ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

Annexes

SUBSTANCE NAME(S): Terphenyl, hydrogenated

IUPAC NAME(S): Terphenyl, hydrogenated

EC NUMBER(S): 262-967-7

CAS NUMBER(S): 61788-32-7

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

Istituto Superiore di Sanità (ISS)
on behalf of

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LIST OF ACRONYMS AND ABBREVIATIONS

CLH	Harmonised Classification and Labelling
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
COM	European Commission
CSP	Concentrated Solar Power
CSR	Chemical Safety Report
C/E	Cost-effectiveness
C&L	Classification and Labelling
EAC	Equivalent Annual Cost
ECHA	European Chemicals Agency
EEA	European Economic Area
EiF	Entry into Force
EPA	Environmental Protection Agency
ERC	Environmental Release Category
EU	European Union
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HTF	Heat Transfer Fluid
ISS	Istituto Superiore di Sanità - Italy
IU	Identified Uses
LR	Lead Registrant
NILU	Norwegian Institute for Air Research
NIVA	Norwegian Institute for Water Research
OC	Operational Condition

OECD	Organisation for Economic Co-operation and Development
OR	Only Representative
ORC	Organic Rankine Cycle
PBT	Persistent, Bioaccumulative and Toxic
PC	Product Category
PEC	Predicted Environmental Concentration
PET	Polyethylene terephthalate
PHT	Partially Hydrogenated Terphenyls
PROC	Process Category
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measures
RMO	Regulatory Management Option
RMOA	Regulatory Management Option Analysis
RO	Restriction Option
SCIP	Substances of Concern In articles as such or in complex objects (Products)
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SDS	Safety Data Sheet
SME	Small and Medium-sized Enterprises
SpERC	Specific Environmental Release Category
STP	Sewage Treatment Plant
SU	Sector of Use
SVHC	Substance of Very High Concern
UK	United Kingdom

USA	United States of America
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and very Bioaccumulative
WWTP	Wastewater Treatment Plant

Annex A: Manufacture and uses

A.1. Manufacture, import and export

Companies are responsible for collecting information on the properties and uses of Terphenyl, hydrogenated (in the following as well abbreviated as PHT from **P**artially **H**ydrogenated **T**erphenyls), if they manufacture or import the substance into the European Union (EU) above one tonne per year. This information is communicated through a registration dossier under the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1].

According to the information from the REACH registration on the European Chemicals Agency (ECHA) public dissemination website (ECHA, 2021a)[2], there are currently 6 active registrants of PHT. The Lead Registrant (LR), Eastman Chemical BV, registered the substance in 2010, the other five co-registrants registered it by the 2018 deadline. At least two of those member-registrants are assumed to be Only Representatives (OR), representing non-EU companies. The last update of the registration dossier was carried out by the LR in 2020.

The list of active registrations is as follows:

Table 1. REACH registrations

Registrant - Supplier	Country	Status	Registered	Updated
Eastman Chemical BV	Netherlands	LR	2010	2014; 2018; 2020
3M Belgium BVBA/SPRL	Belgium	Member Registrant	2018	2019
FRAGOL AG	Germany	Member Registrant	2018	2018; 2019
GCP Produits de Construction S.A.S	France	Member Registrant	2018	2018
LANXESS Distribution GmbH	Germany	Member Registrant	2018	
PPG Europe B.V.	Netherlands	Member Registrant	2018	

All these registrations are full registrations, according to Article 10 of the REACH Regulation.

The amount of PHT manufactured and imported into the EU is, according to registration data on the ECHA public dissemination website (ECHA, 2021a), in the range of 10 000 - 100 000 tonnes per year. This is diverging from the volumes reported by industry.

Information collected during stakeholder consultations, via interviews and questionnaires (as set out on **Annex G** (Stakeholder Information) reveals, that since the United Kingdom (UK) has left the EU, no manufacturing of PHT is taking place in the EU anymore.

Based on information received from stakeholders, the global volume of PHT manufactured in 2020 is approximately 32 000 tonnes per year, and the total volume imported in 2020 into the EU is assumed to be in the order of 7 500 tonnes per year. The EU volume of 7 500 tonnes

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[1] Regulation (EC) No. 1907/2006 (REACH Regulation). Consolidated version 01/03/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20220301&qid=1646849873367

[2] https://echa.europa.eu/registration-dossier/-/registered-dossier/15941

per year includes as well estimates of imports in articles and formulations in the order of 100 tonnes per year. A significant number of articles (> 12 000 entries, status on 2 March 2022) are reported in the Substances of Concern In articles as such or in complex objects (Products) (SCIP) Database (ECHA, 2021b), and it is proven that mixtures containing PHT can be ordered via Internet, for example from the United States of America (USA) to the EU. Moreover, the stakeholder information received indicates that some of the registrants are importing mixtures from non-EU countries into the EU and have therefore conducted a REACH registration.

Table 2 shows the estimated volumes and the global trend in the years 2018 – 2020. Manufacturers of PHT are located in the UK (Eastman), in the USA (Eastman), in China (e.g., Armcoltherm, Jiangsu Zhongneng Chemical) and in Saudi-Arabia (Farabi Petrochemicals). The trend in the EU and globally shows a significant increase of volume during the last two years, (approximately 25% from 2018 to 2019 and approximately 36% from 2019 to 2020 in the EU).

The Danish Environmental Protection Agency (EPA) referenced in its report[3] a steady growth in the Heat Transfer Fluid (HTF) market. This was confirmed by feedback during the public consultation.

Table 2. Estimated volumes globally and in the EU, based on stakeholder information

	PHT Volume Manufactured Globally (tonnes per year)		
	2020	**2019**	**2018**
Total Volume (tonnes per year)	32 000	25 000	23 000
Increase in %	28	9	-
	PHT Volume in EU (tonnes per year) – incl. in Articles imported		
	2020	**2019**	**2018**
Total Volume (tonnes per year)	7 500	5 500	4 400
Increase in %	36	25	-

The manufacturing process as taken from the literature is described under **Annex B.1.1**.

A.2. Uses

An overview of registered uses of PHT from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a) is presented below.

- Manufacture
- Uses as intermediate:
    - None
- Formulation:
    - Formulation, transfer, and packing of substances in preparations and mixtures
    - Formulation of adhesives and sealants
    - Formulation of coatings or inks
    - Formulation – use as additive in plastic applications

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[3] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net).

- Uses at industrial sites
    - Use as HTF
    - Use as adhesive and sealants
    - Use as solvent or process medium
    - Use for coatings or inks applications
    - Use as additive in plastic application
    - Use in laboratory analysis
- Uses by professional workers
    - Use as HTF
    - Use as adhesive and sealants
    - Use for coatings or inks applications
    - Use in laboratory analysis
- Consumer uses
    - None (uses advised against)
- Article service life (articles solely used by workers)
    - Articles produced from use as plasticiser
    - Articles produced from use of coatings and inks
    - Plastic articles

The main use of PHT (approximately 90% of the tonnage according to the stakeholder feedback) is as HTF. A HTF is a liquid or gas which is specifically manufactured for the transmission of heat. HTFs can be used by many sectors for any single- or multiple-station heat-using system. Thus, they are primarily used as an auxiliary fluid to transfer heat from a heat source to other areas of a process with heat demands. The HTF is a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source (heater). Selection of the most suitable HTF is based on the type of industrial applications, stable temperature range for safe operation and lifetime of the HTF. Synthetic HTFs like PHT do not require pressurizing at temperatures up to 350°C. Another advantage of using a mineral or synthetic fluid, as opposed to water, is that it generally has a lower freezing point. Lastly, HTFs also tend to be less reactive and corrosive to pipes and other parts of the system than water.

The use described as "use in laboratory analysis", where small amounts of in-use HTF is analysed to determine its lifetime, is also related to the HTF uses in industrial set-ups.

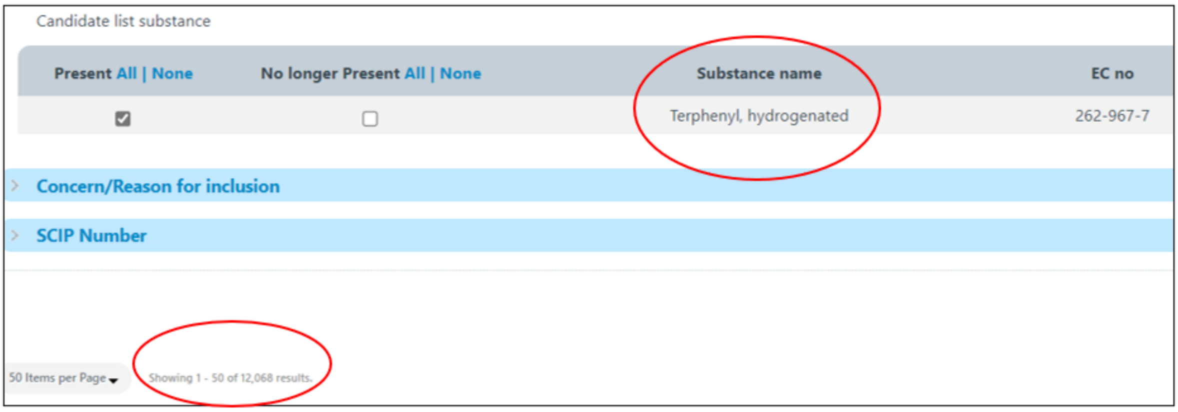
The use of the substance as a plasticiser is the second relevant use, involving around 10% of the tonnage range. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material. PHT is used as a plasticiser mainly for the production of coatings, sealants, and adhesives and in polymer applications. The final coatings, sealants, and adhesives are used in a wide variety of sectors, for example the aerospace industry. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables). This application is addressed in the "additive in plastic application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, PHT is also used as plasticiser in coatings and inks.

The remaining registered uses (both industrial and professional) involve less than 1% of the amount of substance imported into the EU. Consumer uses and intermediate uses have not been registered.

Based on information received from stakeholders, **Table 3** was prepared showing the EU volumes used for the main applications of PHT in the EU. The HTF use accounts for approximately 6 700 tonnes per year, reflecting approximately 90% of the total EU volume used. The non-HTF uses represent approximately 10% of the total volume. Plasticiser uses in sealants, adhesives, castings, and coating make-up for more than 9% of the non-HTF uses, while < 1% remains to processing solvents, corrosion inhibitor oils and laboratory chemicals (e.g., analytical standards, immersion oils).

The SCIP database (ECHA, 2021b) was checked on 2 March 2022. In total more than 12 000 articles containing PHT have been notified to this database. Most entries are related to use in polymers, rubber & elastomers (> 60%), sealants (> 25%), inks (> 5%), sensors (< 1%), paper (> 1%) and a few others. In summary it can be concluded that around 85% of PHT use in articles is related to plasticiser uses. The Dossier Submitter assumes that some additional PHT volume will be entering the EU via articles, due to the high number of notifications in SCIP. The information obtained though analysis of the SCIP database will be addressed in the exposure assessment (please refer to **Annex B.9.**).

Figure 1. Number of notifications to the SCIP database on articles including PHT (Status March 2022)



Candidate list substance

Present All | None	No longer Present All | None	Substance name	EC no
☑	☐	Terphenyl, hydrogenated	262-967-7

Showing 1 - 50 of 12,068 results.

An internet search by the Dossier submitter found 66 Safety Data Sheets (SDSs) in EU and USA format for non-HTF products, mainly plasticiser formulations. The concentration levels of PHT within these mixtures are ranging from < 1 to 60%.

Table 3. Split of volumes per use in the EU based on information provided by stakeholders

EU Uses	**Volume (tonnes per year)**	**%**
HTF	**6 700**	**89.68**
Industrial Adhesives, Castings, Sealants	300	4.02
Aerospace Coatings	250	3.35
Aerospace Sealants	180	2.41
Processing Solvent or Aids	35	0.47
Corrosion Inhibitor Oils	4	0.05
Analytical Standards	1	0.01
Microscope Immersion Oils	0.5	0.01
Total non-HTF	**771**	**10.31**

As shown above, the main use of PHT with approximately 90% annual tonnage is as a high-temperature non-pressurised HTF. When used as an HTF, PHT is a significant utility chemical for EU manufacturing of polyethylene terephthalate (PET) and other polymers, the conversion of biomass to energy, chemicals, and energy production in closed loop manufacturing systems.

Table 4 outlines the use as HTF and it shows the estimated EU installed base in existing plants handling PHT for this use. This information is based on feedback from the stakeholder consultations and individual communications. The assumed EU-wide installed base is approximately 25 000 tonnes. In 2020 approximately 6 700 tonnes of PHT were sold on the EU market, from which around 5% were used for "top-up". The top-up or refill demand is driven by the degradation rate of the HTF and the separated low-boiling and high-boiling degradation products. It needs to be understood that the refill cannot be associated with loss of PHT into the environment. Approximately 34% of that volume (2 275 tonnes) was used for replacements of the whole PHT in existing plants, at the point when the HTF had to be completely exchanged and disposed of. The life cycle was reported with >20 years. 58% (approximately 3 900 tonnes) account for filling new installed plants in the EU.

The degradation rate of the system is determined by the sum of degraded fluid.

Table 4. Installed base in the EU and uses as HTF

Use of HTF volumes on annual base		
	Tonnes	%
Installed Base in EU	25 000	-
Total volume sold in 2020	6 700	
Top-up existing plants	325	5
Replacement existing plants	2 275	35
Filling new plants	3 900	60

According to the data obtained from stakeholders, the total number of closed loop manufacturing systems using PHT as HTF in the EU is close to 1,300 systems, which are installed in 24 of the 27 EU Member States. Around 40% of the plants have an installed capacity of < 10 tonnes, which is pointing to the use of systems in Small and Medium-sized Enterprises (SME) companies, approximately 50% are in the range of systems with > 10 to < 50 tonnes and less than 10% are > 50 tonnes.

Table 6 provides an overview on the number of systems installed and installed volume per EU Member State. Italy, Germany, and France are covering 70% of the volume and 75% of the systems.

Table 5 shows the distribution of the EU HTF use to the different application sectors. The total amount of installed volume is slightly higher compared to **Table 6** since the UK volumes are still included in this table. The highest percentage of HTF use is in the manufacturing of chemicals, specialty chemicals and petrochemicals. It should be noted that approximately 20% of PHT is already used in renewable energy processes. Concentrated Solar Power (CSP) is an innovative technology to transfer heat from the solar collectors to the power cycle. Organic Rankine Cycle (ORC) are considered to be a next generation technology as well for power generation from residual heat, for example for cost-effective power generation using waste or biomass heat from combustion or production processes.

The waste heat evaporates an organic working fluid when temperatures are still relatively low and drives a generator in a closed thermal circuit. The heat used for ORC power generation can then be employed in further processes, for example for heating purposes.

CSP and ORC are both innovative technologies for renewable energy generation. Other HTF uses include manufacturing of polymers, metals, oil and gas processing, process equipment heating, energy recovery, food processing and wood processing.

Table 5. Installed HTF Volume by application sector in 2017

EU HTF Volume installed by Application Sector (2017) (incl. UK)		
Application	**Installed volume (tonnes)**	**%**
Chemicals, Specialties and Petrochemicals	11 900	48.08
Renewable Energy (e.g. ORC, CSP)	5 350	21.62
Polymers & Plastics (incl. PET)	5 000	20.20
Oil and Gas Processing	1 300	5.25
Process Equipment Heating (Food, Aluminium, Wood)	1 200	4.85
Total installed Volume	**24 750**	**100**

The heat used for ORC power generation can then be employed in further processes, for example for heating purposes. CSP and ORC are both innovative technologies for renewable energy generation. Other HTF uses include manufacturing of polymers, metals, oil and gas processing, process equipment heating, energy recovery, food processing and wood processing.

Table 6. Installed HTF volume and number of sites in 2018 per EU Member State

Member State	No. of Systems	Volume (t)	Systems > 50 t (%)	Systems >10<50 t (%)	Systems <10 t (%)
Austria	40 - 50	730 - 750	10	50	40
Belgium	40 - 50	875 - 900			
Bulgaria	< 5	30 - 40			
Croatia	< 5	100 - 120			
Czech Republic	5 - 10	100 - 120			
Denmark	5 - 10	130 - 140			
Estonia	5 - 10	40 - 50			
Finland	10 - 15	100 - 110			
France	175 - 200	2 200 - 2 300			
Germany	375 - 400	5 000 – 5 200			
Greece	25 - 30	600 - 620			
Ireland	5 - 10	15 - 20			
Italy	400 - 420	7 800 – 7 900			
Latvia	10 - 15	180 - 200			
Lithuania	< 5	330 - 350			
Luxembourg	5 - 10	40 - 50			
Netherlands	50 - 60	2 500 – 2 600			
Poland	15 - 20	900 - 950			
Portugal	5 - 10	50 - 70			
Romania	5 - 10	280 - 300			
Slovakia	< 5	120 - 140			
Slovenia	5 - 10	40 - 50			
Spain	35 - 40	750 - 780			
Sweden	5 - 10	130 - 150			
TOTAL	**1 300**	**24 000**			

Considering the REACH use description (ECHA, 2015), information currently available for this substance in the ECHA public dissemination website (ECHA, 2021a) is described next.

