	112-53-8	Dodecan-1-ol	Solvent	n.a.
204-000-3	112-72-1	1-Tetradecanol	Heat stabiliser	n.a.
204-017-6	112-92-5	Octadecan-1-ol	Lubricant	n.a.
204-104-9	115-77-5	Pentaerythritol	Heat Stabiliser	n.a.
204-211-0	117-81-7	Bis(2-ethylhexyl) phthalate	Plasticiser	n.a.
204-398-9	120-46-7	1,3-diphenylpropane-1,3-dione	Heat Stabiliser	n.a.
204-407-6	120-55-8	Oxydiethylene dibenzoate	Plasticiser	n.a.
204-558-8	122-62-3	Bis(2-ethylhexyl) sebacate	Plasticiser	n.a.
204-650-8	123-77-3	C,C'-azodi(formamide)	Blowing agent	n.a.
204-794-1	126-58-9	2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropan-1-ol	Heat Stabiliser	n.a.
204-822-2	127-08-2	Potassium acetate	Heat stabiliser	n.a.
204-881-4	128-37-0	2,6-di-tert-butyl-p-cresol	Heat Stabiliser (intermediate)	n.a.
204-909-5	128-80-3	1,4-bis(p-tolylamino)anthraquinone	Pigment	n.a.
205-016-3	131-17-9	Diallyl phthalate	Plasticiser	Vestolit: Crosslinking agent, HMW PVC