<u>Formulation, transfer and repackaging of substances in preparations and mixtures</u>

Contributing activity/technique for the environment:

- ERC2: Formulation into mixture

Contributing activity/technique for the workers:

- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8b: Transfer of substance or mixture (charging and discharging) at

dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

Formulation of adhesives and sealants

Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15: Use as laboratory reagent

Product category formulated:
- PC 1: Adhesives, sealants
- PC 0: Other: Construction products

Formulation of coatings or inks

Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent

Product category formulated:
- PC 9a: Coatings and paints, thinners, paint removes

- PC 9b: Fillers, putties, plasters, modelling clay

Formulation - use as additive in plastic applications
Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation and handling of substances bound in/on materials or articles
- PROC 24: High (mechanical) energy work-up of substances bound in/on materials and articles

Product category formulated:
- PC 32: Polymer preparations and compounds

Use as HTF at industrial sites
Contributing activity/technique for the environment:
- ERC7: Use of functional fluid at industrial site

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities [EU REACH]
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent
- PROC 16: Use of fuels
- PROC28: Manual maintenance (cleaning and repair) of machinery

Product category used:
- PC 16: HTFs

Sector of end use:
- SU 8: Manufacture of bulk, large scale chemicals (including petroleum

products)
- SU 9: Manufacture of fine chemicals
- SU 0: Other: various SUs

Laboratory analysis
Contributing activity/technique for the environment:
- ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers:
- PROC 15: Use as laboratory reagent

Product category used:
- PC 21: Laboratory chemicals

Use of adhesives and sealants at industrial sites
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation

Product category used:
- PC 1: Adhesives, sealants

Sector of end use:
- SU 0: Other: SU3

Direct use for industrial coatings or inks applications
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at

dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent

Product category used:
- PC 9a: Coatings and paints, thinners, paint removes
- PC 9b: Fillers, putties, plasters, modelling clay

Sector of end use:
- SU 0: Other: SU3

Use as additive in plastic application

Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers:
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Product category used:
- PC 32: Polymer preparations and compounds

Sector of end use:
- SU 12: Manufacture of plastics products, including compounding and conversion

Use as solvent or process medium

Contributing activity/technique for the environment:
- ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at

dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 16: Use of fuel

Sector of end use:
- SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)
- SU 9: Manufacture of fine chemicals

Use as laboratory chemical by professionals

Contributing activity/technique for the environment:
- ERC9a: Widespread use of functional fluid (indoor)

Contributing activity/technique for the workers:
- PROC 15: Use as laboratory reagent

Product category used:
- PC 21: Laboratory chemicals

Sector of end use:
- SU 0: Other: SU22

Use as HTF at professional sites

Further description of the use:

Contributing activity/technique for the environment:
- ERC9a: Widespread use of functional fluid (indoor)
- ERC9b: Widespread use of functional fluid (outdoor)

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

Product category used:
- PC 16: HTFs

Sector of end use:
- SU 0: Other: various SUs

Use of adhesives and sealants by professionals

Contributing activity/technique for the environment:
- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers:
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
  PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 10: Roller application or brushing
- PROC 11: Non-industrial spraying
- PROC 13: Treatment of articles by dipping and pouring

Product category:
- PC 1: Adhesives, sealants

Sector of end use:
- SU 0: Other: SU22

Direct use for professional coatings or inks applications
Contributing activity/technique for the environment:
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 11: Non-industrial spraying
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent
- PROC 28: Manual maintenance (cleaning and repair) of machinery

Product category used:
- PC 9a: Coatings and paints, thinners, paint removes
- PC 9b: Fillers, putties, plasters, modelling clay

Service life of articles produced from use as plasticiser
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of articles produced from use of coatings and inks
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of plastics
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Article Category:

- AC 13: Plastic Articles

In the past PHT was used in carbonless copy paper. PHT contaminants have been detected in food cardboard packages made from recycled material containing carbonless copy paper (Sturaro, A. et al, 1995). However, this use has been terminated many years ago. Via internet search of the Dossier Submitter, one "exotic"[4,5] application was found, PHT was used as evaporation modifier for insecticides in electric vaporizer against mosquitoes. This application seems to have stopped as well.

Annex E will describe in further detail the uses and applications and the impacts resulting from the restriction proposal by the Dossier Submitter.

A.3. Uses advised against by the registrants

Consumer uses have been designated by the registrants as uses advised against according to the ECHA public dissemination website (ECHA, 2021a). Consumer uses on coating or ink applications and as adhesives and sealants are advised against.

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[4] Microsoft Word - 00000000000000173798_1100764895210 (schneckenprofi.de)

[5] EPO - European publication server

Annex B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.1.1. Name and other identifiers of the substance(s)

An overview of the name of the substance and other identifiers is given in **Table 7**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), the Substance of Very High Concern (SVHC) Support Document (ECHA, 2018a) or the Chemical Safety Report (CSR) from the LR (Solutia, 2019).

Table 7. Substance identification information

Property	Substance
Regulatory process name	Terphenyl, hydrogenated Terphenyls, hydrogenated
IUPAC names	Hydrogenated Terphenyl Terphenyl, hydriert Terphenyl, hydrogenated
Other names (trade names and abbreviation)	Partially hydrogenated terphenyls PHT
EC number	262-967-7
EC name	Terphenyl, hydrogenated
CAS number	61788-32-7
CAS name	Terphenyl, hydrogenated
Molecular formula	C18Hn (n >18-36)
Molecular weight range	≥236 - ≤248

Type of substance:

Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Description of the UVCB substance:

PHT is produced by hydrogenation of a mixture of o-, m- and p-terphenyl and various quaterphenyls. The degree of hydrogenation is typically below 75%. PHT is a complex substance containing isomers of terphenyl and quaterphenyls as well as their hydrogenated versions.

Methods of manufacture of the UVCB substance PHT:

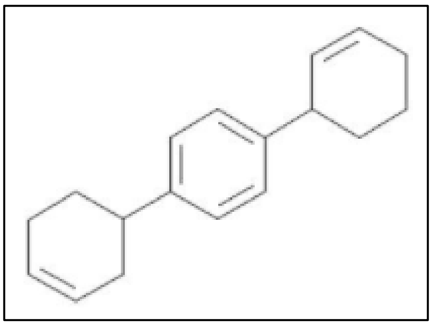
This UVCB substance is manufactured by the batchwise, partial catalytic hydrogenation of the complete mixture of the ortho-, meta- and para- isomers of terphenyl, with a lesser amount of quaterphenyl isomers. There is no physical blending of any of the constituents to make this UVCB substance. Commercially available hydrogenated terphenyls are approximately 40% hydrogenated mixtures of ortho-, meta-, and para-terphenyls in various stages of hydrogenation, which are clear, yellow oils (Boogaard P.A., 2019).[6]

According to a patent (CN103804114A, 2014)[7], PHT is manufactured within the production process of biphenyl ($C_{12}H_{10}$, CAS 92-52-4). Basically, terphenyls are manufactured merely as an accompanying product in the manufacture of biphenyl and vice-versa. Consequently, the economical manufacturing of both substances separately is not possible on commercial scale. The Danish EPA published in its report on Biphenyl (40 - FINAL REPORT, 2014)[8], that Monsanto (now Solutia) is manufacturing biphenyl via the dehydrocondensation of benzene and production is carried out in gas or electrically heated tubular reactors at 700 – 800°C with residence and contact times of only a few seconds. The valuable accompanying substances produced are terphenyls, which come in the form of ortho-, meta-, para-, tri- and poly-terphenyl isomers. The yield is considered to be in the area of 50/50 between biphenyl and terphenyls (Thompson Q., 1992).

Origin:

Organic.

Structural formula:



B.1.2. Composition of the substance(s)

The composition of the substance includes fully aromatic structures such as terphenyls, quaterphenyls, pentaphenyls and structures resulting from the hydrogenation of these constituents such as 1-cyclohex-2-en-1-yl-4-cyclohex-3-en-1-ylbenzene.

According to the SVHC Support Document (ECHA, 2018a), representative structures from identified groups of constituents are shown in **Table 8**:

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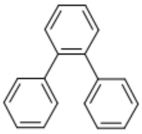
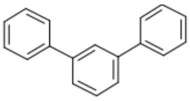
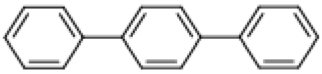
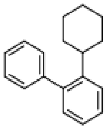
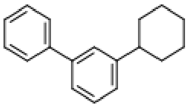
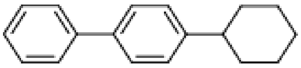
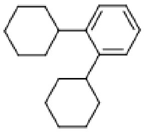
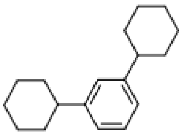
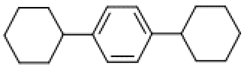
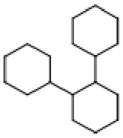
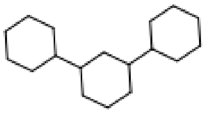
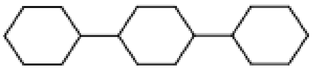
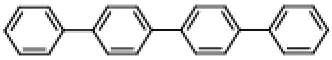
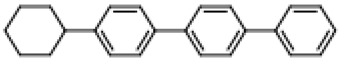
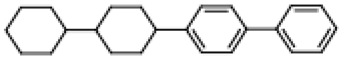
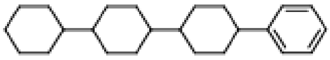
[6] Boogaard P.J., Professor of Environmental Health and Human Biomonitoring, Wageningen University and Research Centre, and Toxicologist, Shell International BV, The Hague (until December 31, 2019). Hydrogenated terphenyl | Advisory report | The Health Council of the Netherlands

[7] CN103804114A - Method for preparing hydrogenated terphenyl - Google Patents

[8] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net) https://prodstoragehoeringspo.blob.core.windows.net/9cbcbe23-83c1-4ff5-92bc-183a263dfe86/40%20-%20FINAL%20REPORT%20-%20Biphenyl%20LOUS%20-%202014%2011%2004.pdf

Table 8. Representative structures from identified groups of constituents

Group	**Contains**	**Representative structure**	
		Name (CAS)	**Structure**
o-T	ortho-terphenyl	1,2-terphenyl (CAS 84-15-1)	
m-T	meta-terphenyl	1,3-terphenyl	
p-T	para-terphenyl	1,4-terphenyl (CAS 92-94-4)	
o-HT1	1-ring hydrogenated terphenyls	2-cyclohexylbiphenyl	
m-HT1		3-cyclohexylbiphenyl	
p-HT1		4-cyclohexylbiphenyl	
o-HT2	2-ring hydrogenated terphenyl	1,2-dicyclohexylbenzene	
m-HT2		1,3-dicyclohexylbenzene	
p-HT2		1,4-dicyclohexylbenzene (CAS 1087-02-1)	

o-HT3	3-ring hydrogenated terphenyls	o-tercyclohexyl	
m-HT3		m-tercyclohexyl	
p-HT3		p-tercyclohexyl	
p-Q	Quaterphenyls	para-quaterpheny	
p-HQ1	1-ring hydrogenated quaterphenyls	4-cyclohexylterphenyl	
p-HQ2	2-ring hydrogenated quaterphenyls	dicyclohexylbiphenyl	
p-HQ3	3-ring hydrogenated quaterphenyls	tercyclohexylbenzene	

It is not possible to know the exact content of these constituents in the final PHT product, However, ortho-terphenyl (which is the constituent that fulfils both vP and vB criteria) occurs in significant concentrations in the UVCB substance (> 0.1%).

The composition of the substance (boundary) according to the SDS[9] is the following:

Table 9. Substance composition

Constituent	Reference name	Concentration range (w/w)	EC number	CAS number
1	Terphenyl, hydrogenated	74 - 87	262-967-7	61788-32-7
2	Terphenyl	3 - 8	247-477-3	26140-60-3
3	Quaterphenyls, Pentaphenyls and hexahydropentaphenyls, their isomers and other hydrocarbons	10 - 8	273-316-1	68956-74-1

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[9] THERMINOL-66-SDS-EASTMAN.pdf (americasinternational.com)

B.1.3. Physicochemical properties

An overview of the physiochemical properties is given in **Table 10**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), the SVHC Support Document (ECHA, 2018a) and the CSR of the LR (Solutia, 2019).

Table 10. Physicochemical properties

Property	Substance	Value	Reference
Physical state	Terphenyl, hydrogenated (CAS 61788-32-7)	Clear pale-yellow liquid	Newport plant specifications for Therminol 66, HB-40 (2008)
Melting point - Freezing point	Terphenyl, hydrogenated (CAS 61788-32-7)	below -24°C (pour point)	Unnamed study report
		below -28°C (pour point)	Secondary source
Boiling point	Terphenyl, hydrogenated (CAS 61788-32-7)	342°C (1013 hPa)	Unnamed study report (2009)
		359°C (1013 hPa)	Secondary source (2003)
Density	Terphenyl, hydrogenated (CAS 61788-32-7)	1 013 (20°C)	Company data (2009)
		1008.4 kg/m^3 (20°C)	Secondary source (2003)
Vapour pressure	Terphenyl, hydrogenated (CAS 61788-32-7)	0.002 hPa (20°C)	Calculation using the Antoine equation
	4-Cyclohexyl-1,1'-biphenyl (CAS 3842-58-8)	2.24E-05 hPa	QSAR tool MPBPWIN v1.43
	1,3-diphenylcyclohexane (CAS 1667-08-9)	8.01E-05 hPa	QSAR tool MPBPWIN v1.43
	3-phenyldicyclohexyl (CAS 20273-26-1)	1.81E-04 hPa	QSAR tool MPBPWIN v1.43
	1,4-dicyclohexylbenzene (CAS 1087-02-1)	1.21E-04 hPa	QSAR tool MPBPWIN v1.43
	1,1':3',1''-Tercyclohexane (CAS 1706-50-9)	1.00E-03 hPa	QSAR tool MPBPWIN v1.43
Partition coefficient	Terphenyl, hydrogenated (CAS 61788-32-7)	6.5 (20°C)	Unnamed study report (2010)
	Terphenyl, hydrogenated (CAS 61788-32-7)	6.1 (20°C)	Secondary source, Monsanto international communication (1979)
Water solubility	Terphenyl, hydrogenated (CAS 61788-32-7)	0.061 mg/L (20°C)	Unnamed study report (1995)

	Terphenyl, hydrogenated (CAS 61788-32-7)	0.08 mg/L (20°C)	Unnamed study report (1995)
Flashpoint	Terphenyl, hydrogenated (CAS 61788-32-7)	170°C (1013 hPa)	Secondary source (2003)
	Terphenyl, hydrogenated (CAS 61788-32-7)	171°C (atmospheric pressure not recorded)	Company data (1997)
	Terphenyl, hydrogenated (CAS 61788-32-7)	188°C (atmospheric pressure not recorded)	Company data (2003)
Auto flammability	Terphenyl, hydrogenated (CAS 61788-32-7)	374°C (1013 hPa)	Company data (1996)
	Terphenyl, hydrogenated (CAS 61788-32-7)	399°C (1013 hPa)	Secondary source (2003)
Viscosity	Terphenyl, hydrogenated (CAS 61788-32-7)	133 mm^2/s (static, 20°C)	Company data (2010)
	Terphenyl, hydrogenated (CAS 61788-32-7)	79.56 mm^2/s (25°C)	Unnamed study report (1994)

B.2. Manufacture and uses (summary)

The data on manufacture and uses are described in **Annex A**: Manufacture and uses.

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Currently there is no harmonised classification for PHT included in Annex VI of the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

There is also no registered proposal on the Registry of Intention for harmonised classification and labelling (CLH).

B.3.2. Classification and labelling in classification and labelling inventory - Industry's self-classification(s) and labelling

Classification and labelling (C&L) Inventory

The range of classifications that have been notified to the C&L Inventory (ECHA, 2021c), alone or combined, is the following:

- Not classified
- Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects)
- Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects)
- Aquatic Chronic 4 (H413: May cause long lasting harmful effects to aquatic life)
- Aquatic Acute 1 (H400: Very toxic to aquatic life)

The status of the notifications in the C&L Inventory (ECHA, 2021c) checked on 12th October 2021 is the following:

- Number of aggregated notifications: 8
- Total number of notifiers: 669

Detailed notifications are given in **Table 11**.