EC/List No.	CAS No.	Substance name	Main function	Other function
205-249-0	136-51-6	Calcium bis(2-ethylhexanoate)	Heat stabiliser	n.a.
205-251-1	136-53-8	Zinc bis(2-ethylhexanoate)	Heat stabiliser	n.a.
205-465-5	141-17-3	Bis(2-(2-butoxyethoxy)ethyl) adipate	Plasticiser	n.a.
205-525-0	142-17-6	Calcium dioleate	Heat stabiliser	n.a.
205-590-5	143-18-0	Potassium oleate	Heat stabiliser	n.a.
205-633-8	144-55-8	sodium hydrogen carbonate	Blowing agent	Foaming agent
205-685-1	147-14-8	29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper	Pigment	n.a.
205-743-6	149-57-5	2-ethylhexanoic acid	Manufacture of other substances	n.a.
207-439-9	471-34-1	Calcium carbonate	Filler	n.a.
208-167-3	513-77-9	Barium carbonate	Heat stabiliser	n.a.
208-293-9	520-45-6	3-acetyl-6-methyl-2H-pyran-2,4(3H)-dione	Heat Stabiliser	n.a.
208-336-1	522-75-8	2-(3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophene-3(2H)-one	Pigment	n.a.
208-551-0	533-00-6	Barium dibenzoate	Heat stabiliser	n.a.
209-047-3	553-72-0	Zinc dibenzoate	Heat stabiliser	n.a.
209-097-6	555-43-1	glycerol tristearate	Lubricant	n.a.
209-151-9	557-05-1	Zinc distearate	Heat stabiliser	Lubricant
209-167-6	557-28-8	Zinc dipropionate	Heat stabiliser	n.a.
209-378-3	574-93-6	29H,31H-phthalocyanine	Pigment	n.a.
209-481-3	582-25-2	Potassium benzoate	Heat stabiliser	n.a.
210-826-5	624-03-3	Ethane-1,2-diyl palmitate	Lubricant	n.a.
211-014-3	627-83-8	Ethylene distearate	Lubricant	n.a.
211-670-0	683-18-1	Dibutyltin dichloride	Heat Stabiliser	n.a.
212-660-9	839-90-7	Tris(2-hydroxyethyl)-1,3,5-triazinetrione	Heat Stabiliser	n.a.
213-561-3	980-26-7	5,12-dihydro-2,9-dimethylquino[2,3-b]acridine-7,14-dione	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
213-879-2	1047-16-1	5,12-dihydroquino[2,3-b]acridine-7,14-dione	Pigment	n.a.
214-987-2	1241-94-7	Diphenyl (2-ethylhexyl) phosphate	Flame retardant	Plasticiser
215-137-3	1305-62-0	Calcium dihydroxide	Heat stabiliser	n.a.
215-138-9	1305-78-8	Calcium oxide	Heat Stabiliser	Dessicant
215-160-9	1308-38-9	Chromium (III) oxide	Pigment	n.a.
215-168-2	1309-37-1	Diiron trioxide	Pigment	n.a.
215-170-3	1309-42-8	Magnesium hydroxide	Flame retardant	Heat Stabiliser. Filler.
215-171-9	1309-48-4	Magnesium oxide	Heat stabiliser	n.a.
215-175-0	1309-64-4	Diantimony trioxide	Flame Retardant	n.a.
215-204-7	1313-27-5	Molybdenum trioxide	Flame Retardant	n.a.
215-222-5	1314-13-2	Zinc oxide	Pigment	Light Stabiliser Kicker for blowing agent
215-277-5	1317-61-9	Triiron tetraoxide	Pigment	n.a.
215-279-6	1317-65-3	Ground Calcium carbonate	Filler	n.a.
215-282-2	1317-80-2	Rutile (TiO2)	Pigment	n.a.
215-283-8	1318-02-1	Zeolite	Heat Stabiliser	n.a.
215-284-3	1318-23-6	Aluminium oxide hydroxide	Flame retardant	n.a.
215-290-6	1319-46-6	Trilead bis(carbonate) dihydroxide	Heat Stabiliser	n.a.
215-524-7	1328-53-6	Polychloro copper phthalocyanine	Pigment	n.a.
215-566-6	1332-07-6	Zinc borate	Flame retardant	n.a.
215-609-9	1333-86-4	Carbon black	Pigment	Electric Conductivity
215-664-9	1338-41-6	Sorbitan stearate	Anti-fogging	n.a.
215-665-4	1338-43-8	Sorbitan oleate	Anti-fogging	n.a.
216-472-8	1592-23-0	Calcium distearate	Heat stabiliser	Lubricant
216-823-5	1675-54-3	2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane	Heat Stabiliser	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
217-420-7	1843-03-4	4,4',4''-(1-methylpropanyl-3-ylidene)tris[6-tert-butyl-m-cresol]	Antioxidant	n.a.
217-421-2	1843-05-6	Octabenzone	Light Stabiliser	n.a.
217-803-9	1962-75-0	Dibutyl terephthalate	Plasticiser	n.a.
218-216-0	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	Antioxidant	n.a.
218-235-4	2090-05-3	Calcium dibenzoate	Heat stabiliser	n.a.
219-470-5	2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	Light Stabiliser	n.a.
219-518-5	2452-01-9	Zinc dilaurate	Heat Stabiliser	Lubricant
219-535-8	2457-01-4	Barium bis(2-ethylhexanoate)	Heat stabiliser	n.a.
221-218-4	3033-29-2	Dihydro-2,2-dioctyl-6H-1,3,2-oxathiastannin-6-one	Heat stabiliser	n.a.
221-264-5	3049-71-6	2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Pigment	n.a.
221-424-4	3089-17-6	2,9-dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione	Pigment	n.a.
221-605-8	3159-62-4	Calcium(2+) 12-hydroxyoctadecanoate	n.a.	n.a.
221-625-7	3164-85-0	Potassium 2-ethylhexanoate	Heat stabiliser	n.a.
222-020-0	3319-31-1	Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	Pigment	n.a.
222-530-3	3520-72-7	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]	Pigment	n.a.
222-883-3	3648-18-8	dioctyltin dilaurate	Heat stabiliser	n.a.
222-884-9	3648-20-2	Diundecyl phthalate	Plasticiser	n.a.
223-276-6	3806-34-6	3,9-Bis (octadecyloxy)-2,4,8,10-tetraoxa-3,9-diphosphaspiro [5.5]undecane	Heat Stabiliser	n.a.
223-445-4	3896-11-5	Bumetrizole	Light Stabiliser	n.a.
223-460-6	3905-19-9	N,N'-phenylene-1,4-bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
223-754-4	4051-63-2	4,4'-diamino[1,1'-bianthracene]-9,9',10,10'-tetraone	Pigment	n.a.
224-081-9	4196-89-8	2,2-dimethylpropane-1,3-diyl dibenzoate	Plasticiser	n.a.
224-597-4	4424-06-0	Bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione	Pigment	n.a.
224-867-1	4531-49-1	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methoxyphenyl)-3-oxobutyramide]	Pigment	n.a.
225-166-3	4696-56-4	Calcium dilaurate	Heat stabiliser	n.a.
225-167-9	4696-57-5	Barium dilaurate	Heat stabiliser	n.a.
225-184-1	4702-90-3	4-[(1,5-dihydro-3-methyl-5-oxo-1-phenyl-4H-pyrazol-4-ylidene)methyl]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one	Pigment	n.a.
225-202-8	4712-55-4	Diphenyl phosphonate	Heat stabiliser	n.a.
225-443-9	4851-50-7	1,4-bis[[4-(1,1-dimethylethyl)phenyl]amino]-5,8-dihydroxyanthraquinone	Pigment	n.a.
225-590-9	4948-15-6	2,9-bis(3,5-dimethylphenyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Pigment	n.a.
225-744-5	5045-40-9	3,3'-[(2-methyl-1,3-phenylene)diimino]bis[4,5,6,7-tetrachloro-1H-isoindol-1-one]	Pigment	n.a.
225-822-9	5102-83-0	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	Pigment	n.a.
225-935-3	5160-02-1	Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]	Pigment	n.a.
226-103-2	5280-68-2	N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
226-106-9	5280-78-4	N,N'-(2-chloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	Pigment	n.a.
226-107-4	5280-80-8	3,3'-[(2,5-dimethyl-p-phenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(5-chloro-o-tolyl)benzamide]	Pigment	n.a.
226-109-5	5281-04-9	Calcium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate	Pigment	n.a.
226-789-3	5468-75-7	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]	Pigment	n.a.
226-866-1	5521-31-3	2,9-dimethylanthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Pigment	n.a.
226-939-8	5567-15-7	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	Pigment	n.a.
226-970-7	5580-57-4	3,3'-[(2-chloro-5-methyl-p-phenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(3-chloro-o-tolyl)benzamide]	Pigment	n.a.
226-999-5	5590-18-1	3,3'-(1,4-phenylenediimino)bis[4,5,6,7-tetrachloro-1H-isoindol-1-one]	Pigment	n.a.
227-217-5	5718-26-3	Methyl 2-[(1,5-dihydro-3-methyl-5-oxo-1-phenyl-4H-pyrazol-4-ylidene)ethylidene]-1,3,3-trimethylindoline-5-carboxylate	Pigment	n.a.
227-930-1	6041-94-7	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-phenylnaphthalene-2-carboxamide	Pigment	n.a.
228-768-4	6358-31-2	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
228-787-8	6358-85-6	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutyramide]	Pigment	n.a.
229-066-0	6408-72-6	1,4-diamino-2,3-diphenoxyanthraquinone	Pigment	n.a.
229-176-9	6422-86-2	Bis(2-ethylhexyl) terephthalate	Plasticiser	n.a.
229-662-0	6642-31-5	6-amino-1,3-dimethyluracil	Heat stabiliser	n.a.
229-722-6	6683-19-8	Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	Antioxidant	n.a.
229-904-5	6829-22-7	14H-benz[4,5]isoquino[2,1-a]perimidin-14-one	Pigment	n.a.
229-934-9	6846-50-0	1-isopropyl-2,2-dimethyltrimethylene diisobutyrate	Plasticiser	n.a.
230-049-5	6925-69-5	12H-phthaloperin-12-one	Pigment	n.a.
230-258-1	6992-11-6	4-[(2,5-dichlorophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxynaphthalene-2-carboxamide	Pigment	n.a.
230-303-5	7023-61-2	Calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	Pigment	n.a.
230-426-4	7128-64-5	2,5-thiophenediylbis(5-tert-butyl-1,3-benzoxazole)	fluorescent whitening agent	n.a.
231-141-8	7440-31-5	Tin dust	Pigment	n.a.
231-159-6	7440-50-8	Copper dust	Pigment	n.a.
231-175-3	7440-66-6	Zinc dust	Pigment	n.a.
231-293-5	7486-38-6	Disodium adipate	Heat stabiliser	n.a.
231-511-9	7601-89-0	Sodium perchlorate	Heat stabiliser	n.a.
231-626-4	7659-86-1	2-ethylhexyl mercaptoacetate	Heat Stabiliser	n.a.
231-784-4	7727-43-7	Barium sulfate	Filler	X-ray absorber
232-190-8	7789-79-9	Calcium phosphinate	Flame retardant	n.a.
232-192-9	7789-82-4	Calcium molybdate	Flame retardant	n.a.
232-274-4	8001-22-7	Soybean oil	Solvent	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
232-278-6	8001-26-1	Linseed oil	Solvent	n.a.
232-292-2	8001-78-3	Castor oil, hydrogenated	Lubricant	n.a.
232-315-6	8002-74-2	Paraffin waxes and Hydrocarbon waxes	Lubricant	n.a.
232-353-3	8007-18-9	Antimony nickel titanium oxide yellow	Pigment	n.a.
232-391-0	8013-07-8	epoxidized soybean oil	Heat Stabiliser	Plasticiser
232-401-3	8016-11-3	Linseed oil, epoxidized	Plasticiser	co-stabiliser
232-455-8	8042-47-5	White mineral oil (petroleum)	Lubricant	n.a.
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	Heat stabiliser	n.a.
233-226-5	10094-45-8	(Z)-N-octadecyldocos-13-enamide	Lubricant	n.a.
233-257-4	10101-66-3	Ammonium manganese(3+) diphosphate	Pigment	n.a.
234-186-1	10584-98-2	2-ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	Heat stabiliser	n.a.
234-319-3	11097-59-9	carbonato(2-)]hexadecahydroxybis(aluminium)hexamagnesium	Heat stabiliser	n.a.
234-853-7	12036-76-9	Lead oxide sulfate (Basic lead sulphate)	Heat Stabiliser	n.a.
235-049-9	12062-81-6	Iron manganese trioxide	Pigment	n.a.
235-067-7	12065-90-6	Pentalead tetraoxide sulphate	Heat Stabiliser	n.a.
235-252-2	12141-20-7	Trilead dioxide phosphonate	Heat Stabiliser	n.a.
235-330-6	12167-74-7	Pentacalcium hydroxide tris(orthophosphate)	Pigment	n.a.
235-380-9	12202-17-4	Tetralead trioxide sulphate	Heat Stabiliser	n.a.
235-425-2	12225-06-8	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	Pigment	n.a.
235-462-4	12236-62-3	2-[(4-chloro-2-nitrophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide	Pigment	n.a.
235-476-0	12239-87-1	Copper chlorophthalocyanine	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
235-558-6	12286-66-7	Calcium bis[4-[[1-[[(2-methylphenyl)amino]carbonyl]-2-oxopropyl]azo]-3-nitrobenzenesulphonate]	Pigment	n.a.
235-702-8	12578-12-0	Dioxobis(stearato)trilead	Heat Stabiliser	n.a.
235-790-8	12737-27-8	Chromium iron oxide	Pigment	n.a.
235-804-2	12767-90-7	Hexaboron dizinc undecaoxide	Flame Retardant	n.a.
235-811-0	12769-96-9	Sodium aluminosilicate violet	Pigment	n.a.
236-671-3	13463-41-7	Pyrithione zinc	Biostabiliser	n.a.
236-675-5	13463-67-7	Titanium dioxide	Pigment	n.a.
237-067-2	13598-37-3	Zinc bis(dihydrogen phosphate)	Pigment	n.a.
237-860-3	14024-63-6	Bis(pentane-2,4-dionato-O,O')zinc	Heat Stabiliser	n.a.
237-898-0	14059-33-7	Bismuth vanadium tetraoxide	Pigment	n.a.
238-238-4	14302-13-7	[1,3,8,16,18,24-hexabromo-2,4,9,10,11,15,17,22,23,25-decachloro-29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]copper	Pigment	n.a.
238-877-9	14807-96-6	Talc (Mg3H2(SiO3)4)	Filler	Flame retardant Lubricant
239-581-2	15535-79-2	2,2-dioctyl-1,3,2-oxathiastannolan-5-one	Heat Stabiliser	n.a.
239-594-3	15546-11-9	Methyl (Z,Z)-8,8-dibutyl-3,6,10-trioxo-2,7,9-trioxa-8-stannatrideca-4,11-dien-13-oate	Heat Stabiliser	n.a.
239-622-4	15571-58-1	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	Heat Stabiliser	n.a.
239-685-8	15602-15-0	Magnesium 2-ethylhexanoate	Heat stabiliser	n.a.
239-716-5	15647-08-2	2-ethylhexyl diphenyl phosphite	Heat Stabiliser	Flame Retardant
239-879-2	15782-05-5	Strontium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (1:1)	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
239-898-6	15793-73-4	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]	Pigment	n.a.
239-937-7	15834-04-5	2,2-bis[[(1-oxopentyl)oxy]methyl]propane-1,3-diyl divalerate	Plasticiser	n.a.
240-385-4	16294-75-0	14H-anthra[2,1,9-mna]thioxanthen-14-one	Pigment	n.a.
240-920-1	16883-83-3	Benzyl 3-isobutyryloxy-1-isopropyl-2,2-dimethylpropyl phthalate	Plasticiser	n.a.
241-029-0	16958-92-2	Bis(tridecyl) adipate	Plasticiser	n.a.
241-753-7	17772-51-9	3-hydroxy-2-(3-hydroxy-2-quinolyl)-1H-inden-1-one	Pigment	n.a.
242-159-0	18282-10-5	Tin dioxide	Pigment	n.a.
242-894-7	19224-26-1	Propylene glycol dibenzoate	Plasticiser	n.a.
243-001-3	19372-44-2	Bis(pentane-2,4-dionato)calcium	Heat Stabiliser	n.a.
243-283-8	19766-89-3	Sodium 2-ethylhexanoate	Heat stabiliser	n.a.
244-007-9	20749-68-2	8,9,10,11-tetrachloro-12H-phthaloperin-12-one	Pigment	n.a.
244-320-0	21295-57-8	6-(cyclohexylamino)-3-methyl-3H-dibenz[f,ij]isoquinoline-2,7-dione	Pigment	n.a.
244-492-7	21645-51-2	Aluminum hydroxide	Flame retardant	Filler
244-776-0	22094-93-5	2,2'-[(2,2',5,5'-tetrachloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	Plasticiser	n.a.
245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide	Flame retardant	n.a.
245-950-9	23949-66-8	N-(2-ethoxyphenyl)-N'-(2-ethylphenyl)oxamide	Light Stabiliser	n.a.
246-466-0	24800-44-0	[(methylethylene)bis(oxy)]dipropanol	Solvent	n.a.
246-770-3	25265-71-8	Oxydipropanol	Solvent	n.a.
246-771-9	25265-77-4	Isobutyric acid, monoester with 2,2,4-trimethylpentane-1,3-diol	Plasticiser	Viscosity depressant for plastisols
246-998-3	25448-25-3	Triisodecyl phosphite	Heat Stabiliser	Flame Retardant