Table 11. C&L notifications

Aggregated Notification	Classification		Labelling		M-Factors	Additional Notified Information	Number of Notifiers	Joint Entries
	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Pictograms and Signal Word Code(s)				
1	Aquatic Chronic 2	H411	H411	GHS09		State or Form	27	X
2	Aquatic Chronic 4	H413	H413			State or Form	596	
3	Aquatic Chronic 2	H411	H411	GHS09			18	
4	Not classified						15	
5	Aquatic Chronic 4	H413	H413		M (Chronic) = 0	State or Form	7	
6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H410	GHS09 Wng		State or Form	3	
7	Aquatic Chronic 1	H410	H410	GHS09 Wng	M (Chronic) = 1		2	
8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H400 H410	GHS09 GHS07 Wng			1	

Self-classification by industry

The co-registrants of PHT provided the following self-classification in the registration dossier (ECHA, 2021a):

- Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects)

The labelling information provided by the registrants in the registration dossier is the following:

- Hazard statement - code: Toxic to aquatic life with long lasting effects - H411

- Pictogram code: GHS09 (environment)

- Signal word code: no signal word

- Precautionary statement - code: Avoid release to the environment - P273
- Precautionary statement - code: Collect spillage - P391

- Precautionary statement - code: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/ supplier or the competent authority to specify whether disposal requirements apply to contents, container, or both - P501.

B.4. Environmental fate properties

The environmental fate properties have been summarised previously (ECHA, 2018a) and were the key arguments leading to the identification of PHT as an SVHC due to its vPvB properties based on a weight of evidence approach of the available data.

From the available data it can be definitively concluded that at least o-terphenyl fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1% w/w), PHT is considered to fulfil the vPvB criteria. In conclusion, PHT meets the criteria to be considered a vPvB substance according to Article 57 (e) of REACH.

The following sub-sections on the environmental fate properties of the substance are therefore just summarizing the full data set for PHT.

B.4.1. Degradation

Biodegradability in water

Several tests have been conducted to assess the biodegradability of hydrogenated Terphenyls. Most of the studies were carried out with hydrogenated Terphenyls as test substance; however, a limited number of study reports are also available for dilutions of the test substance. Whereas the primary test substance contains 40% of hydrogenated Terphenyls, two other test substances consist of 30% hydrogenated Terphenyls and a 40% hydrogenated polyphenyl mixture, respectively.

With the primary test substance different types of biodegradation tests were carried out. Reports of ready biodegradability tests monitoring CO_2 evolution (% of CO_2 produced compared to theoretical CO_2 production) yielded the following results after 35 days: 1% (initial substance concentration 15.1 mg/L) and 3% (initial substance concentration 10.3 mg/L) in the first test, while 3% at starting concentration of 45.8 mg/L in the second test (Saeger et al., 1977). After acclimation of the inoculum in the first test 50% degradation was observed (initial test concentration 16.7 mg/L) after 46 days.

Several reports of inherent biodegradability tests (semi-continuous activated sludge tests - SCAS) with different feed levels, test durations and exposure durations of the inoculum are available. 68.1% primary degradation was observed in 24 hours in a first test (Saeger et al., 1972), whereas an overall disappearance rate of 35.1 ± 8.6% using a 24-hour cycle (overall value calculated over four measurement periods in a testing period of nine months) was calculated in another test (Saeger and Tucker, 1970). With extended exposure of the residue after the normal test period to the activated sludge, nearly complete disappearance was achieved. This observation was confirmed by another SCAS test (Monsanto report AC-71-SS-4, 1970), which indicated that a primary biodegradation rate of 49 ± 7% (using a 24-hour cycle) could be obtained with non-acclimated activated sludge during the latter stage of the test, while significantly lower rates were obtained during the first 12 weeks of the test. In yet another SCAS test an overall primary degradation rate of 64 ± 5% using a 24-hour cycle was observed when using an acclimated inoculum (Saeger et al., 1977). The results clearly indicated the benefits of an extended acclimation period. Furthermore, it was noted that although differences exist in the degradation rate of the various constituents of the test substance, no evidence was found of highly resistant constituents. Finally, a river die away test with the primary test substance showed that 80% of the test substance had disappeared after 50 days when starting at a 1 ppm level (Monsanto report AC-71-SS-4, 1970).

Tests with the two other test substances yielded results that corresponded to expectations based on the composition of the different substances: since the level of hydrogenation is lower than 30% hydrogenated Terphenyls, the substance contains a higher proportion of constituents containing only one hydrogenated ring. The latter are considered to be more biodegradable compared to Terphenyl constituents with two hydrogenated rings. Conversely, the test substance with 40% hydrogenated polyphenyls has a higher degree of hydrogenation and is therefore expected to be less biodegradable.

A river die-away test with 30% hydrogenated Terphenyls showed that after 14 days the initial level of test substance was reduced by 95% (Gagel et al., 1983). After 28 days no constituents of the substance could be detected anymore. In addition, a SCAS test with this substance yielded mean disappearance rates of 68.1 ± 6.5 (95% confidence interval) and 65.6 ± 13.3 (95% confidence interval) at addition rates of 5 and 20 mg per 24h cycle, respectively (Saeger et al., 1972). After 4 weeks, no constituents of the test substance were detected anymore.

Finally, a ready biodegradability test with the test substance with 40% hydrogenated polyphenyls (with initial concentration of 20.9 mg/L) gave a mean value of 14% CO^2 evolution, indicating a low extent of mineralization (Monsanto report ES-80SS-34).

To conclude, it can be stated that the primary test substance with 40% hydrogenated Terphenyls is moderately biodegradable provided that sufficient time for acclimation of the inoculum is provided. Moreover, differences in degradation rates of the various constituents have been observed. However, there is no evidence of highly resistant constituents. Test results with other substances such containing 30% hydrogenated Terphenyls or 40% hydrogenated polyphenyls respectively moreover indicated that the extent of biodegradability is related to the level of hydrogenation.

Biodegradability in soil

The degradation rate (DT50 and DT90) was determined of 14C-labelled 1,4-dicyclohexylbenzene in three different soils (Speyer 2.2 (loam), Speyer 2.3 (sandy loam) and Speyer 6S (clay)) and its degradation route in one of these soils (Tan, 2009). For this purpose, (phenyl-14C(U))-p-dicyclohexylbenzene was incubated in three soils in the dark. The concentration of the substance was determined after various incubation periods by HPLC of the soil extracts. Major metabolites were characterized and identified if feasible. The duration of the incubation was 120 days.

The extractable activity decreased during the first 14 days of incubation from 99% of the applied radioactivity to approximately 25 to 50.3%. In all investigated soils, the soil extractable activity gradually decreased to 8.1 – 10.5% at the end of the incubation.

Phenyl-14C(U))-p-dicyclohexylbenzene quickly degraded and mineralized in the tested soils. In Speyer 6S soil three major metabolites were formed that were above 10% of the applied activity. In Speyer 2.3 two metabolites were twice above 5% of the applied radioactivity at two consecutive time points. The major metabolites degraded rapidly. Other metabolites were only formed in minor amounts.

The DT50 (d) for the parent compound was 4.1, 4.6 and 1.8 in Speyer 2.2, Speyer 2.3, and Speyer 6S, respectively.

B.4.2. Environmental distribution

The Koc and log Koc values of the main peak of the test substance were 3.0 x 10e+05 and 5.5 (Baltussen E., 2010). The Koc and log Koc values of additional peaks of the test substance ranged from 1.8 x 10e+04 - 1.2 x 10e+06 and from 4.2 to 6.1.

B.4.3. Bioaccumulation

The information included in this Section is mainly extracted from IUCLID data set (ECHA, 2021a).

For the assessment of the bioaccumulative or bioconcentration potential three studies were available, one of which clearly presented the most complete, reliable, and relevant data. In this study, bluegill fish (Lepomis macrochirus) were exposed to a mean concentration of 32 µg/L of the mixture of PHT, partially hydrogenated quater- and polyphenyls, and Terphenyl in a flow through system for 42 days, after which a depuration phase of 42 days took place (Heidolph et al., 1983). The bioconcentration factors for the mixture of PHT, partially hydrogenated quater- and polyphenyls, and Terphenyl (whole substance) calculated for whole fish and muscle tissue were 2 000 (3 000 Biofac) and 700 (1 300 Biofac), respectively. The uptake and depuration rate constants, T1/2, and time to equilibrium for whole fish were calculated by the Biofac model to be 192 L/kg/day, 0.06 days 1 ,11 days and 3 days, respectively.

It should be noted though that the relevance of this study is mainly situated in the results of the responses of group I (representing probably o-Terphenyl and some Terphenyl with one ring saturated) and group II (mixture of Terphenyls with one and two rings saturated). For group I, the mean exposure concentration was 1.5 µg/L and the calculated bioconcentration BCFs were 5 200 (9 100 Biofac) and 2 000 (3 100 Biofac) for whole fish and muscle tissue, respectively. For group II the mean exposure concentration was 19 µg/L and the calculated BCFs for whole fish and muscle tissue were 2 400 (3 700 Biofac) and 800 (1 200 Biofac), respectively.

Aim of a further key study (Schlechtriem et al., 2017) was to evaluate the use of column-generated analyte concentrations (CGACs) for fish BCF studies with hydrophobic organic chemicals (HOCs). The test followed basic parameters of guideline 305 of the Organisation for Economic Co-operation and Development (OECD). A solid-phase desorption dosing system was developed to generate stable concentrations of HOCs without using solubilizing agents. In the flow-through tanks a continuous flow of approximately 22 L/h (first study) or 21 L/h (second study) was maintained throughout the test, equivalent to 7.5 volume replacement and 7.2 volume replacement, respectively, per day. In both studies, the test groups were exposed for 56 days (uptake period) and then transferred into a new aquarium where the fish were kept in clean water (depuration period), which was constantly replaced at the same rate as the previously applied test medium. The depuration periods were 28 days and 56 days during the first and second BCF studies, respectively. A kinetic BCF of 12 040 (L/kg wet wt) was determined for o-Terphenyl, indicating the bioaccumulation potential of the compound. The tested solid-phase desorption dosing system is suitable to provide stable aqueous concentrations of HOCs required to determine BCF in fish and represents a viable alternative to the use of solubilizing agents for the preparation of test solutions.

The available supporting study MITI of 2004 (the full reference is not available) was also indicative of the bioaccumulative potential of the substance. This is however currently a K4 study since the original study report is not available (MITI, 2004).

B.4.4. Secondary poisoning

The hazard assessment conclusion for secondary poisoning (PNEC oral) is 2.22 mg/kg food.

B.5. Human health hazard assessment

This restriction dossier is based on the established Persistent, Bioaccumulative, and Toxic (PBT) and vPvB properties of PHT. Therefore, the following human health endpoints relevant for T-criterion assessment are considered: carcinogenicity, mutagenicity, toxicity to reproduction and repeated dose toxicity (chronic toxicity). In addition, this section includes information on toxicokinetics since this is relevant for the bioaccumulation assessment.

The information is mainly extracted from IUCLID data set (ECHA, 2021a).

B.5.1. Toxicokinetics (absorption, metabolism, distribution, and elimination)

In this section, relevant toxicokinetic studies on PHT reported in the disseminated REACH registration dossier are included.

A key study was performed with PHT to determine the disposition and localization in rats as a function of dose and time, and to determine the effects on liver and kidney microsomal drug-metabolizing enzymes following oral and inhalation administration (Hotz and Brewster, 1990). In this study, PHT was administered to male Sprague Dawley rats as either a single oral dose at 0, 100, or 300 mg/kg body weight, or as a single 6-hour inhalation exposure of 0 or 350 mg/m³, or in the diet at concentrations of 0, 100, 500 or 5 000 ppm, or as a repeated inhalation exposure for 6 hours/day for 14 days at 0, 25, 250, at 1 200 mg/m³. Ethoxycoumarin-o-deethylase (ECOD) and aryl hydrocarbon hydroxylase (AHH) activities were determined in liver and kidney S-9 preparations.

Little change in body weight was observed in animals administered PHT via the diet except at 5 000 ppm. The body weight gain of animals exposed to PHT via inhalation decreased in a dose dependent manner over the 2-week exposure period and was significantly different from control at both 250 and 1 200 mg/m³. Absolute liver weights from animals administered 5000 ppm in the diet or 250 mg/m³ or 1 200 mg/m³ via inhalation were 30 to 70% higher than control liver weights.

Single oral and inhalation exposures to PHT produced little or no induction of hepatic aryl hydrocarbon hydroxylase (AHH) activity. However, hepatic AHH activity in animals administered 5 000 ppm in the diet, and in animals repeatedly exposed to 250 mg/m³ or 1 200 mg/m³ via inhalation, was significantly increased above that of control animals. Ethoxycoumarin-o-deethylase (ECOD) activity in the inhalation and diet groups was increased only in animals receiving the highest doses of PHT. In general, renal AHH activity was statistically decreased at high exposure levels, whereas renal ECOD activity appeared to be slightly but not significantly increased compared to controls, regardless of route or length of exposure. PHT produced less induction of microsomal enzymes in the kidney than in the liver for both AHH and ECOD.

Dietary and inhalation exposures produced similar induction patterns in both ECOD and AHH activity However, animals exposed to PHT via inhalation demonstrated a greater hepatic inductive effect than did animals exposed to PHT via the diet. This effect may be due to greater absorption of PHT after inhalation exposure compared to that after dietary exposure. Results from the disposition study indicated that PHT did not appear to accumulate in the body tissues and did not appear to be extensively absorbed after a single oral dose of 300 mg/kg. Whole body elimination was approximately 47 hours and occurred primarily via the feces. Absorption was estimated to be approximately 30% of the administered dose. Of this, 1/3 was eliminated in the urine over the 168-hour observation period. The major route of elimination for PHT appeared to be the feces.

In summary, approximately 30% of an oral dose of PHT was absorbed from the gastrointestinal tract, there was little accumulation in tissues, and the whole-body half-life was less than 1 day. Induction of drug metabolizing enzymes was evident only at the 2 highest doses and the liver was more sensitive to the enzyme inducing effects of PHT than was the kidney. ECOD activity was affected to a greater extent than was AHH activity and inhalation produced a greater effect than did dietary exposure.

In addition, supporting literature data were available on mice that were exposed by inhalation for 4 or 7 hours to radioactive (partial) PHT at 10 µCi/mL (Adamson and Furlong, 1974). Clearance of the radiolabel from the respiratory tract was complete within 24 hours. Radioactivity in the gut, which was significantly increased immediately after inhalation, was reportedly equivalent to control values within 24 hours of compound administration. No accumulation was noted in the gut, kidney, and liver since radioactivity levels 24 hours after the final exposure were similar for mice exposed once compared with mice exposed for five consecutive days. In the same study, mice were also exposed by oral administration to radioactive (partial) PHT at 100 µCi/mL and demonstrated radioactivity in the gut, liver, and kidney. The radioactivity was maximal at 4 to 5 hours after administration and steadily disappeared to background levels within 7 days.

No additional data on absorption, besides the estimated oral absorption of 30% after gavage of 300 mg/kg PHT in rats, is available. In consequence, absorption rates can be estimated by physico-chemical parameters, as indicated in ECHA’s guidance R.7c (ECHA 2017).

Relevant parameters are described in the **Table 12**:

Table 12. Relevant physico-chemical parameters for PHT

Endpoint	**Hydrogenated Terphenyl**
Appearance	Clear pale yellow liquid at 20°C and 1013 hPa
Molecular weight	236 - 248 g/mol
Melting point	-24°C
Boiling point	342°C
Density	1.013 (relative)
Vapour pressure	0.00174 hPa @ 20°C
Partition coefficient	> 6.5
Water solubility	Max. 0.061 mg/L
Skin Irritation	Not irritating (Draize test)
Eye Irritation	Not irritating (Draize test)

In general, based on the physico-chemical parameters, the poor oral absorption is feasible.

The substance is non-volatile, making exposure via inhalation limited. For the e.g., accidentally inhaled amount, either a prolonged exposure due to deposition and subsequent absorption or immediate absorption by micellular solubilisation has to be assumed. The latter mechanism may be of particular importance for highly lipophilic compounds (LogPow > 4), particularly those that are poorly soluble in water (1 mg/L or less) and is hence the only relevant here. To be readily soluble in blood, a gas, vapour, or dust must be soluble in water and increasing water solubility would increase the amount absorbed per breath.

However, the gas, vapour or dust must also be sufficiently lipophilic to cross the alveolar and capillary membranes. Therefore, a moderate log P value (between -1 and 4) would be favourable for absorption. Generally, liquids, solids in solution and water-soluble dusts would readily diffuse/dissolve into the mucus lining the respiratory tract. Hence, with a LogPow of > 6.5 and a virtually non-existing water solubility, the absorption of this fraction which may not be subjected to ciliary clearance can be considered as very limited by the rate at which the substance partitions out of the fluid in the lung surface.

For absorption of deposited material similar criteria as for gastrointestinal (GI) absorption can be applied. So, it can be estimated that the absorption via inhalation would be similar to the one via the oral route. In addition, according to the Reference preliminary Technical Guidance Document (TGD, 2003), Part III, Human health hazard assessment, Part of Preliminary TGD, it is proposed, in the absence of route-specific information on the starting route, to include a default factor of 2 (i.e., the absorption percentage for the starting route is half that of the end route) in the case of oral-to-inhalation extrapolation. The inclusion of this factor 2 means for example that 50% (instead of 100%) absorption is assumed for oral absorption, and 100% for inhalation. So, a worst-case of inhalation absorption of 60% will be assumed, most likely overestimating the actual absorption.

In order to cross the skin, a compound must first penetrate into the stratum corneum and may subsequently reach the epidermis, the dermis, and the vascular network. Above a LogPow of 6, the rate of transfer between the stratum corneum and the epidermis will be slow and will limit absorption across the skin. The substance is not irritating, so no additional, absorption-enhancing factors need to be regarded.

For the substance a QSAR-based model published by DERWIN (DERWIN, 2012), taking into account molecular mass and log Kow, estimated a dermal permeability constant Kp of 30.4 cm/h. Similar to the approach taken by Kroes et al. (2007), the maximum flux Imax (Imax = Kp [cm/h] x water solubility [mg/cm^3]) was calculated, resulting in dermal absorption of 0.001854 µg/cm^2/h. Generally, this value, i.e., < 0.01 µg/cm^2/h, is considered to indicate a dermal absorption of approximately 1% (Mostert and Goergens, 2011). Therefore, the calculated dermal uptake indicates that the substance has a very potential for dermal absorption. However, according to ECHA’s Guidance Chapter R.7c: Endpoint specific guidance Version 2.0 – November 2014, the lowest default dermal absorption value is 10%, so this value will be chosen for further assessment as a worst-case scenario, also most likely overestimating the actual absorption.

B.5.2. Acute toxicity

Not relevant for this dossier.

B.5.3. Irritation

Not relevant for this dossier.

B.5.4. Corrosivity

Not relevant for this dossier.

B.5.5. Sensitisation

Not relevant for this dossier.

B.5.6. Repeated dosed toxicity

A key study for oral repeated dose administration was performed in rats with PHT (Monsanto, 1984); the study was conducted according to OECD 408 and GLP testing guidelines, and was considered to be reliable, adequate, and relevant. Dosing was performed during 90 days via dietary mixture to 72 Sprague-Dawley CD rats (12/sex/group) at dose levels of 50, 200 and 2 000 ppm in the diet for a period of approximately 14 weeks, corresponding with nominal doses of 3, 12 and 120 mg/kg body weight/day. Control animals (12/sex/group) received a standard laboratory diet. All rats survived; the mean body weights of the high-dose females were slightly lower than control throughout the treatment-period. The mean food consumption values of high-dose males and females were slightly lower than control during the first week of the study and were unremarkable for the remainder of the treatment-period. The high-dose males exhibited slight decrease in mean haemoglobin concentration, haematocrit and erythrocyte counts and a slight increase in mean platelet count. The high-dose males exhibited slight, statistically significant elevations in mean cholesterol and albumin level. The high-dose females exhibited a slight reduction in mean glucose levels. There was an increased incidence of a spontaneously occurring renal tubular lesions in high dose males when compared to control males. The lesion incidence in low and mild dose males was similar to that observed in controls. Females were essentially free of the lesion. The etiology and toxicopathological significance of the increased incidence rate in high-dose males was unclear. The NOAEL was determined at 200 ppm in the diet, corresponding to nominal 12 mg/kg body weight/day which was shown to be after analytical verification 14.8 mg/kg bw/day in males and 17.0 mg/kg bw/day in females.

A dose range finding study with PHT (also Klimisch 1) was done for two weeks at dietary concentrations of 1 000, 5 000, 10 000, 20 000 ppm, corresponding with 60, 300, 600, 1 200 mg/kg bw/day (Monsanto, 1985a). Except for slight liver weight increases, there were no changes at 1 000 ppm. At 5 000 ppm, body weight decreases (F), liver weight increases and spleen weight increases (F) were observed, as well as liver gross pathological changes. At 10 000 ppm, body weight decreases, food consumption increases (M), liver weight increases and spleen weight increases (F) were observed, as well as liver gross pathological changes. At 20,000 ppm, mortality increased (M), (the cause of death was not determined), body weight decreased, food consumption increased (M), and weights were changed for kidney (decrease), liver and spleen (increases). The NOAEL was 1 000 ppm in the diet, corresponding with 60 mg/kg body weight/day.

Additional studies with PHT in rats, followed by a 4-week recovery period, were not taken into account for safety assessment since IBT studies are considered to be unreliable unless otherwise stated (as documented in the OECD HPV manual) (Monsanto, 1972).

There were other studies with PHT given to rats and rabbits for 70 days at doses of 1.004, 4.016, 10.04 mg/kg bw/day, however systematic illness in rats and an infection in rabbits led to the conclusion that these studies are also not considered to be reliable (Monsanto Report number 48).

Finally, the test material was also given to mice for 112 days (1 or 2 doses/week) at doses of 20 to 2 000 mg/kg bw/day (Adamson, 1973). Effects observed were kidney histopathogical findings in males at 600 (slight) and 1 200 mg/kg bw/day. NOAEL was 600 mg/kg body weight/day.

A key study for dermal repeated dose administration performed in rats with PHT was conducted according to GLP testing guidelines, and was considered to be reliable, adequate, and relevant (Monsanto, 1981). PHT was administered by dermal application to three groups of 10 male and 10 female New Zealand White rabbits, one-half with intact skin and one-half with abraded skin, five days per week for three consecutive weeks at dosage levels of 0, 125, 500 and 2 000 mg/kg. One rabbit at the high dosage level (2 000 mg/kg) was found dead on study Day 7 and one control rabbit was found dead on study Day 14. A number of incidental and spontaneous signs were noted in the control and test groups. Possible anorexia was observed in an occasional animal in the control, 500 and 2 000 mg/kg groups. No statistically significant differences were seen in group mean body weights. Very slight to moderate erythema, edema, atonia, desquamation, coriaceousness and very slight marked fissuring were observed for some rabbits in all test groups. Several animals in all test groups exhibited marked desquamation during the latter part of the study. Blanching (125 and 2 000 mg/kg) and subcutaneous hemorrhaging (125 and 500 mg/kg) were observed. No relevant changes were observed for haematology and clinical chemistry. No toxicologically significant test article-related weight variations (absolute or relative) were observed among animals sacrificed at study termination. At macroscopic examination, commonly observed findings were thickening and crust formation of the skin which were observed at all dose levels in both sexes. Test article-related histological changes on the skin application sites were observed among all male and female rabbits at all dose levels; consisting of epithelial acanthosis, epidermal hyperkeratosis and inflammatory cell infiltrates among animals sacrificed at study termination. Micro abscesses were present at the 2 000 mg/kg dosage level. One male animal at 2 000 mg/kg dosage level that died on the study, also showed similar type of changes on the skin application site mentioned above. The distribution and relative severity of the above skin changes were generally more pronounced among male and female rabbits at the 2 000 mg/kg dosage level. The changes described in tissues other than the skin application sites were regarded as spontaneous in nature, not unusual for rabbits of this age and strain and unrelated to compound application. In conclusion, daily administration of PHT to the skin of rabbits for 21-days produced gross and microscopic changes at the dosage levels of 125, 500 and 2 000 mg/kg/day. There were however no major signs of systemic toxicity; the findings are considered to be related to the dermal application of PHT; the distribution and severity were generally more pronounced among male and female rabbits at the 2 000 mg/kg dose level.

Several animals in all test groups exhibited marked desquamation during the latter part of the study. Blanching (125 and 2 000 mg/kg) and subcutaneous haemorrhaging (125 and 500 mg/kg) were observed, however there was no systemic toxicity observed. Descriptor: LOAEL = 125 mg/kg; Corrected LOAEL = 125 mg/kg x 2.5 kg / 170 cm^2 = 1.84 mg/cm^2

A key study for inhalation repeated dose administration was performed in rats with PHT; the study was conducted according to OECD 413 and GLP testing guidelines, and was considered to be reliable, adequate, and relevant (Monsanto, 1986a). PHT when administered by whole-body inhalation exposure as an aerosol to 90 CD (Sprague-Dawley derived) rats (15/sex/group) for six hours per day, five days per week for thirteen weeks at target concentrations of 0, 10, 100 and 500 mg /m³ (groups I, II, III, IV). One Group I female and one Group II female died spontaneously during the study. The Group II female's death was not considered treatment related. Increased incidences of chromodacryorrhea, excess lacrimation and rough coat were exhibited by all groups of treated males compared to control males. Increased incidences of dried brown material around the facial area were exhibited by all treated groups of females compared to control females. These findings were considered to be treatment related. The mean body weights were decreased approximately 8% for the Group IV males during the study compared to the control males. The differences between Group IV and control males were considered suggestive of a treatment related effect. Although some statistically significant differences were seen at study termination between clinical chemistry values for control and treated groups, values were generally within control ranges and the absence of supporting microscopic lesions or organ weight findings suggests these clinical chemistry results were insufficient to be considered toxicologically significant. The mean absolute and relative liver weights were increased for all groups of treated males compared to control males. The differences between treated and control males were statistically significant for all comparisons except for the absolute liver weights of Group II and III males. Post-mortem findings observed grossly and microscopically, either occurred in the treated and control animals with comparable incidence and severity or they occurred sporadically. These findings did not appear to be related to the test article. The NOAEL was considered to be 100 mg/m³ or 0.1 mg/L air.

Additional inhalation studies with lower Klimisch scores (3-4) were available in various species, however these were IBT studies not taken into account for safety assessment as IBT studies are considered to be unreliable (as documented in the OECD HPV manual) (Monsanto, 1976 and 1979).

In mice, PHT was exposed as an aerosol for up to 8 days at a concentration of 0.5 mg/L air, followed by a 56-day recovery period. Histopathology of the lungs showed change of mitochondria in alveolar type 2 cells; however, this change was reversible 42 days after final exposure (Adamson, 1969). A 30-day pilot aerosol inhalation toxicity study in rats with PHT at target chamber concentrations 0, 10, 50 and 250 mg/m³ air showed some hypoactivity only noted in the high dose group and only during the exposure period. The NOAEL was between 0.05 and 0.025 mg/L air.

B.5.7. Mutagenicity

Key studies were available for in vitro studies including bacterial reverse mutation, mammalian forward mutation and unscheduled DNA synthesis, as well for in vivo micronucleus testing.

A key study for bacterial mutagenicity was performed with PHT in an Ames reverse mutation test with 4 Salmonella typhimurium strains (TA 1535, TA 1537, TA 98, and TA 100) at test concentration of 0.01, 0.04, 0.2, 1.0, 3.0, 10.0 µL/plate with and without metabolic activation (Kulik and Ross, 1978). A toxic screen was run with the test compound at concentrations of 100.0, 30.0, 10.0, 1.0, 0.3 and 0.1 µL per plate using Salmonella tester strain TA100. In the absence and the presence of metabolic activation, a maximum concentration of 100 µL per plate was tolerated by the bacteria without toxic effects. All strains were tested to be negative for mutagenicity. The study was conducted according to OECD 471 guidelines, and was considered to be reliable, adequate, and relevant.

A key study for the cell mutation assay in Chines Hamster Ovary (CHO) cells was performed with PHT at 25, 50, 75, 100 and 300 µg/mL with and without metabolic activation (Godek et al., 1985). The study was conducted equivalent to OECD 476 on the hypoxanthine-guanine phosphorybosil transferase (HGPRT) target gene according to GLP guidelines, and was considered to be reliable, adequate, and relevant. Cytotoxicity was not observed up to 1 000 µg/mL; however, precipitation of the test article was apparent in the treatment media at all doses above 100 µg/mL. There were no statistically significant increases in the mutation frequencies of the PHT treated cultures when compared to the negative controls at the doses and S-9 concentrations tested.

A key study for DNA damage and repair was performed with PHT in an in vitro UDS study with primary rat hepatocyte cultures at 0.1, 0.5, 1.0, 5.0, 10.0, 50.0, 100.0, 250.0, 500.0 and 1 000.0 µg/mL with and without metabolic activation (Steinmetz and Mirsalis, 1985). The study was conducted according to GLP guidelines, and was considered to be reliable, adequate, and relevant. Cytotoxicity was not observed up to 5 000 µg/mL. The study was negative.

A key study for in vivo chromosome aberration was performed with PHT in the micronucleus assay (Monsanto, 1986b). The study was conducted according to OECD 475 and GLP guidelines, and was considered to be reliable, adequate, and relevant. This study assessed the ability of PHT administered by intraperitoneal injection to induce chromosomal damage in bone marrow cells of Fischer-344 rats. In the definitive study, rats were given PHT at doses of 0, 250, 1 250, and 2 500 mg/kg body weight. Groups of animals were sacrificed 6, 12, and 24 hr after treatment. The positive control groups received triethylenemelamine (0.2 mg/kg body weight 1 by intraperitoneal injection and were sacrificed 24 hr after treatment. Cells from animals exposed to 0 and 2 500 mg/kg and those from animals in the positive control groups were evaluated microscopically for mitotic index and chromosomal abnormalities. On the basis of the results, it was concluded that PHT does not induce chromosomal damage in male or female Fischer-344 rats under the conditions used in this study.

Supporting studies (Klimisch 4) were also available for bacterial reverse mutagenicity and DNA damage and repair. A study for bacterial mutagenicity was performed with PHT in an Ames reverse mutation test with 4 Salmonella typhimurium strains (TA 1535, TA 1537, TA 98, and TA 100) with and without metabolic activation (Clark et al., 1979). All strains were tested to be negative for mutagenicity up to 10 000 µg/plate with and without metabolic activation. There were no signs of cytotoxicity. A study for DNA damage and repair was performed with PHT (NBP2087922) in an in vitro UDS study with primary rat hepatocyte cultures (Monsanto, 1982). The test was negative.

B.5.8. Carcinogenicity

Literature studies were available as weight of evidence for carcinogenicity testing for the skin. PHT was dermally administered from tail to neck over a 2 cm swathe on the back, at a dose of 50 mg/week for 37 weeks to male and female Balb/c mice, followed by 22 weeks with croton oil administration (Henderson & Weeks, 1973). The mice were examined weekly. Each one of the early tumors was drawn as soon as it appeared. The late tumors were drawn during surveys in which whole experiments were depicted at monthly intervals. An autopsy was done on every mouse dying during the experiments and on every survivor at the end. Tissues, excised post-mortem or, in a few -instances, during life tinder anaesthesia, were fixed by buffered formalin and stained with hematoxylin and phloxine. There were no abnormal clinical observations, gross pathological observations, and histopathological findings. The NOAEL for carcinogenicity was therefore 50 mg/week, corresponding with 280 mg/kg bw/day (50 mg/week = 7 mg/day/25g = 280 mg/kg bw day).

In a second part of the study, PHT was dermally administered from tail to neck over a 2 cm swathe on the back at 50 mg/week for 37 weeks to male and female Balb/c mice (Henderson and Weeks, 1973). The mice of one group were painted five times a week, those of another group four times, of another group three times, of another group twice and of the fifth group one once per week. After 14 weeks applications of PHT were stopped and all were painted thereafter twice weekly with croton oil. The mice were examined weekly. Each one of the early tumors was drawn as soon as it appeared. The late tumors were drawn during surveys in which whole experiments were depicted at monthly intervals. An autopsy was done on every mouse dying during the experiments and on every survivor at the end. Tissues, excised post-mortem or, in a few -instances, during life tinder anaesthesia, were fixed by buffered formalin and stained with haematoxylin and phloxine. There were no abnormal gross pathological observations and histopathological findings. All the PHT painted mice continued to grow hair; the dorsal fur of those most painted was difficult to clip and it formed a matted shield for the skin beneath. No skin tumor resulted. The NOAEL for carcinogenicity was 50 mg/week, corresponding with 280 mg/kg bw/day.

Finally, PHT was dermally administered from tail to neck over a 2 cm swathe on the back, at a dose of once a week 50 mg for 37 weeks to male and female PLA mice (Henderson & Weeks, 1973). The mice were examined weekly. Each one of the early tumors was drawn as soon as it appeared. The late tumors were drawn during surveys in which whole experiments were depicted at monthly intervals. An autopsy was done on every mouse dying during the experiments and on every survivor at the end. Tissues, excised post-mortem or, in a few -instances, during life under anaesthesia, were fixed by buffered formalin and stained with hematoxylin and phloxine. There were no abnormal clinical observations, gross pathological observations, and histopathological findings. The NOAEL for carcinogenicity was therefore 50 mg/week, corresponding with 280 mg/kg bw/day.