EC/List No.	CAS No.	Substance name	Main function	Other function
247-038-6	25496-72-4	Oleic acid, monoester with glycerol	Antistatic	n.a.
247-098-3	25550-98-5	Diisodecyl phenyl phosphite	Heat Stabiliser	Flame Retardant
247-304-1	25869-00-5	Ammonium iron(3+) hexakis(cyano-C)ferrate(4-)	Pigment	n.a.
247-384-8	25973-55-1	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol	Light Stabiliser	n.a.
247-426-5	26040-51-7	Bis(2-ethylhexyl) tetrabromophthalate	Flame Retardant	Plasticiser
247-660-8	26401-35-4	Diisotridecyl adipate	Plasticiser	n.a.
247-693-8	26444-49-5	Diphenyl tolyl phosphate	Flame Retardant	Plasticiser
247-759-6	26523-78-4	Tris(nonylphenyl) phosphite	Heat Stabiliser	Antioxidant
247-761-7	26530-20-1	octhilinone (ISO); 2-octyl-2H-isothiazol-3-one	Biostabiliser	n.a.
247-777-4	26544-23-0	Isodecyl diphenyl phosphite	Heat Stabiliser	Flame Retardant
247-952-5	26741-53-7	3,9-bis(2,4-di-tert-butylphenoxy)-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane	Antioxidant	n.a.
247-978-7	26761-42-2	Potassium neodecanoate	Heat stabiliser	n.a.
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	Heat Stabiliser	n.a.
248-258-5	27138-31-4	Oxydipropyl dibenzoate	Plasticiser	n.a.
248-299-9	27178-16-1	Diisodecyl adipate	Plasticiser	n.a.
248-368-3	27253-26-5	Diisotridecyl phthalate	Plasticiser	n.a.
248-370-4	27253-29-8	Zinc neodecanoate	Heat stabiliser	n.a.
248-375-1	27253-33-4	Calcium neodecanoate	Heat stabiliser	n.a.
249-044-4	28472-97-1	Diisodecyl azelate	Plasticiser	n.a.
249-047-0	28473-19-0	Diisodecyl sebacate	Plasticiser	n.a.
249-079-5	28553-12-0	Di-''isononyl'' phthalate	Plasticiser	n.a.
249-125-4	28654-73-1	[N,N,N',N',N'',N''-hexaethyl-29H,31H-phthalocyaninetrimethylaminato(2-)-N29,N30,N31,N32]copper	Pigment	n.a.
249-828-6	29761-21-5	Isodecyl diphenyl phosphate	Plasticiser	Flame Retardant