B.5.9. Toxicity for reproduction

Effects on fertility

A key study for reproductive toxicity in male and female rats was performed with PHT in a two-generation reproductive toxicity study. The study was conducted according to OECD 416 and GLP guidelines, and was considered to be reliable, adequate, and relevant Male and female Sprague-Dawley rats (30 adults/sex/dose) were continuously fed PHT through two generations at target levels of 0, 30, 100, 300 and 1 000 ppm in their diet (Naylor & Ruecker, 1991). Analyses to verify the stability of the test material both neat and when mixed with the diet, the diet homogeneity, and concentrations of the test material in the diet were all performed with satisfactory results. Overall study averages for consumption of test material (mg PHT/kilogram body weight/day), based on the target concentrations, were as follows: 1.8, 6.1, 18.5 and 62.0 for males and 2.5, 8.3, 24.4 and 81.2 for females (for the F0 adults) and 1.9, 6.1, 18.2 and 63.1 for males and 2.4, 8.1, 24.3 and 80.6 for females (for the F1a adults), at the lowest to highest levels, respectively.

Non-reproductive effects attributed to treatment in adult rats were limited to a minor decrease in group mean body weights of high level F0 males near the end of the study, and slightly decreased body weights of F1a dams during gestation. There were no adverse reproductive effects in any of the measured parameter/indices in adult rats or their offspring.

On the basis of the above findings, the 1 000 ppm dietary level was considered the no-observed-adverse-effect-level (NOAEL) for reproductive effects (corresponding to 62 -81 mg/kg bw/day), and the 300 ppm dietary level was considered the NOAEL for subchronic toxicity in this study (corresponding to 18 -24 mg/kg bw/day).

Developmental toxicity

A key study for developmental toxicity / teratogenicity was performed in a teratology study with PHT in Sprague-Dawley rats (24/group) from day 6-15 of pregnancy (Schroeder & Daly, 1986). The study was conducted according to OECD 414 and GLP guidelines, and was considered to be reliable, adequate, and relevant. Oral doses given were 0, 125, 500, 1 500 mg/kg bw/day, based upon a preceding dose range finding study. No mortality occurred in the control, low- or mid-dose groups. At the high-dose level, 4 females died, however, the death of one female was attributed to an intubation error. Excluding this one female, the mortality rate in the high-dose group was 12.5%.

No adverse effect of treatment was evident in pregnancy rate data. At the high-dose level, mean body weights were significantly lower than control. In the mid-dose and high group, mean food consumption was significantly lower than control. At the mid-dose level, the incidence of females with areas of alopecia was notably increased. At the high-dose level, the incidence of females with staining of the fur in the anogenital area and/ or soft stool was increased during the treatment interval of gestation. Additionally, several high-dose females were noted early in gestation (Day 9) as emaciated with red material about the snout.

No adverse effect of treatment at the low- or mid-dose level was evident from uterine implantation data. An increase in both the mean number of resorption sites and the mean ratio of resorptions to implants was seen at the high-dose level, however it was not clear if the increase represents an adverse effect of treatment. No increase in the incidence of malformations was seen during the external, visceral, or skeletal evaluations of foetuses recovered from females treated at the low- or mid-dose levels. At the high-dose level, no increase in malformation rate was seen during fetal external evaluations; however, the incidence of foetuses with a glassy (shiny) appearance, considered to be an external variation observation, was significantly increased. Foetuses noted as having a glassy (shiny) appearance were usually the smaller foetuses within the litters and the observation was considered related to retarded fetal development within this group. No adverse effect of treatment at the high-dose level was evident from the fetal visceral evaluations. During the skeletal evaluations, the incidence of high dose foetuses with malformations was statistically higher than control. Skeletal malformations were seen in seven high-dose foetuses (an incidence of 5.9%) in respect to the control incidence of 0.6% (one foetus with a skeletal malformation). Two of the seven high-dose foetuses (one foetus from each of two litters) had dissimilar, relatively minor malformations which were not considered related to treatment. Five high-dose foetuses (four foetuses from one litter and one foetus from a second litter) had one or more malformations from a syndrome of observations that involved misshapen and fusion defects of the exoccipital bones, fused ribs, cervical vertebral defects, or misaligned thoracic vertebral centre. The two females whose litters contained foetuses with one or more skeletal malformations from the above stated syndrome of observations were quite stressed during the treatment period. Both females experienced weight loss during the Day 6-9 gestation interval and at Day 9, were noted with marked staining of the fur in the anogenital area and extreme soft stool; therefore, it is not clear if this syndrome of skeletal malformations as seen with increased frequency among the high-dose foetuses represents a response to treatment or is secondary to maternal toxicity encountered at this same dose level.

In conclusion, NOAEL for maternal toxicity was 125 mg/kg bw/day; NOAEL for fetotoxicity was 500 mg/kg bw/day.

A dose range finding supporting study was performed in a teratology study with PHT in Sprague-Dawley rats (5/group) from day 6-15 of pregnancy (Monsanto, 1985b). Doses given were 0, 125, 250, 500, 1 000, 2 000 mg/kg bw/day. Females were sacrificed on Day 20 of gestation and uterine implantation data were evaluated. Foetuses recovered at this time were weighed, sexed, and evaluated for external malformations. 250 mg/kg bw/day was the maternal NOAEL. At 500 and 1 000 mg/kg bw/day, maternal food consumption was decreased, however there were no offspring effects; at 1,000 mg/kg bw/day. 1 000 mg/kg bw/day was the developmental NOAEL. At 2 000 mg/kg bw/day, embryonic death and decreased fetal weights were observed.

A developmental toxicity study in the 2nd species (rabbit) is waived based on following reasons:

- The study in the first species (rat) was conducted under exaggerated conditions. Based on the relevant dose levels given, there was no concern for development toxicity.
- Based on existing data, a study in the 2nd species (rabbit) is expected lead to severe gastro-intestinal and other problems and will not deliver added value to the existing information.

B.5.10. Other effects

Not relevant for this dossier.

B.5.11. Derivation of DNEL(s)/DMEL(s)

Table 13. Hazard conclusions for workers

Route	**Type of effect**	**Hazard conclusion**	**Most sensitive endpoint**
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 2.01mg/m³	repeated dose toxicity (by inhalation)

Inhalation	Systemic effects - Acute	no hazard identified	---
Inhalation	Local effects - Long-term	no hazard identified	---
Inhalation	Local effects - Acute	no hazard identified	---
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.622mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	---
Dermal	Local effects - Long-term	low hazard (no threshold derived)	---
Dermal	Local effects - Acute	no hazard identified	---
Eyes	Local effects	no hazard identified	---

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEC

Modified dose descriptor starting point: NOAEC

The subchronic inhalation toxicity study conducted in rats by 6-hour nose-only exposure was used as a starting point for the DNEL derivation. The systemic NOAEC of 100 mg/m^3 was corrected for duration of exposure (6 to 8 hours; factor *6/8) and a correction for the inhalation volume of a worker was taken into account (*6.7/10):

corrected NOAEC = 100 mg/m^3 * (6 h/d / 8 h/d) * (6.7 m^3/d / 10 m^3/d) = 50.3 mg/m^3.

A corrected NOAEC of 50.3 mg/m^3 is derived.

Overall Assessment Factor: 25

AF for dose response relationship: 1 (default, starting points is a NOAEL)

AF for difference in duration of exposure: 2 (default for subchronic to chronic)

AF for interspecies differences (allometric scaling): 1 (already regarded by deriving a corrected NOAEC)

AF for other interspecies differences: 2.5 (default for remaining interspecies differences)

AF for intraspecies differences: 5 (default for worker)

AF for the quality of the whole database: 1 (default)

AF for remaining uncertainties: 1 (default)

Further explanation on hazard conclusions: Taking into account the above-mentioned assessment factors, an overall assessment factor of 25 is obtained.

The worker-DNEL long-term for inhalation route - systemic is derived to be 50.3mg/m^3/ 25 = 2.01 mg/m^3.

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions: Provided high-peak acute exposure for inhalation is unlikely to occur due to the low vapour pressure of the test substance and precautionary handling, an acute exposure hazard by the inhalation pathway is unlikely for humans. The long-term inhalation DNEL for systemic effects is sufficient to ensure that acute effects are covered. Moreover, acute DNELs for inhalation (systemic and local) are not necessary since there is no acute toxic hazard by inhalation (LC50 >5 mg/L), which can be concluded from the acute oral, dermal and inhalation toxicity study. Therefore, DNEL is not calculated, according to Appendix R. 8-8 (page 109) of the Chapter R.8 'Characterisation of dose [concentration]-response for human health' of the Guidance on information requirements and chemical safety assessment (ECHA, 2012).

Inhalation Local effects - Long-term

Further explanation on hazard conclusions: The subchronic inhalation toxicity study conducted in rats by 6-hour nose-only exposure was used as a starting point for long-term DNEL systemic derivation. There was a NOAEC of 100 mg/m³ based on systemic effects, however there were no microscopical lesions in the respiratory tract up to 500 mg/m³. The long-term inhalation DNEL for systemic effects is sufficient to ensure that acute effects are covered. Therefore, this DNEL is not calculated (ECHA, 2012).

Inhalation Local effects - Acute

Further explanation on hazard conclusions: Due to the low vapour pressure of the test substance as well as its physical state and taken precautions a hazard by prolonged inhalation exposure is unlikely for humans. Moreover, acute DNELs for inhalation (systemic and local) are not necessary since there is no acute toxic hazard by inhalation (LC50 > 5 mg/L), which can be concluded from the acute oral, dermal and inhalation toxicity study. Further, the substance was not classified as irritant, neither to the skin nor eye. Therefore, this DNEL is not calculated (ECHA, 2012).

Dermal Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEL

Despite the fact that a repeated dose toxicity study via the dermal route is available, the OECD 408 repeated dose study via the oral route was chosen as the starting point. The oral study is with 13 weeks of subchronic duration, whereas the dermal study is with 21 days only in the lower subacute range. This allows a better assessment of potential long-term effects of the substance, which could be missed in a study with shorter duration. Further, the oral study gives a definitive NOAEL value, whereas the dermal one only indicates NOAEL ≥ 2 000 mg/kg bw/d, which does not only allow to calculate with a distinct value but also indicates that systemic exposure occurred. Last but not least, the present oral NOAEL is with 14.8 mg/kg bw/d the most sensitive value; even the 13-week inhalative NOAEL is with approximately 16.5 mg/kg bw/d (recalculated from exposure) higher than the oral one, and so, the most conservative approach was followed.

Using this dose descriptor starting point, all further calculations were performed with the DNEL calculator.

Overall Assessment Factor: 100

AF for dose response relationship: 1 (default, starting point is a NOAEL)

AF for difference in duration of exposure: 2 (default for subchronic to chronic)

AF for interspecies differences (allometric scaling): 4 (default for allometric scaling (rat to human))

AF for other interspecies differences: 2.5 (default for remaining interspecies differences)

AF for intraspecies differences: 5 (default for workers)

AF for the quality of the whole database: 1 (default)

AF for remaining uncertainties: 1 (default)

Further explanation on hazard conclusions:

Taking into account the above-mentioned assessment factors, an overall assessment factor of 100 is obtained.

The worker-DNEL long-term for dermal route - systemic is derived to be 62.2 mg/kg bw/day / 100 = 0.622 mg/kg bw/day.

Dermal Systemic effects - Acute

Further explanation on hazard conclusions: The long-term dermal DNEL for systemic effects is sufficient to ensure that acute effects are covered. Moreover, acute DNELs for dermal exposure (systemic and local) are not necessary since there is no acute toxic hazard by dermal contact (LD50 > 2 000 mg/kg bw), which can be concluded from the acute oral, dermal and inhalation toxicity study. Therefore, this DNEL is not calculated (ECHA, 2012).

Dermal Local effects - Long-term

Further explanation on hazard conclusions: There is one repeated dose dermal toxicity study available. Therein, toxicologically significant compound-related gross macroscopic lesions were observed in male and female rabbits receiving 125, 500 and 2,000 mg/kg. The lesions commonly observed were thickening and crust formation. Test article-related morphologic changes on the skin application sites were observed among all male and female rabbits at all dose levels; consisting of epithelial acanthosis, epidermal hyperkeratosis and inflammatory cell infiltrates among animals sacrificed at study termination.

This allows the conclusion that the test item related adverse effects were noted upon repeated dose dermal exposure making it necessary to conclude a “low hazard” for the dermal, long-term local route of exposure.

Dermal Local effects - Acute

Further explanation on hazard conclusions: No toxicity hazard (LD50 >2 000 mg/kg bw) was identified. In addition, the substance is not classified as irritating to the skin or eyes. Therefore, this DNEL is not calculated (ECHA, 2012).

The long-term DNELs relevant for workers were based on a key study for oral repeated dose administration, performed in rats, and on a key study for inhalation repeated dose administration, performed in rats (please refer to B.5.6. Repeated dose toxicity)

Table 14. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.358mg/m³	repeated dose toxicity (by inhalation)
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	no hazard identified	
Inhalation	Local effects - Acute	no hazard identified	
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.222mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	low hazard (no threshold derived)	
Dermal	Local effects - Acute	no hazard identified	
Oral	Systemic effects - Long-term	DNEL (Derived No Effect Level) 74 µg/kg bw/day	repeated dose toxicity (Oral)
Oral	Systemic effects - Acute	no hazard identified	
Eyes	Local effects	no hazard identified	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEC

Modified dose descriptor starting point: NOAEC

The subchronic inhalation toxicity study conducted in rats by 6-hour nose-only exposure was used as a starting point for DNEL derivations.

The systemic NOAEC of 100 mg/m³ was corrected for duration of exposure (6 to 24hrs; factor *6/24) and a correction for exposure days per week (5 d/week to 7 d/week; factor: *5/7):

corrected NOAEC = 100 mg/m³ * (6 h/d / 24 h/d) * (5 d/week / 7 d/week) = 17.9 mg/m³.

A corrected NOAEC of 17.9 mg/m³ is derived.

Overall Assessment Factor: 50

AF for dose response relationship: 1 (default, starting point is a NOAEC)

AF for difference in duration of exposure: 2 (default for subchronic to chronic)

AF for interspecies differences (allometric scaling): 1 (already regarded by deriving a corrected NOAEC)

AF for other interspecies differences: 2.5 (default for remaining interspecies differences)

AF for intraspecies differences: 10 (default for general population)

AF for the quality of the whole database: 1 (default)

AF for remaining uncertainties: 1 (default)

Further explanation on hazard conclusions: Taking into account the above-mentioned assessment factors, an overall assessment factor of 50 is obtained.

The consumer-DNEL long-term for inhalation route - systemic is derived to be 17.9 mg/m³/ 50 = 0.358 mg/m³.

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions: Provided high-peak acute exposure for inhalation is unlikely to occur due to the low vapour pressure of the test substance and precautionary handling, an acute exposure hazard by the inhalation pathway is unlikely for humans. The long-term inhalation DNEL for systemic effects is sufficient to ensure that acute effects are covered. Moreover, acute DNELs for inhalation (systemic and local) are not necessary since there is no acute toxic hazard by inhalation (LC50 > 5 mg/L), which can be concluded from the acute oral, dermal and inhalation toxicity study. Therefore, this DNEL is not calculated (ECHA, 2012).

Inhalation Local effects - Long-term

Further explanation on hazard conclusions: The subchronic inhalation toxicity study conducted in rats by 6-hour nose-only exposure was used as a starting point for DNEL derivation. There was a NOAEC of 100 mg/m³ based on systemic effects, however there were no microscopical lesions in the respiratory tract up to 500 mg/m³.

Inhalation Local effects - Acute

Further explanation on hazard conclusions: Due to the low vapour pressure of the test substance as well as its physical state and taken precautions a hazard by prolonged inhalation exposure is unlikely for humans. Moreover, acute DNELs for inhalation (systemic and local) are not necessary since there is no acute toxic hazard by inhalation (LC50 > 5 mg/L), which can be concluded from the acute oral, dermal and inhalation toxicity study. Further, the substance was not classified as irritant, neither to the skin nor eye. Therefore, this DNEL is not calculated (ECHA, 2012).

Dermal Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEL

Despite the fact that a repeated dose toxicity study via the dermal route is available, the OECD 408 repeated dose study via the oral route was chosen as the starting point. The oral study is with 13 weeks of subchronic duration, whereas the dermal study is with 21 days only in the lower subacute range. This allows a better assessment of potential long-term effects of the substance, which could be missed in a study with shorter duration. Further, the oral study gives a definitive NOAEL value, whereas the dermal one only indicates NOAEL ≥ 2 000 mg/kg bw/d, which does not only allow calculating with a distinct value but also indicates that systemic exposure occurred. Last but not least, the present oral NOAEL is with 14.8 mg/kg bw/d the most sensitive value; even the 13-week inhalative NOAEL is with approximately 16.5 mg/kg bw/d (recalculated from exposure) higher than the oral one, and so, the most conservative approach was followed.

Using this dose descriptor starting point, all further calculations were performed with the DNEL calculator.

Overall Assessment Factor: 200

AF for dose response relationship: 1 (default, starting point is a NOAEL)

AF for difference in duration of exposure: 2 (default for subchronic to chronic)

AF for interspecies differences (allometric scaling): 4 (default for allometric scaling (rat to human))

AF for other interspecies differences: 2.5 (default for remaining interspecies differences)

AF for intraspecies differences: 10 (default for general population)

AF for the quality of the whole database: 1 (default)

AF for remaining uncertainties: 1 (default)

Further explanation on hazard conclusions:

Taking into account the above-mentioned assessment factors, an overall assessment factor of 200 is obtained.

The consumer-DNEL long-term for dermal route - systemic is derived to be 44.4 mg/kg bw/d / 200 = 0.222 mg/kg bw/d.

Dermal Systemic effects - Acute

Further explanation on hazard conclusions: The long-term dermal DNEL for systemic effects is sufficient to ensure that acute effects are covered. Moreover, acute DNELs for dermal exposure (systemic and local) are not necessary since there is no acute toxic hazard by dermal contact (LD50 > 2 000 mg/kg bw), which can be concluded from the acute oral, dermal and inhalation toxicity study. Therefore, this DNEL is not calculated (ECHA, 2012).

Dermal Local effects - Long-term

Further explanation on hazard conclusions: There is one repeated dose dermal toxicity study available. Therein, toxicologically significant compound-related gross macroscopic lesions were observed in male and female rabbits receiving 125, 500 and 2 000 mg/kg. The lesions commonly observed were thickening and crust formation. Test article-related morphologic changes on the skin application sites were observed among all male and female rabbits at all dose levels; consisting of epithelial acanthosis, epidermal hyperkeratosis and inflammatory cell infiltrates among animals sacrificed at study termination.

This allows the conclusion that the test item related adverse effects were noted upon repeated dose dermal exposure making it necessary to conclude a “low hazard” for the dermal, long-term local route of exposure.

Dermal Local effects - Acute

Further explanation on hazard conclusions: No toxicity hazard (LD50 >2 000 mg/kg bw) and the substance is not classified as irritating to the skin or eyes. Therefore, this DNEL is not calculated (ECHA, 2012).

Oral Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEL

No modification of the starting point is necessary.

Overall Assessment Factor: 200

AF for dose response relationship: 1 (default, starting point is a NOAEL)

AF for difference in duration of exposure: 2 (default for subchronic to chronic)

AF for interspecies differences (allometric scaling): 4 (default for allometric scaling (rat to human))

AF for other interspecies differences: 2.5 (default for remaining interspecies differences)

AF for intraspecies differences: 10 (default for general population)

AF for the quality of the whole database: 1 (default)

AF for remaining uncertainties: 1 (default)

Further explanation on hazard conclusions:

Taking into account the above-mentioned assessment factors, an overall assessment factor of 200 is obtained.

The consumer-DNEL long-term for dermal route - systemic is derived to be 14.8 mg/kg bw/d / 200 = 0.074 mg/kg bw/d = 74 µg/kg bw/d.

Oral Systemic effects - Acute

Further explanation on hazard conclusions: The long-term oral DNEL for systemic effects is sufficient to ensure that acute effects are covered. Moreover, acute DNELs for oral exposure are not necessary since there is no acute toxic hazard by ingestion (LD50 > 2 000 mg/kg bw), which can be concluded from the acute oral, dermal and inhalation toxicity study. Therefore, this DNEL is not calculated (ECHA, 2012).

The long-term DNELs (oral and dermal) were based on a key study for oral repeated dose administration, performed in rats. For more details, please refer to section B.5.6 and on the key study described in the section for workers (inhalation DNEL).

B.6. Human health hazard assessment of physicochemical properties

B.6.1. Explosivity

A study of the Explosivity did not have to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties. Moreover, this study is not relevant for the proposal.

B.6.2. Flammability

A study of the Flammability has not been conducted because the substance is a liquid. Moreover, this study is not relevant for the proposal.

B.6.3. Oxidising potential

A study of the oxidising potential has not been conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied. Moreover, this study is not relevant for the proposal.

B.7. Environmental hazard assessment

B.7.1. Aquatic compartment (including sediments)

The information provided is based on those studies and pieces of information, relevant for risk assessment purposes (ECHA, 2021a). More specifically, this information is considered relevant for classification and labelling purposes of the substance and PNEC derivation. Additional studies were included in the IUCLID data set for PBT purposes. However, these studies are not dealt with in detail for the purpose of the restriction proposal, because the chemical is a vPvB substance.

Summary on aquatic toxicity:

Aquatic toxicity related to hydrogenated terphenyls has been assessed both in acute and chronic toxicity tests. These tests however cover different trophic levels (fish, invertebrate, algae) and among the fish and invertebrates, different species were used.

Fish

From the fish tests (all acute 96h tests) it was concluded that the substance is not acutely toxic towards fish at concentrations well above the water solubility (Griffin, 1979; Thompson, 1979; Rice, 1972; Adams 1979; BTL, 1972). In four out of five tests, the LC50 (96h) was reported to be > 1 000 mg/L test substance. The fifth test yielded a 10 ppm < LC50 (96h) < 100 ppm. It should be noted however that this fifth test was the only one that was not carried out with the primary test substance with 40% hydrogenated terphenyls, but with a substance containing 30% hydrogenated terphenyls, which thereby has a slightly different composition compared to the primary test substance (BTL, 1972).

Invertebrates

The acute toxicity towards aquatic invertebrates for the primary test substance was evaluated for multiple species: Daphnia magna, Mysidopsis bahia, Gammarus fasciatus, and Paratanytarsus parthenogenetica. Based on the results reported in all these studies, no toxicity was observed up to water solubility levels (approximately 0.06 mg/L).

The most recently performed study was the only study reporting measured exposure concentrations (Powell and Moser, 1996). This limit test with PHT indicated that the EC50 (48h) is > 1.34 mg/L (measured concentration). It should be noted however that a dispersant was used to dissolve the test substance. The other EC50 (48h) values for freshwater invertebrates reported for PHT ranged from 0.1 mg/L to > 1.5 mg/L, all based on nominal concentrations in the presence of a solvent (Forbis, 1979; Powel and Moser, 1996; Adams, 1979; Gledhill, 1984; Hoberg, 1984a and 1984b). Additional tests performed with a "read-across" substance (substance containing 40% hydrogenated polyphenyls) on Daphnia magna and Chironomus tentans, generally indicated a higher toxicity of this substance with EC50 48h values ranging from 0.011 to 0.52 mg/L (Renaudette and Adams, 1984; Monsanto, 1980; Calvert et al., 1982). However, due to the difference in chemical composition of the substance (which contains a larger fraction of hydrogenated quaterphenyls in comparison to the primary test substance), these values were not taken into account further in the risk assessment. To conclude, although the lowest EC50 (48h) is 0.1 mg/L, the test reporting an EC50 (48h) > 1.34 mg/L is considered the most relevant and reliable study. For risk assessment purposes this result is taken into account.

The determined chronic toxicity towards aquatic invertebrates is based on the 21 days reproduction study performed with Daphnia magna on Water Accommodated Fractions of 1 and 5 mg/L PHT (Tobor-Kaplon M.A., 2014). This test resulted in a No Observed Effect Loading Rate (NOELR) for reproduction < 1 mg/L, a NOELR for mortality of 1 mg/L and a NOELR for growth < 1 mg/L. At the Loading Rate of 1 mg/L, a 32% reduction of the reproduction was observed. As the test design did not include lower concentrations, this due to technical reasons, no exact NOELR could be determined.

Algae

Two phytotoxicity studies (K1 & K2) are available, evaluating the effect of hydrogenated terphenyls on the freshwater alga Selenastrum capricornutum (new name is Pseudokirchneriella subcapitata) (Hollister, 1979; Weltens, 2010). In the oldest study (K2), only nominal concentrations were reported (10, 32, 56, 100 and 320 mg/L). The basis of the reported effects was in vivo chlorophyll a (for all time points) and cell numbers (96h). Based on the decrease of in vivo chlorophyll a, the calculated 96-hour EC50 was 44 ppm (95% CL 1 - 1586 ppm). The calculated 96-hour EC50 based on cell number decrease was 56 ppm (CL 95% of 4 -743 ppm). In the most recent study (K1), algae were exposed to water soluble fractions of hydrogenated terphenyls. The presence of PHT in these WAFs could be measured with HPLC when solutions were freshly prepared. This soluble fraction however disappeared during the exposure time both in filtered and unfiltered WAFs and it was not clear from the results how fast the test substance disappears. The initial presence of these soluble compounds in the WAFs however does not interfere with normal algal growth rate for WAFs produced with nominal concentrations up to 100 mg/L PHT. As no effects were seen in the test range, no effect values could be defined either.

Conclusion

Based on the available data, it can be concluded that invertebrates (more specifically Daphnia magna) are the most sensitive species. As both acute and long-term toxicity information is available covering that species there is no need to collect more ecotoxicology related information on other (vertebrate) organisms.

B.7.2. Terrestrial compartment

No relevant and reliable information is available for the terrestrial compartment.

B.7.3. Atmospheric compartment

No relevant and reliable information is available for the atmospheric compartment.

B.7.4. Microbiological activity in sewage treatment systems

According to Column 2 of Annex IX and X of REACH, toxicity testing in soil microorganisms shall be proposed if the chemical safety assessment indicates the need to further assess the effects on soil organisms. Based on the currently available dataset, the EPM calculated PNEC values for the soil compartment, and the risk assessment, there is no need to propose any further testing on soil organisms. RCR values are all below 1 (Solutia, 2019).

B.7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

No relevant and reliable information is available for the food chain (secondary poisoning).

B.8. PBT and vPvB assessment

B.8.1. Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

PHT is a very persistent and very bioaccumulative (vPvB) substance according to article 57 (e) of Regulation (EC) No 1907/2006 (REACH). The ECHA Member States Committee included the substance on the list of Substances of Very High Concern on 27.06.2018. See as well **Annex B.4.1.** on Degradation and **Annex B.4.3** on Bioaccumulation for more information.

Further details as the basis for these conclusions are available in the corresponding decision of the ECHA MSC[10] and support documents (ECHA, 2018a) available on the ECHA Website. Readers are referred directly to these documents for additional information. Furthermore, detailed information is provided in Section 8 to the CSR of the LR (Solutia, 2019).

The UVCB substance was assessed by evaluating the different relevant constituents present in the substance. The P, vP, B, and vB behaviours of some of the constituents defined in **Table 8** are detailed in **Table 15**:

Table 15. P/vP and B/vB conclusions of selected constituents of PHT

Group	**Contains**	**Name (CAS)**	**Persistence**	**Bioaccumulation**
o-T	ortho-terphenyl	1,2-terphenyl (CAS 84-15-1)	P and vP	B and vB
m-T	meta-terphenyl	1,3-terphenyl	Potentially P or vP	Not possible to conclude
p-T	para-terphenyl	1,4-terphenyl (CAS 92-94-4)	P and vP	Potentially B and vB
p-HT1	1-ring hydrogenated terphenyl	4-cyclohexylbiphenyl	Potentially P or vP	B and vB
p-HT2	2-ring hydrogenated terphenyl	1,4-dicyclohexylbenzene (CAS 1087-02-1)	Potentially P or vP	B and vB
p-HT3	3-ring hydrogenated terphenyls	p-tercyclohexyl	Potentially P or vP	Potentially B
p-Q	Quaterphenyls	para-quaterpheny	P and vP	B
p-HQ1	1-ring hydrogenated quaterphenyls	4-cyclohexylterphenyl	Potentially P or vP	Potentially B and vB
p-HQ2	2-ring	dicyclohexylbiphenyl	Potentially P or vP	Potentially B and vB

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[10] https://echa-term.echa.europa.eu/web/guest/candidate-list-table/-/dislist/details/0b0236e18250183f

	hydrogenated quaterphenyls			
p-HQ3	3-ring hydrogenated quaterphenyls	tercyclohexylbenzene	Potentially P or vP	Potentially B and vB

At least o-terphenyl fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1%), the UVCB substance PHT is considered to fulfil vPvB criteria.

Justification of vPvB classification for o-terphenyl

For ortho-terphenyl and meta-terphenyl, the potential for primary and ultimate degradation is demonstrated in studies on ortho-terphenyl. According to the approach of the study authors the half-life for disappearance of parent substance is below the threshold for freshwater and the original calculations based on study results revealed very short dissipation half-lifes, demonstrating that the mixture as tested does not persist in soil. Based on recent evaluation results of the environmental Member State competent authority (Finland), the modelling approach chosen by the study authors was not appropriate to describe the degradation of the compound in soil. According to the outcome of remodelling of the study results by the Finnish competent authority, terphenyl fulfils the vP criterion in soil based on the degradation study. The different isomers of terphenyl, quaterphenyl, and polyphenyl were not differentiated in this study. Nevertheless, the reliability of this soil dissipation test is limited due to the fact that information on the composition of the tested mixture is missing. In general, the Finnish competent authority considers that degradation of a hydrocarbon in a mixture study may be overestimated compared to testing of each constituent separately (due to co-metabolism).

However, in the present case the possible overestimation is acceptable as the half-life for terphenyl fulfils the vP criterion.

B.8.2. Emission Characterisation

The objective of an emission characterisation is to identify and estimate the amount of the releases of a PBT or vPvB-substance to the environment; and to identify exposure routes by which humans and the environment are exposed to a PBT or vPvB-substance. Further information on potential emissions and exposure is provided under Section B.9. Exposure Assessment.

B.9. Exposure assessment

According to registration information, PHT is not manufactured within the EU. It is mainly used as HTF within closed systems at industrial sites. Also related to the HTF uses is the industrial "use in laboratory analysis" where small amounts of in-use HTF is analysed to determine its lifetime. The use of this substance as a plasticiser is the second relevant use. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material. PHT is used as a plasticiser mainly for the production of sealants and adhesives. The final sealants/adhesives are used in a wide variety of sectors, for example the aerospace industry. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables). This application is addressed in the "additive in plastic application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, PHT is also used as plasticiser in coatings and inks. In addition, professional service life scenarios are also relevant for PHT since the substance is incorporated into/onto articles when used in adhesives/sealants as well as in coatings/inks.

Furthermore, PHT is also used as solvent or process medium by the industry and as laboratory chemical (e.g. as microscope immersion oils) by professionals.

In addition, a general scenario ("Formulation, transfer and repackaging of substances in preparations and mixtures") related to the formulation life cycle stage was indicated as relevant for PHT. Since specific formulation scenarios are also indicated ("Formulation of adhesives and sealants", "Formulation of coatings/inks" and "Formulation - use as additive in plastic applications") the general formulation will herein solely be used to cover formulation of laboratory chemicals used by professionals.

Moreover, the SCIP database was screened for PHT. At the date of access (2 March 2022) well over 12 000 articles containing PHT are included in the SCIP database. Most of them relate to polymers as well as rubber and elastomers (in sum > 60%). Moreover, the number of sealants containing PHT is quite high (> 25%). Some further articles such as inks and sensors (e.g., in ovens) are also found. The total number of entries in these cases was significantly lower. The information obtained through analysis of the SCIP database will be addressed in the exposure assessment (please refer to **Annex B.9.**).

Exposure of PHT mainly occurs from releases to air and water from point sources as well as via diffuse emissions. After emission to the environment the substance is distributed by various processes such as deposition from air to soil/water bodies and adsorption to sludge in the sewage treatment plant (STP).

During the data collection phase of this proposal in summer 2021 via a Socio-Economic Assessment (SEA) Questionnaire to downstream users (see **Annex E**: Impact Assessment), the Dossier Submitter did ask as well on assessment of relevant emissions. The responses (obtained only from HTF users) have been reported collectively as negligible.

Currently there are six active registrations for PHT in the EU (see also **Annex A** and **Annex B.9.2.** for further information).

Up until now only a few international measurements of PHT in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with PHT, while Sturaro et al. (1995) detected PHT as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by the Norwegian Institute for Air Research (NILU) and the Norwegian Institute for Water Research (NIVA) (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including PHT.

Due to the vPvB property of PHT, emissions will lead to an increased exposure of humans and the environment since the substance will build up over time. Measures to reduce the ongoing emissions are therefore regarded as mandatory.

Currently, PHT is used in the following applications:

- Use in adhesives and sealants.
- Use in coatings and inks.
- Use as additive in plastic applications.
- Use as HTF.
- Use as solvent/process medium.
- Use as laboratory chemical.

The following exposure assessment considering these six main areas of use from all relevant life cycle stages includes:

- Formulation.
- Industrial use.
- Professional use.
- Release over the service life of articles.
- Release from waste.

"Manufacture" is also indicated on the ECHA's dissemination website as a relevant exposure scenario for PHT. As of today, only the LR is manufacturing PHT at the plant in Newport (UK). However, since the UK left the EU on 31 of January 2020, the manufacture conducted by the LR is no longer taking place within the EU. Since no other registrants manufacture PHT within the EU, it is not necessary to address the manufacture life cycle stage in the context of this restriction proposal.