EC/List No.	CAS No.	Substance name	Main function	Other function
249-828-6	29761-21-5	Isodecyl diphenyl phosphate	Flame Retardant	Plasticiser
250-063-5	30125-47-4	3,4,5,6-tetrachloro-N-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolyl]phthalimide	Pigment	n.a.
250-705-4	31566-31-1	glycerol monostearate	Lubricant	Antistatic
250-800-0	31778-10-6	Butyl 2-[[3-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-hydroxy-1-naphthyl]azo]benzoate	Pigment	n.a.
250-830-4	31837-42-0	2-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzoic acid	Pigment	n.a.
251-156-3	32687-78-8	2',3-bis[[3-[3,5-di-tert-butyl-4-hydroxyphenyl]propionyl]]propionohydrazide	Antioxidant	Metal deactivator
251-178-3	32724-62-2	1,4-bis[(2,6-diethyl-4-methylphenyl)amino]anthraquinone	Pigment	n.a.
251-646-7	33703-08-1	Diisononyl adipate	Plasticiser	n.a.
252-104-2	34590-94-8	(2-methoxymethylethoxy)propanol	Solvent	n.a.
252-669-5	35674-68-1	Zinc bis[12-hydroxyoctadecanoate]	Heat Stabiliser	n.a.
252-722-2	35773-43-4	3-(5-chlorobenzoxazol-2-yl)-7-(diethylamino)-2-benzopyrone	Pigment	n.a.
252-772-5	35869-64-8	N,N'-(2-chloro-1,4-phenylene)bis[4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	Pigment	n.a.
252-917-2	36211-43-5	Barium 3,5,5-trimethylhexanoate	Heat stabiliser	n.a.
252-939-2	36265-41-5	Didodecyl 1,4-dihydro-2,6-dimethylpyridine-3,5-dicarboxylate (DHP)	Heat stabiliser	n.a.
252-939-2	36265-41-5	Di-docecyl-1,4-dihydro-2,6-dimethylpyridin-3,5-dicarboxylat,	Heat stabiliser	n.a.
253-039-2	36443-68-2	Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl)propionate]	Antioxidant	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
253-138-0	36631-30-8	Triisodecyl benzene-1,2,4-tricarboxylate	Plasticiser	n.a.
253-256-2	36888-99-0	5,5'-(1H-isoindole-1,3(2H)-diylidene)dibarbituric acid	Pigment	n.a.
255-005-2	40618-31-3	N,N'-(2,5-dichloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	Pigment	n.a.
255-460-7	41611-76-1	1,4-bis[(2-ethyl-6-methylphenyl)amino]anthraquinone	Pigment	n.a.
255-965-2	42844-93-9	[1,3-dihydro-5,6-bis[[(2-hydroxy-1-naphthyl)methylene]amino]-2H-benzimidazol-2-onato(2-)-N5,N6,O5,O6]nickel	Pigment	n.a.
256-367-4	49553-76-6	Oleic acid, monoester with oxybis(propanediol)	Lubricant	n.a.
257-098-5	51274-00-1	Iron hydroxide oxide yellow	Pigment	n.a.
257-515-0	51920-12-8	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-methyl-4-[(methylamino)sulphonyl]phenyl]azo]naphthalene-2-carboxamide	Pigment	n.a.
258-469-4	53306-54-0	Bis(2-propylheptyl) phthalate	Plasticiser	n.a.
258-847-9	53894-23-8	Triisononyl benzene-1,2,4-tricarboxylate	Plasticiser	n.a.
258-964-5	54079-53-7	[[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene]malononitrile	Pigment	n.a.
259-509-3	55172-98-0	Barium neodecanoate	Heat stabiliser	n.a.
260-742-8	57453-97-1	magnesium neodecanoate	Heat stabiliser	n.a.
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	Heat Stabiliser	n.a.
260-829-0	57583-35-4	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	Heat Stabiliser	n.a.
261-257-4	58446-52-9	Phenylicosane-1,3-dione	heat stabiliser	n.a.
261-645-3	59185-95-4	DioctylTin di(2ethylhexylmercaptopropionate)	Heat stabiliser	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
261-785-5	59487-23-9	4-[[5-[[[4-(aminocarbonyl)phenyl]amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	Pigment	n.a.
263-272-1	61847-48-1	Methyl 4-[[(2,5-dichlorophenyl)amino]carbonyl]-2-[[2-hydroxy-3-[[(2-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]benzoate	Pigment	n.a.
263-467-1	62229-08-7	Sulfurous acid, lead salt, dibasic	Heat Stabiliser	n.a.
264-038-1	63231-60-7	Paraffin waxes and Hydrocarbon waxes, microcryst.	n.a.	n.a.
264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro	Plasticiser	Flame Retardant
264-843-8	64359-81-5	4,5-dichloro-2-octyl-2H-isothiazol-3-one	Biostabiliser	n.a.
265-233-4	64771-72-8	Paraffins (petroleum), normal C5-C20	Lubricant	n.a.
265-634-4	65212-77-3	Calcium 4,5-dichloro-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulphonatophenyl)-1H-pyrazol-4-yl]azo]benzenesulphonate	Pigment	n.a.
266-928-5	67701-03-5	Fatty acids, C16-18	Lubricant	n.a.
266-936-9	67701-12-6	Fatty acids, C14-18 and C16-18-unsatd., zinc salts	Heat stabiliser	n.a.
267-015-4	67762-38-3	Fatty acids, C16-18 and C18-unsatd., Me esters	Viscosity modifier	n.a.
267-051-0	67774-74-7	Benzene, C10-13-alkyl derivs.	Viscosity modifier	n.a.
267-466-7	67874-37-7	Diisotridecyl phenyl phosphite	Heat stabiliser	n.a.
268-459-1	68092-46-6	Zinc m-toluate	Heat stabiliser	n.a.
268-460-7	68092-47-7	Barium m-toluate	Heat stabiliser	n.a.
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	Heat Stabiliser	n.a.
269-047-4	68186-85-6	Cobalt titanite green spinel	Pigment	n.a.
269-049-5	68186-87-8	Cobalt zinc aluminate blue spinel	Pigment	n.a.
269-050-0	68186-88-9	Zinc iron chromite brown spinel	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
269-052-1	68186-90-3	Chrome antimony titanium buff rutile	Pigment	n.a.
269-053-7	68186-91-4	Copper chromite black spinel	Pigment	n.a.
269-054-2	68186-92-5	Chrome tungsten titanium buff rutile	Pigment	n.a.
269-056-3	68186-94-7	Manganese ferrite black spinel	Pigment	n.a.
269-060-5	68186-97-0	Iron cobalt chromite black spinel	Pigment	n.a.
269-072-0	68187-11-1	Cobalt chromite blue green spinel	Pigment	n.a.
269-075-7	68187-15-5	Zirconium praseodymium yellow zircon	Pigment	n.a.
269-101-7	68187-49-5	Cobalt chromite green spinel	Pigment	n.a.
269-103-8	68187-51-9	Zinc ferrite brown spinel	Pigment	n.a.
269-144-1	68188-18-1	Sulfonic acids, C14-17-sec-alkane, sodium salts	Antistatic	Emulsifier
270-185-2	68412-38-4	Manganese antimony titanium buff rutile	Pigment	n.a.
270-487-4	68442-70-6	1,2-Benzenedicarboxylic acid, mixed cetyl and stearyl esters	Lubricant	n.a.
270-958-4	68512-13-0	Copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, brominated chlorinated	Pigment	n.a.
271-082-5	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	Plasticiser	n.a.
271-084-6	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	Plasticiser	Lubricant
271-085-1	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	Plasticiser	n.a.
271-089-3	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	Plasticiser	n.a.
271-090-9	68515-48-0	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich	Plasticiser	n.a.
271-091-4	68515-49-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich	Plasticiser	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
271-176-6	68516-73-4	Tetramethyl 2,2'-[1,4-phenylenebis[imino(1-acetyl-2-oxoethane-1,2-diyl)azo]]bisterephthalate	Pigment	n.a.
271-235-6	68526-86-3	Alcohols, C11-14-iso-, C13-rich	Solvent	n.a.
271-376-3	68551-41-7	Fatty acids, C6-19-branched, calcium salts, overbased	Heat stabiliser	n.a.
272-713-7	68909-79-5	Hematite, chromium green black	Pigment	n.a.
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)	Flame Retardant	Plasticiser
273-688-5	69011-06-9	[Phthalato(2-)] dioxotrilead	Heat Stabiliser	n.a.
274-324-8	70131-50-9	Bentonite, acid-leached	Filler	n.a.
274-570-6	70321-86-7	2-(2H-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol	Light Stabiliser	n.a.
274-668-9	70546-25-7	3-(benzothiazol-2-yl)-7-(diethylamino)-2-oxo-2H-1-benzopyran-4-carbonitrile	Pigment	n.a.
275-063-2	70955-74-7	Diisotridecyl phosphonate	Heat stabiliser	n.a.
275-738-1	71631-15-7	Nickel iron chromite black spinel	Pigment	n.a.
276-057-2	71832-85-4	Calcium bis[4-[[1-[[(2-chlorophenyl)amino]carbonyl]-2-oxopropyl]azo]-3-nitrobenzenesulphonate]	Pigment	n.a.
276-158-1	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	Plasticiser	n.a.
276-344-2	72102-84-2	5-[(2,3-dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl)azo]barbituric acid	Pigment	n.a.
277-146-9	72968-71-9	Methyl 4-cyano-5-[[5-cyano-2,6-bis[(3-methoxypropyl)amino]-4-methyl-3-pyridyl]azo]-3-methyl-2-thenoate	Pigment	n.a.
277-873-1	74441-05-7	N-[4-(aminocarbonyl)phenyl]-4-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzamide	Pigment	n.a.
278-758-9	77745-66-5	Triisotridecyl phosphite	Heat Stabiliser	Flame Retardant

EC/List No.	CAS No.	Substance name	Main function	Other function
278-770-4	77804-81-0	2,2'-[ethylenebis(oxyphenyl-2,1-eneazo)]bis[N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide	Pigment	n.a.
279-356-6	79953-85-8	3,3'-[(2-chloro-5-methyl-p-phenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-[2-(4-chlorophenoxy)-5-(trifluoromethyl)phenyl]benzamide]	Pigment	n.a.
279-767-0	81457-65-0	Copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, [[3-(1-methylethoxy)propyl]amino]sulfonyl derivs.	Pigment	n.a.
281-192-5	83897-84-1	Calcium magnesium carbonate oxide	Filler	n.a.
282-780-4	84418-68-8	Neodecanoic acid, zinc salt, basic	Heat stabiliser	n.a.
283-563-7	84682-03-1	Zinc 3,5,5-trimethylhexanoate	Heat stabiliser	n.a.
284-660-7	84961-70-6	Benzene, mono-C10-13-alkyl derivs., distn. residues	Lubricant	n.a.
286-272-3	85203-81-2	zinc octanoate, basic	Heat stabiliser	n.a.
286-484-6	85251-71-4	Fatty acids, C16-18, calcium salts	Heat stabiliser	n.a.
286-490-9	85251-77-0	Glycerides, C16-18 mono- and di-	Lubricant	n.a.
287-477-0	85535-85-9	Alkanes, C14-17, chloro	Plasticiser	Flame Retardant
290-580-3	90193-76-3	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters	Plasticiser	n.a.
290-656-6	90194-45-9	Benzenesulfonic acid, mono-C10-13-alkyl derivs., sodium salts	Antifriction agent	n.a.
290-754-9	90218-76-1	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters	Plasticiser	n.a.
292-811-3	91001-42-2	Fatty acids, C12-20 and C12-20-unsatd., 2-ethylhexyl esters	Viscosity modifier	n.a.
292-883-6	91002-07-2	Fatty acids, C16-18, barium salts	Heat stabiliser	n.a.
292-932-1	91031-31-1	Fatty acids, C16-18, esters with ethylene glycol	Lubricant	n.a.
292-951-5	91031-48-0	Fatty acids, C16-18, 2-ethylhexyl esters	Lubricant	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
292-966-7	91031-62-8	Fatty acids, C16-18, lead salts	Heat Stabiliser	Lubricant
293-048-9	91051-00-2	Fatty acids, C8-10, zinc salts	Heat Stabiliser	Lubricant
293-049-4	91051-01-3	Fatty acids, C16-18, zinc salts	Heat Stabiliser	Lubricant
293-208-8	91052-47-0	Glycerides, C16-18 mono-	Lubricant	Antistatic
293-215-6	91052-54-9	Glycerides, C16-18 mono-, di- and tri-	Lubricant	n.a.
293-728-5	91082-17-6	Sulfonic acids, C10-21-alkane, Ph esters	Plasticiser	n.a.
295-361-6	92044-82-1	Fatty acids, C9-13-neo-, barium salts	Heat stabiliser	n.a.
295-362-1	92044-83-2	Fatty acids, C9-13-neo-, potassium salts	Heat stabiliser	n.a.
295-363-7	92044-84-3	Fatty acids, C9-13-neo-, zinc salts	Heat stabiliser	n.a.
296-473-8	92704-41-1	Kaolin, calcined	Filler	n.a.
300-141-0	93922-04-4	barium 4-dodecylphenolate	Heat stabiliser	n.a.
304-780-6	94279-36-4	1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters	Plasticiser	n.a.
305-962-8	95370-96-0	Fatty acids, C14-22, 2-ethylhexyl esters, epoxidized	heat Stabiliser	n.a.
305-998-4	95465-85-3	Fatty acids, C14-18 and C16-18-unsatd., barium salts	Heat stabiliser	n.a.
306-084-8	95912-88-2	Fatty acids, C16-18, isotridecyl esters	Lubricant	n.a.
306-797-4	97404-33-6	Fatty acids, C16-18, C16-18-alkyl esters	Lubricant	n.a.
307-055-2	97489-15-1	Sulfonic acids, C14-17-sec-alkane, sodium salts	Antistatic	Emulsifier
308-208-6	97925-95-6	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	Antistatic	n.a.
309-928-3	101357-30-6	Silicic acid, aluminum sodium salt, sulfurized	Pigment	n.a.
310-193-6	1345-16-0	Cobalt aluminate blue spinel	Pigment	n.a.
401-540-3	84632-65-5	Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro-	Pigment	n.a.
401-990-0	106990-43-6	N,N',N'',N'''-tetrakis(4,6-bis(butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine	Antioxidant	n.a.
404-410-4	12027-96-2	Stannate (Sn(OH)62-), zinc (1:1), (OC-6-11)-	Flame retardant	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
405-290-6	12036-37-2	Zinc stannate	Flame retardant	n.a.
406-040-9	125643-61-0	reaction mass of isomers of: C7-9-alkyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	Antioxidant	n.a.
406-750-9	129757-67-1	A mixture of: bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decanedioate; 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-decan-1,10-dioyl)piperidin-1-yl)oxy]octane	Light Stabiliser	n.a.
411-080-5		Calcium 2-((5-amino-3-methyl-1-(3-sulfonatophenyl)-1H-pyrazol-4-yl)azo)-4,5-dichloro-benzenesulfonate	Pigment	n.a.
411-220-5	134701-20-5	2,4-dimethyl-6-(1-methyl-pentadecyl)phenol	Antioxidant	n.a.
411-380-6	147315-50-2	2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-((hexyl)oxy)phenol	Light Stabiliser	n.a.
413-890-4	82469-79-2	1,2,3-Propanetricarboxylic acid, 2-(1-oxobutoxy)-, 1,2,3-trihexyl ester (BTHC)	Plasticiser	n.a.
413-920-6	88949-33-1	Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis([1,1'-biphenyl]-4-yl)-2,5-dihydro-	Pigment	n.a.
416-250-2	84632-59-7	Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis[4-(1,1-dimethylethyl)phenyl]-2,5-dihydro-	Pigment	n.a.
419-370-3	84632-66-6	Pyrrolo[3,4-c]pyrrole-1,4-dione, 2,5-dihydro-3,6-bis(4-methylphenyl)-	Pigment	n.a.
421-090-1	131298-44-7	Benzoic acid, C9-11, C10-rich, branched alkyl esters	Plasticiser	n.a.
421-640-0		Reaction mass of 9-[(12-oxo-6a,12-dihydro-4H-isoindolo[2,1-a]heteropolycycl-10-yl)oxy]-12H-isoindolo[2,1-a]heteropolycycl-12-one, 10,10'-oxydi(12H-isoindolo[2,1-a]heteropolycycl-12-one) and 9,9'-oxydi(12H-isoindolo[2,1-a]heteropolycycl-12-one)	Pigment	n.a.
423-570-6	169314-88-9	aluminium-magnesium-zinc-carbonate-hydroxide	Heat Stabiliser	n.a.
431-890-2	166412-78-8	1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester	Plasticiser	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
432-420-9		6-(2,5-Dimethylbenzoyl)-3-hydroxy-2-(3-hydroxy-2-quinolinyl)-1 H-Inden-1 -one	Pigment	n.a.
433-240-3	253430-12-5	C.I. Pigment Yellow 214	Pigment	n.a.
447-010-5	670241-72-2	Nonylbenzoate, branched and linear	Plasticiser	n.a.
480-340-8	156157-97-0	Di(µ-2,2´,2´´-nitrilotris(ethanol)-diperchlorato)dinatrium	Heat Stabiliser	n.a.
500-015-7	9004-96-0	Oleic acid, ethoxylated	Viscosity modifier	n.a.
500-195-7	68131-39-5	Alcohols, C12-15, ethoxylated	Anti-fogging	n.a.
500-241-6	69011-36-5	Isotridecanol, ethoxylated	Antistatic	n.a.
600-734-7	106276-78-2	Benzoic acid, 2,3,4,5-tetrachloro-6-cyano-, methyl ester, reaction products with 4-[2-(4-aminophenyl)diazenyl]-3-methylbenzenamine and methanol sodium salt (1:1)	Pigment	n.a.
601-214-2	112926-00-8	Silicon dioxide	n.a.	n.a.
601-420-2	116265-68-0	Poly (dipropyleneglycol) Phenyl phosphite	Antioxidant	n.a.
602-617-6	12236-03-2	C.I. Disperse Orange 47	Pigment	n.a.
603-155-8	12671-74-8	C.I. Solvent Yellow 98	Pigment	n.a.
603-331-4	129423-54-7	4-Chloro-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid calcium salt (1:1)	Pigment	n.a.
603-411-9	1303-96-4	Sodium tetraborate decahydrate	Confidential	Flame Retardant
604-984-8	154946-66-4	Benzenesulfonic acid, 4-chloro-2-[2-[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazol-4-yl]diazenyl]-5-methyl-, ammonium salt (1:2)	Pigment	n.a.
605-352-4	164251-88-1	C.I. Solvent Red 195	Pigment	n.a.
606-790-9	215247-95-3	Diindolo[2,3-c:2',3'-n]triphenodioxazine, 9,19-dichloro-5,15-diethyl-5,15-dihydro-	Pigment	n.a.
607-104-0	225375-65-5	Polyhedral Oligomeric Silsesquioxane	Flame retardant	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
607-457-0	24937-78-8	Ethylene Vinyl Acetate	Impact modifier	n.a.
607-511-3	25053-09-2	methyl methacrylate-butadiene-styrene copolymer	Impact modifier	n.a.
607-520-2	250640-08-5	Benzoic acid, 4-[2-(2-hydroxy-6-sulfo-1-naphthalenyl)diazenyl]-, strontium salt (2:1)	Pigment	n.a.
607-544-3	25101-03-5	Hexanedioic acid, polymer with 1,2-propanediol	Plasticiser	n.a.
607-756-6	25608-33-7	Methylmethacrylate butylmethacrylate copolymer	Lubricant	n.a.
608-050-0	27136-15-8	Methyl methacrylate-butyl acrylate-styrene copolymer	Impact modifier	Lubricant
608-534-1	308069-39-8	silver phosphate glass	Biostabiliser	n.a.
608-609-9	31370-61-3	Benzene, 1,3-diisocyanatomethyl-, homopolymer	Adhesion-improving agent	n.a.
611-533-9	57455-37-5	C.I. Pigment Blue 29	Pigment	n.a.
612-812-8	61951-89-1	C.I. Solvent Violet 36	Pigment	n.a.
612-923-1	61969-44-6	C.I solvent blue 97	Pigment	n.a.
613-688-8	64754-90-1	Chlorinated polyethylene	Impact modifier	n.a.
614-115-4	67762-35-0	Coconut oil, ethoxylated	Lubricant	n.a.
614-498-8	68441-17-8	Ethene, homopolymer, oxidized	Lubricant	n.a.
614-625-7	68585-36-4	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C10-14-alkyl ethers, phosphates	Dispersing agent	n.a.
614-875-7	68989-03-7	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, ethoxylated, Me sulfates	Antistatic	n.a.
615-609-2	71838-95-4	C.I. Reactive Orange 82	Pigment	n.a.
615-613-4	71839-01-5	C.I. SOLVENT GREEN 28	Pigment	n.a.
616-600-6	78245-94-0	2,2'-((3,3'-Dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)- 3-oxobutanamide)	Pigment	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
617-600-9	84632-50-8	Benzonitrile, 3,3'-(2,3,5,6-tetrahydro-3,6-dioxopyrrolo[3,4-c]pyrrole-1,4-diyl)bis-	Pigment	n.a.
617-601-4	84632-59-7	Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis[4-(1,1-dimethylethyl)phenyl]-2,5-dihydro-	Pigment	n.a.
618-223-2	88949-33-1	C.I. Pigment Red 264	Pigment	n.a.
618-357-1	9003-18-3	Acrylonitrile Butadiene Rubber	Impact modifier	n.a.
618-371-8	9003-56-9	Acrylonitrile Butadiene Styrene	Impact modifier	n.a.
618-396-4	9004-81-3	Polyethylene glycol monolaureate	Lubricant	Antistatic
618-466-4	9011-14-7	Methylmethacrylate homopolymer	Lubricant	n.a.
618-500-8	9017-01-0	Benzene, 1,3-diisocyanatomethyl-, homopolymer	Bonding Agent	n.a.
618-500-8	9017-01-0	Benzene, 1,3-diisocyanato-2-methyl-, polymer with 2,4-diisocyanato-1-methylbenzene	Bonding Agent	n.a.
619-088-2	94945-26-3	C.I. Solvent Yellow 130	Pigment	n.a.
630-433-6	25852-37-3	2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate	Plasticiser	n.a.
638-753-8	68989-03-7	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, ethoxylated, Me sulfates	Antistatic	n.a.
639-967-4	24937-93-7	1,3-Butylene glycol, adipic acid polymer	Plasticiser	n.a.
680-352-5	9002-88-4	polyethylene wax	Lubricant	n.a.
688-127-3	68989-03-7	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, ethoxylated, Me sulfates	Antistatic	n.a.
700-073-5	1215036-04-6	Fatty acids, C8-10, diesters with 1,4:3,6-dianhydro-D-glucitol	Anti-fogging	n.a.
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	heat stabiliser	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
700-989-5		1,2-benzenedicarboxylic acid, di-C10-12-branched alkyl esters	Plasticiser	n.a.
700-990-0		Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate	Plasticiser	Flame Retardant
701-257-8	91082-17-6	C14-17 alkanes, sec-mono- and disulfonic acids, phenyl esters	Plasticiser	n.a.
701-279-8	1931129-39-3	benzyl butyl cis-cyclohexane-1,2-dicarboxylate	Plasticiser	n.a.
800-029-6	1290049-56-7	Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated	Heat stabiliser	n.a.
809-930-9	1330-78-5	Tris(methylphenyl) phosphate	Flame Retardant	Plasticiser
843-673-3	73018-26-5	Hexanedioic acid, polymer with 1,3-butanediol and 1,2-propanediol, 2-ethylhexyl ester	Plasticiser	n.a.
843-673-3	73018-26-5	polyesters of 1,2-propanediol and/ or 1,3- and/or 1,4-butanediol and/ or polypropyleneglycol with adipic acid, which may be end- capped with acetic acid or fatty acids C 12-C 18 or n-octanol and/or n-decanol	Plasticiser	n.a.
905-983-8		Reaction mass of benzyl 2-ethylhexyl adipate and bis(2-ethylhexyl) adipate and dibenzyl adipate	Plasticiser	n.a.
907-434-8		Reaction mass of ethylenebis(oxyethylene) dibenzoate and oxydiethylene dibenzoate and oxydipropyl dibenzoate	Plasticiser	n.a.
907-437-4		Reaction mass of oxydiethylene dibenzoate and oxydipropyl dibenzoate	Plasticiser	n.a.
914-460-3		Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters and Fatty acids, montan-wax, calcium salts and Montan wax	lubricant	n.a.