The substance is registered in the EU under the REACH Regulation and, only limited information on the releases to the environment is available from the disseminated information on ECHA's webpage. In addition, specific information on the Identified Uses (IU) of the substance as well as its exposure patterns are obtained in a survey conducted in 2019 by the LR. Thereby, an advanced Exposure & Release Questionnaire was sent out to users as well as distributors. In this questionnaire, exposure related information on human health and the environment was requested. General information such as technical functions of the substance, total tonnages, relevant life-cycle steps and their respective use descriptors (Environmental Release Categories (ERCs), Process Categories (PROCs), Sectors of Use (Sus), and Product Categories (PCs)) was obtained, as well as process specific data on the IU. This included the identification of specific contributing scenarios incl. their Operational Conditions (OCs) and applied Risk Management Measures (RMMs). The Exposure & Release Questionnaire is attached in Appendix 1.

In total, more than 50 companies were contacted. Overall, 17 companies from different industry sectors provided a completed questionnaire. Hence, this extensive feedback has been evaluated and used for the following exposure and risk assessment. If no specific information was available, worst-case release estimates for the relevant scenarios are used.

- Formulation. Releases to the environment can occur from formulation of adhesives and sealants and coatings and inks. Information regarding the routes of release for sealants and adhesives is taken from FEICA / EFCC SPERC 2.1a.v3. For the coatings and inks CEPE SpERC 2.1c.v2 is applicable.

  Additionally a generic formulation scenario is indicated on ECHA's dissemination page to cover general formation, transfer and repackaging of the substance. A minor amount of PHT is used as solvent/process medium by the industry or as laboratory chemical by professional. The formulation, transfer and repacking of PHT used as solvent/process medium by the industry or as laboratory chemical by professional is covered by this formulation scenario. No specific information on the releases to the environment is available.

  Moreover a generic formulation scenario the "Formulation - use as additive in plastic applications" is found on ECHA's webpage. Although this use is also listed in this report it is not assessed since it is already sufficiently covered by the following uses: "Formulation of coatings/inks" as well as "Formulation of adhesives and sealants". Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

- Industrial use. Releases to the environment can occur from various industrial uses:

the use as HTF, laboratory analysis of HTF samples, adhesives/sealants, coatings/inks, and as solvent/process medium. For the use as HTF and the laboratory analysis of HTF samples information is taken from the Exposure & Release Questionnaire. For the adhesives/sealants, the coatings/inks use and the use as solvent/process medium FEICA SPERC 5.1a.v3, CEPE SPERC 5.1a.v2 and ESVOC SPERC 4.1.v2, respectively, were used.

- Professional use. Releases to the environment can occur from various professional uses: the use as HTF, adhesives/sealants, coatings/inks and as laboratory chemical. For the adhesives/sealants and the coatings/inks use FEICA / EFCC SPERC 8f.1a.v2 and CEPE SPERC 8f.3a.v2, respectively, were used. For the use as laboratory chemical by professional no refinement was possible since no suitable information is available.
- Article service life. Releases to the environment are likely to occur from long-life materials with low release, e.g., plastic articles such as cables or coatings/sealants used by the aerospace industry. Releases could occur during indoor as well as outdoor use of articles. No public information is available and only limited information is provided in the Exposure & Release Questionnaire (2018).

Below all IU including ERCs and PROCs, as listed on ECHA's dissemination page of the PHT dossier, are indicated.

The ERC describes the activity from the environmental (release) perspective. The PROC describes the tasks, application techniques or process types defined from the occupational perspective, including use and processing of articles by workers.

Hence, ERCs describe the process from which releases to the environment could occur and PROCs describe the processes from which occupational exposure could occur.

Formulation, transfer and repackaging of substances in preparations and mixtures
Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

Formulation of adhesives and sealants
Contributing activity/technique for the environment :
- ERC2: Formulation into mixture

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises

- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15: Use as laboratory reagent

Formulation of coatings/inks
Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent

Formulation - use as additive in plastic applications
Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation and handling of substances bound in/on materials or articles

- PROC 24: High (mechanical) energy work-up of substances bound in /on materials and articles

Use as HTF at industrial sites
Contributing activity/technique for the environment:
- ERC7: Use of functional fluid at industrial site

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities [EU REACH]
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent
- PROC 16: Use of fuels
- PROC28: Manual maintenance (cleaning and repair) of machinery

Laboratory analysis
Contributing activity/technique for the environment :
- ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers :
- PROC 15: Use as laboratory reagent

Use of adhesives and sealants at industrial sites
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 13 : Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation

Direct use for industrial coatings/inks applications

Contributing activity/technique for the environment :

- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers :

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent

Use as additive in plastic application

Contributing activity/technique for the environment :

- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers :

- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Use as solvent/process medium

Contributing activity/technique for the environment :

- ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers :

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 16: Use of fuel

Use as laboratory chemical by professionals
Contributing activity/technique for the environment :
- ERC9a: Widespread use of functional fluid (indoor)

Contributing activity/technique for the workers :
- PROC 15: Use as laboratory reagent

Use as HTF at professional sites
Further description of the use:
Contributing activity/technique for the environment :
- ERC9a: Widespread use of functional fluid (indoor)
- ERC9b: Widespread use of functional fluid (outdoor)

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

Use of adhesives and sealants by professionals
Contributing activity/technique for the environment :
- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers :
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
  PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 10: Roller application or brushing
- PROC 11: Non industrial spraying
- PROC 13: Treatment of articles by dipping and pouring

Direct use for professional coatings/inks applications
Contributing activity/technique for the environment :
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent

containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 11: Non industrial spraying
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent
- PROC 28: Manual maintenance (cleaning and repair) of machinery

Service life of articles produced from use as plasticiser
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of articles produced from use of coatings and inks
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of plastics
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

The environmental exposure assessment is based on the default release factors in accordance with ECHA Guidance R.16.

In case other information on the releases are available and applicable for PHT, e.g., Specific Environmental Release Categories (SpERCs) or OECD Emission Scenario Documents this information is used in preference to the default release factors as indicated in ECHA Guidance R.16. Additionally, specific information was made available through the Exposure & Release Questionnaire (2018) by the LR.

The main objective for the approach of the environmental exposure assessment was to present a realistic assessment. The default release factors represent a worst-case approach overestimating the actual emissions to the environment. Hence, the default release factors give an indication of the relative release potential from the various processes but do not take into account the physico-chemical properties of the substance or any RMM that is used during the process.

Using more specific information (if available) instead of the default release factors guarantees a more realistic exposure assessment which is based on actual emissions.

However, since no other information was available the default release factors as indicated in ECHA Guidance R.16 (ECHA, 2016) had to be used. In the **Table 16** below, the default release factors for the relevant ERCs are indicated.

Table 16. Default release factors for the relevant ERCs

ERC	ERC description	Default release factor to air	Default release factor to water	Default release factor to soil
2	Formulation into mixture	2.5%	2%	0.01%
4	Use of non-reactive processing aid at industrial site (no inclusion into or onto article)	100%	100%	5%
5	Use at industrial site leading to inclusion into/onto article	50%	50%	1%
6b	Use of reactive processing aid at industrial site (no inclusion into or onto article)	0.1%	5%	0.025%
7	Use of functional fluid at industrial site	5%	5%	5%
8c	Widespread use leading to inclusion into/onto article (indoor)	15%	30%*	n.a.
8f	Widespread use leading to inclusion into/onto article (outdoor)	15%	5%	0.5%
9a	Widespread use of functional fluid (indoor)	5%	5%	n.a.
9b	Widespread use of functional fluid (outdoor)	5%	5%	5%
10a	Widespread use of articles with low release (outdoor)	0.05%	3.2%	3.2%
11a	Widespread use of articles with low release (indoor)	0.05%	0.05%	n.a.

* The default release factor of 30% applies to activities/processes where the substance is dissolved/dispersed in a surplus of water and applied to an article via dipping/immersion or spreading (e.g. textile dyeing/finishing or application of polishes with floor cleaning water). For other widespread uses (e.g. use of paints and adhesives, including water based products) the release factor of 5% is applicable.

As indicated before, using the default release factors has to be regarded as worst-case approach overestimating the actual emissions (further referred to as "upper estimate"). For most of the IU it was possible to refine the exposure assessment using applicable SpERCs, OECD Emission Scenario Document and specific information made available through the Exposure & Release Questionnaire (2018). For further information refer to the respective scenario. The estimates of the refined assessment are referred to as "lower estimate". They are assumed to represent the reasonable worst-case emissions.

It is to be noticed that the number of articles containing PHT imported into the EU and exported from the EU is not known with any certainty. Hence, the exposure assessment for the service life scenarios is based on the volume of PHT itself supplied to the EU market. However, the total volume used for the exposure assessment (7 471 tonnes per year) is regarded as a worst-case estimate. Hence it is assumed that PHT in imported articles is sufficiently covered.

For the exposure assessment the total volume is derived by summarising the imported volumes reported by the registrants or using the upper limit of the tonnage band of a registration. For each of the exposure scenarios the used parameters are indicated in the following sections. Due to the fact that ranges are used (e.g., for the releases) a lower and upper range is also reported for the exposure estimates.

The properties of PHT that have been assumed in the exposure assessment were taken from ECHA's dissemination page. A summary of the physico-chemical and fate properties is given in the table below (**Table 17**).

Table 17. Properties of PHT used in the exposure assessment

Substance property	**Value**
Molecular weight	236 - 248
Molecular weight used for the assessment	248
Melting point at 101 325 Pa	-24°C
Vapour pressure	1.74E-3 hPa at 20°C
Partition coefficient (Log Kow)	6.5 at 20°C
Water solubility	0.061 mg/L at 20°C
Biodegradation in water: screening tests	inherently biodegradable
Half-life in soil	4.6 d
Bioaccumulation: BCF (aquatic species)	5.2E3
Adsorption/Desorption: Koc at 20°C	3.16E5

The exposure assessment is presented in two parts for each exposure scenario. For each exposure scenario an overview table with the input parameters is given as well as a table displaying the initial releases to air, water and soil based on the release rates. The releases are calculated using generic exposure methods.

The second part refers to the distribution in the environment, e.g., the distribution of the releases in the STP.

Thereby the distribution within the STP is estimated using default percentages as calculated by SimpleTreat (RIVM, 1994) 3.0 (please refer to **Table 18**). Although the last stand-alone version of this assessment tool is 4.0, SimpleTreat 3.0 is used as it is implemented in CHESAR v3.7 (ECHA, 2022a). CHESAR v3.7 is the standard modelling tool to be used for exposure and risk assessments under REACH. In addition, the results of the two versions are identical. SimpleTreat 3.0 estimated the likely behaviour of a substance within the STP based on its properties. The herein assessed PHT is likely to adsorb onto sewage sludge which might subsequently be applied to agricultural soil as fertilizer.

PECs are calculated based on the estimations.

Table 18. Estimated distribution in a STP for PHT

Release to water	7.554%
Release to air	8.465%
Release to sludge	83.98%
Release degraded	0

Uncertainties associated with this approach are discussed in Appendix F.

B.9.1. General discussion on releases and exposure

B.9.1.1. Summary of the existing legal requirements

PHT itself is currently not regulated by any legislation in the EU other than REACH. For this reason, other EU legislation related to PBT/vPvB substances is mentioned here.

The CLP Regulation, which implements the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), does not include the possibility of classifying a substance as PBT/vPvB, since these categories are not part of the GHS. However, the classification 'hazardous for the aquatic environment' does include 'ready degradability' and 'potential to bioaccumulate' as criteria to consider, meaning that some aspects of persistence are taken into account.

The EU Water Framework Directive (Directive 2000/60/EC) provides a framework for the protection of inland surface waters, transitional waters, coastal water, and groundwater. The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment are controlled by national measures including environmental permits. The Water Framework Directive manages surface water pollutants by identifying and regulating those of greatest concern across the EU known as 'Priority Substances' (PS) and by requiring Member States to identify substances of national or local concern (river basin specific pollutants). Measures must be taken to reduce the emissions, discharges and losses of the PS and to phase out those deemed the most harmful ('Priority Hazardous Substances' - PHS). Environmental Quality Standards (EQS) are set in the Environmental Quality Standards Directive (2008/105/EC) for PS and PHS[11]. Member States must ensure that the EQS for the Priority Substances, are met in order to achieve 'good chemical status' in accordance with Water Framework Directive Article 4 and Annex V 1.4.3[12]. The PS list was replaced in 2013 via Directive 2013/39/EU, which also includes EQS and other provisions for chemical pollutants. The provisions involve improving the efficiency of monitoring and the clarity of reporting with regard to certain PBT substances. PHT is not currently identified as a PS or PHS.

The Industrial Emissions Directive (2010/75/EU)[13] establishes the main principles for permitting and control of large industrial installations based on an integrated approach and the application of Best Available Techniques (BAT) to achieve a high level of environmental protection. The manufacture and some uses of PHT are covered by the Industrial Emissions Directive (IED). However, as no BAT reference documents related to the use of PHT are available, the IED is considered of limited applicability for the risk management of PHT.

From an EU policy standpoint, the European Commission's (COM) new Circular Economy Action Plan announces initiatives along the entire life cycle of products. It targets their design and promotes circular economy processes to stimulate sustainable consumption. It also aims to ensure that the resources used are kept in the EU economy for as long as possible, thus reducing waste.

The Waste Framework Directive (2008/98/EC) sets out measures addressing the adverse impacts of the generation and management of waste on the environment and human health, and for improving efficient use of resources. An amendment[14] to the Waste Framework Directive prescribes that from 5 January 2021 suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA thus

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[11] http://ec.europa.eu/environment/water/water-dangersub/index.htm

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0060-20141120

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0075

[14] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste

providing waste operators with information about hazardous substances in the waste they are processing.

B.9.1.2. Summary of the effectiveness of the implemented OCs and RMMs

According to the responses received to the SEA questionnaire (Appendix 4), when PHT is used as HTF, the substance is included in a closed system in which the potential releases to the environment can be considered negligible. Regarding RMMs, all of the respondents informed about the presence of different containment devices (e.g., collection vessels, retention systems in pumps and valves, etc.). In most cases, the system is designed with the piping lines fully welded, and only some specific items are flanged (as pumps or control valves). These flanged elements are specifically protected against leakages.

These RMMs are already considered during the design step of the system to guarantee its tightness, thinking on the applicable normative (as the Pressure Equipment Directive – PED[15]) and international standards (as DIN 4754-1).

Regarding OCs, HTF systems are usually managed by expert trained operators, and they are periodically inspected, internally or by external competent technical bodies. Furthermore, internal control tests (e.g., to check the suitability of joints) and programs (e.g., periodical surveillance of potential leakages) are in place. The most important controls are the PHT level monitoring, because it is the best tool to quickly identify any loss of substance volume from the closed system, and the analysis of the PHT quality (basically defined by the content of low boiling fraction), to guarantee an efficient work of the system.

Special operations, such as sampling, drain of the system, and replacement of the PHT, are performed following specific procedures to avoid the release of the substance. Most of the sites have calamity basins to control potential accidents during these processes. Also, there are specific procedures for the storage and disposal of the exhausted PHT, that is treated through licensed waste handling companies. The amount of PHT disposed per year varies between a few kilos to 10 tonnes, depending on the size of the closed system, but this amount can increase drastically when the HTF is completely replaced (commonly, after 20 years of use or more). The typical disposal treatment is incineration, as in the case of other oils (e.g., lubricating oils), for energetic valorisation.

All these measures are focused on the release of PHT to the soil and the aquatic environment because, due to the low volatility of the substance, potential emissions to air are considered non-existent (less than 1 kilo per year, according to some respondents of the SEA questionnaire). Furthermore, the low boiling fraction generated during the deterioration of PHT is vented in closed loops to be internally incinerated (through the furnaces, steam boilers, flares, etc., installed in the sites).

There is no information from the SEA questionnaires related to the RMMs and OCs applied by companies that are using PHT as plasticiser or in other uses different to the HTF one.

B.9.2. Manufacturing

Companies are responsible for collecting information on the properties and uses of PHT if they manufacture or import into the EU above one tonne per year. This information is communicated through a REACH registration dossier.

According to the information from the REACH Registrations on ECHA's public dissemination website (ECHA, 2021a), there are currently 6 active registrants of PHT. The LR (Eastman Chemical BV) registered the substance in 2010, the other five co-registrants registered it by

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[15] PED. Current consolidated text: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0068-20140717&qid=1639053469715

the 2018 deadline. At least two of those co-registrants are ORs representing non-EU companies; it is likely they are acting as internal ORs. The last update of the registration dossier was carried out by the LR in 2020. All registrations are full registrations, according to Article 10 of the REACH Regulation.

According to registration data on the ECHA public dissemination website (ECHA, 2021a), PHT is manufactured/used in the range of 10,000-100,000 tonnes per year.

Thereby Eastman as the LR has registered in the highest tonnage band (>1 000 tonnes per year), hence a major part of the volume used within the EU is attributed to the LR registration. One volume update was conducted by one of the member registrants to 100 – 1 000 tonnes per year.