EC/List No.	CAS No.	Substance name	Main function	Other function
914-469-2		Reaction mass of Fatty acids, montan-wax and Glycerides, montan-wax and Montan wax	lubricant	n.a.
915-316-2		Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione	Heat stabiliser	n.a.
918-481-9		Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics	Solvent	n.a.
919-029-3		Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics,	Solvent	n.a.
919-164-8		Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	Solvent	n.a.
920-107-4		Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics	Solvent	n.a.
931-251-2		bis(decyl and/or dodecyl) benzene-1,2-dicarboxylate	Plasticiser	n.a.
931-299-4	68390-94-3	Amides, C16-18 and C18-unsatd., N,N'-ethylenebis-	Lubricant	n.a.
931-434-7		Reaction products resulting from the esterification of Sorbitol with C8 – 18 (even) and C18 unsaturated fatty acids in the ratio of 1:1	Anti-fogging	n.a.
939-379-0		Reaction mass of melamine and Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes	Pigment	n.a.
939-505-4		Reaction mass of p-t-butylphenyldiphenyl phosphate and bis(p-t-butylphenyl) phenyl phosphate	Flame Retardant	Plasticiser
939-588-7	91744-35-3	Reaction mass of dilauric acid, ester with dihydroxypropaneyl acetate and lauric acid, ester with hydroxypropanediyl diacetate	Plasticiser	Lubricant

EC/List No.	CAS No.	Substance name	Main function	Other function
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	Flame Retardant	Plasticiser
949-147-0	1041263-42-6	Tris(2-propylheptyl) phosphite	Heat stabiliser	n.a.
950-347-5		1,2-Cyclohexanedicarboxylic Acid, 1-(phenylmethyl) ester, ester with 2,2,4-trimethyl, 1,3-petanediol mono(2-methyl propanoate)	Plasticiser	n.a.

Table 21. List of PVC additives in focus for the investigation report prioritised as explained in section 3.2 of this report and Appendix B.2

Function	Subgroup	EC No.	CAS No.	Substance Name
Heat stabilisers	Organotin substances	239-622-4	15571-58-1	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
		239-581-2	15535-79-2	2,2-dioctyl-1,3,2-oxathiastannolan-5-one
		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
		222-883-3	3648-18-8	dioctyltin dilaurate
		260-829-0	57583-35-4	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
		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
		261-645-3	59185-95-4	2-ethylhexyl 12-ethyl-5,5-dioctyl-9-oxo-10-oxa-4,6-dithia-5-stannahexadecanoate
		234-186-1	10584-98-2	2-ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
		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

Function	Subgroup	EC No.	CAS No.	Substance Name
	Mono-, di- and triphenylphosphite derivatives	247-777-4	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	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(NLP)
Plasticisers	Ortho-phthalates	201-553-2	84-69-5	Diisobutyl phthalate
		205-016-3	131-17-9	Diallyl phthalate
		201-557-4	84-74-2	Dibutyl phthalate
		201-622-7	85-68-7	Benzyl butyl phthalate
		204-211-0	117-81-7	Bis(2-ethylhexyl) phthalate
		276-158-1	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich
		249-079-5	28553-12-0	Di-''isononyl'' phthalate
		258-469-4	53306-54-0	Bis(2-propylheptyl) phthalate
		271-082-5	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters
		271-084-6	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
		271-090-9	68515-48-0	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich
		222-884-9	3648-20-2	Diundecyl phthalate
		248-368-3	27253-26-5	Diisotridecyl phthalate
		271-085-1	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters

Function	Subgroup	EC No.	CAS No.	Substance Name
		271-089-3	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich
		271-091-4	68515-49-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich
		290-580-3	90193-76-3	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters
		700-989-5		1,2-benzenedicarboxylic acid, di-C10-12-branched alkyl esters
		931-251-2		bis(decyl and/or dodecyl) benzene-1,2-dicarboxylate
	Terephthalates	217-803-9	1962-75-0	Dibutyl terephthalate
		229-176-9	6422-86-2	Bis(2-ethylhexyl) terephthalate
	Trimellitates	304-780-6	94279-36-4	1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters
		290-754-9	90218-76-1	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters
		201-877-4	89-04-3	Trioctyl benzene-1,2,4-tricarboxylate
		258-847-9	53894-23-8	Triisononyl benzene-1,2,4-tricarboxylate
		253-138-0	36631-30-8	Triisodecyl benzene-1,2,4-tricarboxylate
	Benzoates	447-010-5	670241-72-2	Nonylbenzoate, branched and linear
		421-090-1	131298-44-7	Benzoic acid, C9-11, C10-rich, branched alkyl esters
Flame retardants	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
		809-930-9	1330-78-5	Tris(methylphenyl)phosphat
		939-505-4		Reaction mass of p-t-butylphenyldiphenyl phosphate and bis(p-t-butylphenyl) phenyl phosphate
		247-693-8	26444-49-5	Diphenyl tolyl phosphate
		700-990-0		Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate
		201-116-6	78-42-2	Tris-(2-ethylhexyl) phosphate
	Inorganic	215-175-0	1309-64-4	Diantimony trioxide
		245-322-4	22914-58-5	Dimolybdenum trizinc nonaoxide
		215-566-6	1332-07-6	Boric acid, zinc salt

Function	**Subgroup**	**EC No.**	**CAS No.**	**Substance Name**
		235-804-2	12767-90-7	Hexaboron dizinc undecaoxide
	Halogenated	264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro
		247-426-5	26040-51-7	Bis(2-ethylhexyl) tetrabromophthalate

REFERENCES

ASIF, M., MUNEER, T. & KUBIE, J. 2005. Sustainability analysis of window frames. *Building Services Engineering Research and Technology,* 26**,** 71-87.

BAITZ, M., KREIßIG, J., BYRNE, E., MAKISHI, C., KUPFER, T., FREES, N., BEY, N., SÖES HANSEN, M., HANSEN, A. & BOSCH, T. 2004. Life Cycle Assessment of PVC and of principal competing materials. *Commissioned by the European Commission.(July 2004),* 24.

BASSANI, F., RODRIGUES, C., MARQUES, P. & FREIRE, F. 2022. Life cycle assessment of pharmaceutical packaging. *The International Journal of Life Cycle Assessment,* 27**,** 978-992.

BLUM, A., BEHL, M., BIRNBAUM, L. S., DIAMOND, M. L., PHILLIPS, A., SINGLA, V., SIPES, N. S., STAPLETON, H. M. & VENIER, M. 2019. Organophosphate ester flame retardants: are they a regrettable substitution for polybrominated diphenyl ethers? *Environmental Science & Technology Letters,* 6**,** 638-649.

BYWALL, L. & CEDERLUND, S. 2020. Analysis of market and requirements of plasticizers for flexible PVC-With a focus on Perstorp's non-phthalate plasticizer Pevalen.

CARLISLE, S. & FRIEDLANDER, E. 2016. The influence of durability and recycling on life cycle impacts of window frame assemblies. *The International Journal of Life Cycle Assessment,* 21**,** 1645-1657.

CERESANA 2020. Market Study Windows & Doors. Not available online.

CHEMORBIS 2022a. Plasticizers - Europe H1 January 2022. Available at: https://www.chemorbis.com/en/plastics-news/Plasticisers---Europe-H1-January-2022-/2022/01/14/834608&isflashhaber=true#reportH.

CHEMORBIS 2022b. Plasticizers - Europe H2 April 2022. Available at: https://www.chemorbis.com/en/plastics-news/Plasticizers---Europe-H2-April-2022/2022/04/29/843220#reportH.

EC 2022. Request to the European Chemicals Agency to prepare an investigation report on PVC and PVC additives. Available at: https://www.echa.europa.eu/documents/10162/17233/mandate_pvc_and_additives_rev_en.pdf/a860fd87-4231-5ed4-157b-f6cda1ee5832?t=1655711170555.

EC 2023a. Better regulation toolbox. Available at: https://commission.europa.eu/system/files/2023-09/BR%20toolbox%20-%20Jul%202023%20-%20FINAL.pdf.

EC 2023b. Commission Regulation (EU) …/… of 25.9.2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles. Available at: https://single-market-economy.ec.europa.eu/system/files/2023-09/C_2023_6419_F1_COMMISSION_REGULATION_UNDER_ECT_EN_V5_P1_2620969.PDF.

EC 2023c. Plastics strategy. Available at: https://environment.ec.europa.eu/strategy/plastics-strategy_en.

EC 2023d. Proposal for a regulation of the European Parliament and of the Council on preventing plastic pellet losses to reduce microplastic pollution. Brussels, 16.10.2023, COM(2023) 645 final, 2023/0373 (COD). https://environment.ec.europa.eu/publications/proposal-regulation-preventing-pellet-losses_en.

ECHA 2006. Data on manufacture, import, export, uses and releases of bis(2-ethylhexyl)phthalate (DEHP) as well as information on potential alternatives to its use. Available at: https://echa.europa.eu/documents/10162/8fd5a74b-6807-42b6-ae1f-d1d7f04f40f8.

ECHA 2022. Medium-chain chlorinated paraffins (MCCP) Restriction Dossier. Available at: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18682f8e1.

ECHA 2023a. ECHA's completed activities on restriction. Available at: https://echa.europa.eu/completed-activities-on-restriction.

ECHA 2023b. Regulatory strategy for flame retardants. Available at: https://echa.europa.eu/documents/10162/ec392d86-7bfe-1eca-0f65-44c65b2c417f.

ECVM 2019. ECVM industry charter for the production of vinyl chloride monomer & PVC. Available at: https://pvc.org/wp-content/uploads/2023/04/ECVM-charter-pages.pdf.

EU 2022. The use of PVC (poly vinyl chloride) in the context of a non-toxic environment : final report. Available at: https://op.europa.eu/en/publication-detail/-/publication/e9e7684a-906b-11ec-b4e4-01aa75ed71a1.

EURO CHLOR 2023. Chlor-alkali industry review 2021-2022. Euro Chlor on its own transition pathways. Available at: https://www.chlorineindustryreview.com/wp-content/uploads/2022/08/Industry-Review-2021-2022.pdf.

EUROPEAN PLASTICISERS 2023. Plasticisers. Available at: https://www.plasticisers.org/plasticisers/.

EUROSTAT 2022. Game on! Extra-EU toy imports totalled €7.1 billion. Available at: https://ec.europa.eu/eurostat/en/web/products-eurostat-news/w/edn-20221228-1.

EUROSTAT 2023. HICP - all items - annual average indices. Available at: https://ec.europa.eu/eurostat/databrowser/view/tec00027/default/table?lang=en.

FENSTER, V. & FASSADE 2017. Die europäischen Fenstermärkte. Not available online.

FENSTER, V. & FASSADE 2023. Die europäischen Fenstermärkte. Not available online.

GIRARDI, P., BARBIERO, F., BACCINI, M., COMBA, P., PIRASTU, R., MASTRANGELO, G., BALLARIN, M. N., BIGGERI, A. & FEDELI, U. 2022. Mortality for lung cancer among PVC baggers employed in the vinyl chloride industry. *International Journal of Environmental Research and Public Health,* 19**,** 6246.

GLOBAL-MARKET-INSIGHTS 2021. Europe Medical Polymer Market Report. https://pvcmed.org/healthcare/facts-figures/.

HBM4EU 2022. Policy brief - Phthalates. Available at: https://www.hbm4eu.eu/wp-content/uploads/2022/07/HBM4EU_Policy-Brief-Phthalates-1.pdf.

HBM4EU 2023. Phthalates and Hexamoll® DINCH. Available at: https://www.hbm4eu.eu/hbm4eu-substances/phthalates-and-hexamoll-dinch/.

INTRATEC 2023. Dioctyl Phthalate Price | Current and Forecast. Available at: https://www.intratec.us/chemical-markets/dioctyl-phthalate-price.

MAAG, J., BRANDT, U. K., MIKKELSEN, S. H. & LASSEN, C. 2010. Inclusion of HBCDD, DEHP, BBP, DBP and additive use of TBBPA in annex IV of the Commission's recast proposal of the RoHS Directive. *Danish Environmental Protection Agency*.

MARANGONI, A. & GARBARINO 2011. PVC products competitiveness. A total cost of ownership approach. *Brussels, Belgium*.

MASTRANGELO, G., FEDELI, U., FADDA, E., MILAN, G., TURATO, A. & PAVANELLO, S. 2003. Lung cancer risk in workers exposed to poly (vinyl chloride) dust: a nested case-referent study. *Occupational and environmental medicine,* 60**,** 423-428.

MEYER, M., DIETRICH, S., SCHULZ, H. & MONDSCHEIN, A. 2021. Comparison of the technical performance of leather, artificial leather, and trendy alternatives. *Coatings,* 11**,** 226.

NORDIC EXPERT GROUP 2010. The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals, 143. Phosphate triesters with flame retardant properties; nr 2010; 44(6); isbn 978-91-85971-23-7; https://gupea.ub.gu.se/bitstream/2077/23825/1/gupea_2077_23825_1.pdf.

OECD 2009. ENV/JM/MONO(2009)1. Data Analysis of the Identification Of Correlations Between Polymer Characteristics and Potential for Health or Ecotoxicological Concern. https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf.

OWSIANIAK, M., BJØRN, A., BUGGE, H. B., CARVALHO, S. M., JEBAHAR, L., RASMUSSEN, J., WHITE, C. M. & OLSEN, S. I. 2018. Illustrative Case Study: Life Cycle Assessment of Four Window Alternatives. *Life cycle assessment: theory and practice***,** 1059-1146.

PINASSEAU, A., ZERGER, B., ROTH, J., CANOVA, M. & ROUDIER, S. 2018. Best Available Techniques (BAT) Reference Document for Waste Treatment. Available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/JRC113018_WT_Bref.pdf.

POLCHER, A., POTRYKUS, A., SCHÖPEL, M., WEIßENBACHER, J. & ZOTZ, F. 2020. Sachstand über die Schadstoffe in Kunststoffen und ihre Auswirkungen auf die Entsorgung. *Ramboll Deutschland GmbH*.

RAJU, G., SARKAR, P., SINGLA, E., SINGH, H. & SHARMA, R. K. 2016. Comparison of environmental sustainability of pharmaceutical packaging. *Perspectives in Science,* 8**,** 683-685.

SAADATIAN, S., FREIRE, F. & SIMOES, N. 2021a. Embodied impacts of window systems: A comparative assessment of framing and glazing alternatives. *Journal of Building Engineering,* 35**,** 102042.

SAADATIAN, S., SIMOES, N. & FREIRE, F. 2021b. Integrated environmental, energy and cost life-cycle analysis of windows: Optimal selection of components. *Building and Environment,* 188**,** 107516.

SADAT-SHOJAI, M. 2011. Polymer Degradation and Stability 96 (2011) 404-415.

SARAVANABHAVAN, G. & MURRAY, J. 2012. Human biological monitoring of diisononyl phthalate and diisodecyl phthalate: a review. *Journal of Environmental and Public Health,* 2012.

SEAC 2021. SEAC's approach to assessing changes in producer surplus. Available at: https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf.

SOUTAR, C., MILLER, B., GREGG, N., JONES, A., CULLEN, R. & BOLTON, R. 1997. Assessment of human risks from exposure to low toxicity occupational dusts. *The Annals of occupational hygiene,* 41**,** 123-133.

SOUVIRON, J., VAN MOESEKE, G. & KHAN, A. Z. 2019. Analysing the environmental impact of windows: A review. *Building and environment,* 161**,** 106268.

SPHERA 2022. Update of information in the study "Life Cycle Assessment of PVC and of principal competing materials". V 2.0. 21/09/2022. 338 p.

STUDNICKA, M., MENZINGER, G., DRLICEK, M., MARUNA, H. & NEUMANN, M. 1995. Pneumoconiosis and systemic sclerosis following 10 years of exposure to polyvinyl chloride dust. *Thorax,* 50**,** 583-589.

SVENSSON, K. 1994. Legislation, control and research in the Nordic countries on plastics for packaging food. *Food Additives & Contaminants,* 11**,** 241-248.

VINYLPLUS 2017. PVC recycling technologies. Available at: https://vinylplus.eu/wp-content/uploads/2017/02/VinylPlus_PVC_recycling_tech_20092017.pdf.

VINYLPLUS 2023. Progress report 2023. Reporting on 2022 activities. Available at: https://www.vinylplus.eu/our-achievements/progress-report-2023/.

WANG, Y., ZHU, H. & KANNAN, K. 2019. A review of biomonitoring of phthalate exposures. *Toxics,* 7**,** 21.

WAXWEILER, R. J., SMITH, A. H., FALK, H. & TYROLER, H. A. 1981. Excess lung cancer risk in a synthetic chemicals plant. *Environmental Health Perspectives,* 41**,** 159-165.

WEIL, E. D., LEVCHIK, S. & MOY, P. 2006. Flame and smoke retardants in vinyl chloride polymers–commercial usage and current developments. *Journal of Fire Sciences,* 24**,** 211-236.

ZHANG, Y.-T., WEI, W., SUN, J., XU, Q. & NI, B.-J. 2020. Long-term effects of polyvinyl chloride microplastics on anaerobic granular sludge for recovering methane from wastewater. *Environmental science & technology,* 54**,** 9662-9671.