The latest update of the LR’s dossier took place on 9 of January 2020. Thereby the LR’s manufacturing site was indicated to be “Newport (UK)”. In the context of this restriction report it must be noted that the UK has left the EU on 31 of January 2020. Hence the manufacture of the LR is no longer taking place within the EU. Additionally, none of the Member Registrants manufactures within the EU.

Globally, the major production sites are located in the UK and in the US. Additionally, there are also production sites in China and the Middle East, whereas the volumes produced are noticeably lower. The major part of the volume used within the EU is imported from the UK and the US. A minor is imported from China or the Middle East.

The volumes used within the EU and the IU have been used as starting point of the environmental release estimation.

B.9.2.1. Occupational exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.2.2. Environmental release

PHT is not manufactured within the EU and all of the PHT used is imported. To date, PHT is manufactured within the UK, the USA, China and the Middle East. Hence there are no releases to the environment in the EU related to the manufacture of the substance.

B.9.3. Use 1: Use as HTF at industrial sites

B.9.3.1. General information

PHT is used as HTF at multiple industrial and professional sites. Specific information on the releases to the environment of PHT during its use as HTF is obtained in the Exposure & Release Questionnaire (2018). Additionally, measured data are available.

B.9.3.2. Exposure estimation

Table 19 shows the exposure estimation.

Table 19. Exposure estimation

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	71.7%		
Total tonnage used as HTF at ind. sites	5 360	tonnes per year	
Number of emission days	365	days per year	
Daily amount of PHT used at a site (local scenario)	1 200	tonnes per day	Amount in biggest HTF system installed in the EU.
Fraction released to air	0 - 0.05		Exposure & Release Questionnaire (2018) Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0 - 0.05		Exposure & Release Questionnaire (2018) Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.05		Exposure & Release Questionnaire (2018) Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	No solid waste is generated during the use of PHT as HTF		Reasonable worst-case assumption
Estimated release to air	0 – 60 000	Kg per year	
Estimated release to wastewater	0 – 60 000	Kg per year	
Estimated release to industrial soil	0 – 60 000	Kg per year	
Estimated amount to solid waste for disposal	0	Kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 20.** These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 20. Estimated EU releases to the environment from industrial use as HTF in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	0	65 079
Water	0	4 532.4
Agricultural soil via application of sludge	0	110 388
Total	**0**	**179 999.4**

B.9.3.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.3.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.3.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 21**.

Table 21. Estimated indirect local exposure of human via the environment from industrial use as HTF in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	0	4.34	mg/kg bw/d
Fraction of total dose through intake of drinking water	0	0.0002	
Daily dose through intake of fish	0	4	mg/kg bw/d
Fraction of total dose through intake of fish	0	0.0002	
Daily dose through intake of leaf crops	0	0.114	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0	0.0000	
Daily dose through intake of root crops	0	1.78E+4	mg/kg bw/d
Fraction of total dose through intake of root crops	0	0.9948	
Daily dose through intake of meat	0	53.67	mg/kg bw/d
Fraction of total dose through intake of meat	0	0.003	
Daily dose through intake of milk	0	31.63	mg/kg bw/d
Fraction of total dose through intake of milk	0	0.0018	
Local total daily intake of humans	0	1.79E+4	mg/kg bw/d
Man via environment - inhalation (systemic effects)	0	4.60E-2	mg/m^3
Man via environment - oral	0	1.79E+4	mg/kg bw/d

B.9.3.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 22**.

Table 22. Estimated environmental local exposure from industrial use as HTF in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	0	153.7	mg/L
$PEClocal_{freshwater\ sediment}$	0	4.86E+6	mg/kg dw
$PEClocal_{marinewater}$	0	15.37	mg/L
$PEClocal_{marinewater\ sediment}$	0	4.86E+5	mg/kg dw
$PEClocal_{STP}$	0	2.27E+3	mg/L
$PEClocal_{air}$	0	0.046	mg/m^3
$PEClocal_{agricultural\ soil}$	0	9.65E+5	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	0	1.1E+4	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	0	1.1E+3	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	0	2.21E+3	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	0	2.63E+6	mg/kg ww

B.9.3.3. Exposure measurements

In order to obtain updated information on potential environmental emissions of PHT from industrial uses as HTF, a monitoring program was designed and developed at a number of industrial sites that use PHT in this application. Companies that participated in this program were requested to collect both air and soil samples, from locations at which releases of PHT could be regarded to be more likely.

The technical part of the project has been coordinated by the Institute of Occupational Medicine (IOM) in Edinburgh[16], UK. For the purpose of collecting environmental samples, the following material was used:

- IOM Samplers
- Sample Pumps (including chargers): SKC 224-SMTXM / SKC AirCheck Essential
- SKC Tubing
- PTFE Filters
- Calibrators
- Sample Transport Holders
- Tubes for Soil Samples, where relevant
- Chain Of Custody Paperwork

The IOM sampler is designed and closely adheres to the definition for sampling of inhalable dust given in EN481 (CEN, 1995). To fit a filter, the front plate is unscrewed. The cassette, comprising the inlet spout and filter support grid can then be removed by pulling forward gently. The two halves of the cassette clip together and can be separated with gentle pressure. Once separated, a PTFE filter is placed in the support grid. The inlet spout is snapped into the support grid making sure it is seated down properly. The cassette is then replaced into the body of the sampler and the front plate screwed on firmly so that all of the O-ring seals are compressed, thus ensuring there are no leaks (see **Figure 2**).

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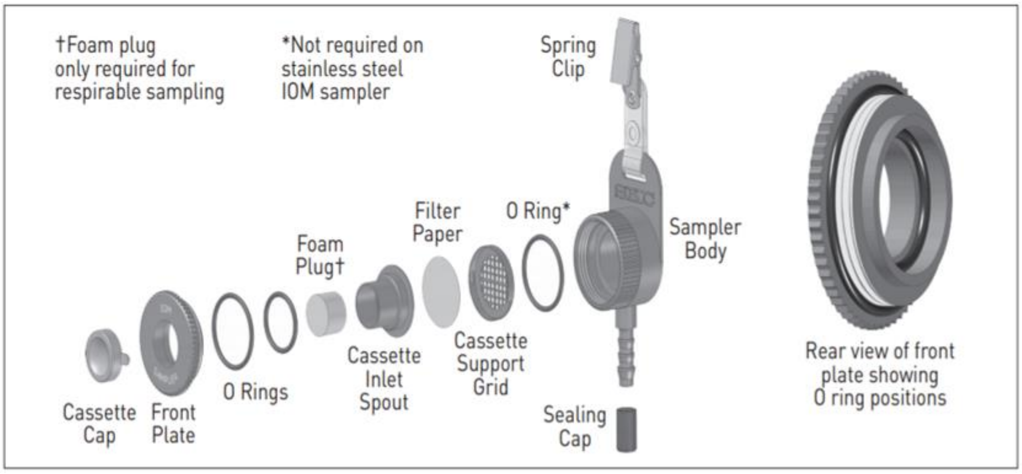
[16] IOM | Institute of Occupational Medicine (iom-world.org)

Figure 2. IOM sampler components



In this monitoring program, and in order to avoid any contamination of the PTFE filter, the cassettes were prepared in the IOM laboratory and delivered to the monitoring sites using sample transport holders[17]. Therefore, site staff in charge of the monitoring process only need to put the cassettes into the body of the sampler and to close it by screwing the front plate. At the end of the monitoring process, the cassette is extracted from the body of the sampler and is returned to the IOM laboratory, for analysis purposes, inside the same sample transport holders.

The collection of samples was performed on a best effort basis by site staff. Instructions from the technical partner were followed in order to ensure adequate sampling and chain of custody of collected samples. Air samplers were placed in the vicinity of the heat transfer system, near locations in which it was considered more likely that unintended emissions may occur (e.g., pumps, valves, flanges). In addition, each site collected one sample at an area in which no exposure to PHT is expected. Measurements were run for a minimum of 4 hours at a flow rate of approximately 2 litre/min. Finally, samples were labelled and stored until delivery to the IOM laboratory for analysis.

Soil samples are collected from an area as close as possible to points in which it is reasonably expected (or known) that leaks from the heat transfer system may have occurred in the past. Where possible, minimum 1.5 kg/samples were collected, spiked down until minimum 10 cm from the surface. It must be underlined that collection of soil samples was rare, since the vast majority of heat transfer systems currently operating are located on concrete floors, which makes it impossible to collect reliable soil samples.

Adequate chain of custody and sample tracking methods have been put in place. The Chain of Custody Form requires, as a minimum:

- Start/End time and date
- Flow rate at the start/end and during sampling
- Sample number (this will be provided on the sample cassette supplied)
- Brief description of the location in which the sampler was placed

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[17] The original plan in this environmental monitoring program for PHT, which was scheduled to start in March 2020, was to have an IOM technician present on site when the samples were collected. However, this was not possible due to the Covid-19 pandemic.

- Basic weather conditions (for external measurements)

The NIOSH method 5021 (CDC, 1994) for o-terphenyl is based on GCMS analysis from material collected using a PTFE filter. This was the analytical method used for determination of PHT collected in the air samples. A pure PHT sample was used as pattern to compare results obtained from the sites. As stated in the NIOSH method 5021, o-terphenyl is used as a calibration standard. There are limitations with this method as IOM can report what is found but cannot guarantee that all terphenyls present in the air will be trapped on the filter, therefore, there may be other compounds present in the air that IOM cannot detect.

A total of 13 plants participated in this monitoring exercise.

The results of the air measurements are shown in the next table (**Table 23**):

Table 23. Summary of results of air measurements

Site	Location	PHT (as o-terphenyl)	
		µg	mg/m^3
S-01	Non-exposure area	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
	Pump 3	<0.4	<0.001
S-02	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
	Pump 3	<0.4	<0.001
S-03	Equipment 1	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
S-04	Pump 1	<0.4	<0.003
	Pump 2	<0.4	<0.001
S-05	Non-exposure area	<0.4	<0.001
	Expansion tank	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
S-06	Non-exposure area	<0.4	<0.001
	Pump system	<0.4	<0.001
S-07	Non-exposure area	<0.4	<0.001
	Pump	<0.4	<0.001
S-08	Non-exposure area	<0.4	<0.001
	Pump	<0.4	<0.001
S-09	Non-exposure area	<0.4	<0.001
	Pump	<0.4	<0.001
S-10	Non-exposure area	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001

S-11	Non-exposure area	<0.4	<0,001
	Pumps	<0.4	<0,001
	Transport pipes	<0.4	<0,001
S-12	Non-exposure area	<0.4	<0,001
	Pump	<0.4	<0,001
S-13	Non-exposure area	<0.4	<0,001
	Pump	<0.4	<0,001

As it can be seen from **Table 23**, the presence of o-terphenyl was not determined above the reporting limit (0.4 µg) in any of the measurements carried out, neither in the areas of possible exposure nor in the areas of non-exposure. Therefore, it can be concluded that no emissions of PHT were detected in any of the monitoring sites.

It is interesting to note that during the measurements performed in the exposure area (pump) on Site S-06, there was a minor leakage of PHT (few drops – see Pictures 7 and 8 below). However, no o-terphenyl was detected in the results of the corresponding sample analysis. This observation is interesting because it suggests that releases of PHT are possible, even if they are not detected via air sampling. Indeed, the low volatility of PHT would explain the fact that no o-terphenyl was detected in the relevant sample for this site. Also, the fact that air monitoring was limited to a relatively reduced time (4 hours in one single sampling event at each site) can explain the fact that no o-terphenyl was detected in any of the air samples collected. However, a closer evaluation of the situation at some sites (e.g., S-06, Picture 7) suggests that releases of PHT could be relatively frequent.

The results of the soil measurements are shown in the next table (**Table 24**):

Table 24. Summary of results of soil measurements

		PHT (as o-terphenyl)		
Code	**Location**	**µg**	**mg/kg**	**%**
S-01	Hot Transfer System 1	2 033.3	1 873.5	0.19
	Hot Transfer System 2	2.5	1.9	< 0.01

Site S-01 is the only installation in which some sections of their heat transfer systems (PHT filling points) are not placed on concrete floor, which has allowed for soil samples to be taken.

In this case, the amount of o-terphenyl in the samples was above the reporting limit (1.0 µg) and it has been detected in the IOM laboratory analyses. This suggests that potential unintended PHT emissions to soil could occur from heat transfer systems, reinforcing the earlier comments related to the visual analysis of some of the pictures collected at sites that have participated at the monitoring campaign.

Below is a brief description of the monitored heat transfer systems per site.

Table 25Table 25. Number of monitoring sites per country shows the number of monitoring sites per country:

Table 25. Number of monitoring sites per country

Country	Number of sites
Italy	5
Netherlands	4
Belgium	1
Finland	1
Germany	1
Poland	1

Site S-01 is dedicated to the production of basic chemicals and operates three heat transfer systems, dated 1985, 1997, and 2007. The total volume of PHT operated by these systems is 60 m^3. The three systems have an expansion hot oil tank and a drain tank, and they are heated with natural gas. The operating temperature range is from 220 to 310°C and the pressure is 7 barg.[18] The low boiling components are vented to the process vent systems, they are partly condensed and the non-condensable part is transferred to the waste gas incinerator and the steam boilers for elimination. PHT degraded is drained and sent to an authorised external waste handler.

Figure 3. Air sample point in Site S-01

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[18] Barg is the unit for the measurement of gauge pressure. Gauge pressure is measured against the ambient pressure. Therefore, it is equal to absolute pressure minus atmospheric pressure. Moreover, barg is the unit for the measurement of the pressure given by absolute pressure minus atmospheric pressure.

Figure 4. Soil sample point in Site S-01

Site S-02 and site S-03 belong to the same company, that is dedicated to the production of fuels and petrochemicals. Site S-02 runs two heat transfer systems, dated 1979 and 2000, operating at a temperature range of 280-340°C and a pressure of 18 barg, with a total volume of PHT of 1,300 tonnes. Both systems have expansion tanks, pumps with mechanic seal systems, and a common buffer storage tank for the draining process. The low boiling components are vented to flare and the PHT degraded is disposed for waste incineration. Site S-03 has only one heat transfer system, dated in 2018, that operates at 330°C and a pressure of 13.5 barg. The PHT volume used in this system is 250 tonnes. The installation is very similar to the one at Site S-02. In these sites was not possible to collect samples in non-exposure areas.

Figure 5. Air sample point in Site S-02

Figure 6. Air sample point in Site S-03

Site S-04 is dedicated to the manufacture of basic chemical products (phenols and aromatics). The site includes one heat transfer system that operates at a maximum temperature of 328°C and a pressure range from 400 to 1 000 kPa, using 230 tonnes of PHT. The system is 40 years old and has a collection tank, two drain tanks, and sealed pumps and valves. The low boiling components are vented to a gas combustion unit and the PHT degraded is sent to an authorised external waste company. In this site was not possible to collect samples in non-exposure areas.

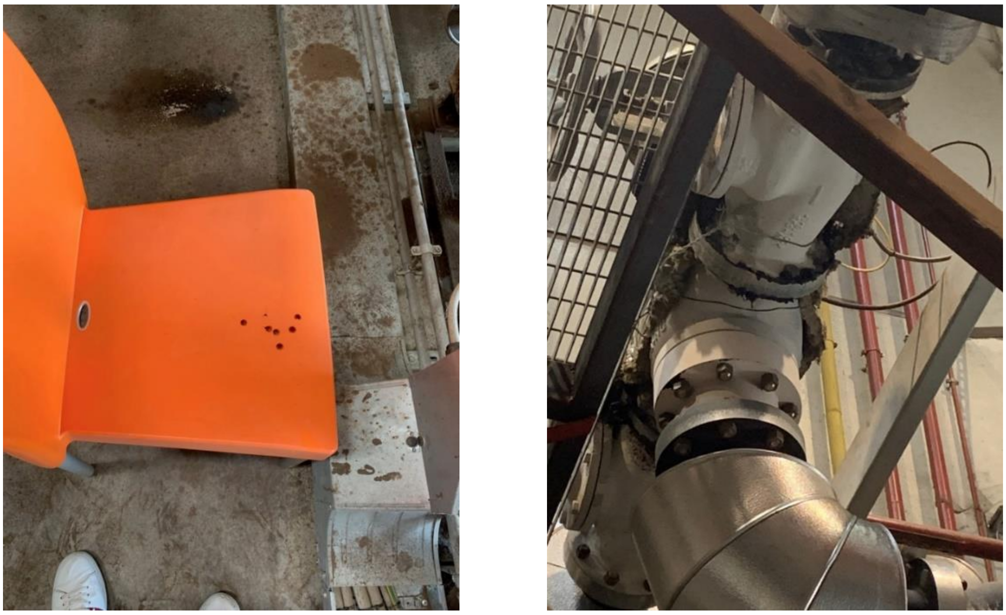
Site S-05 operates only one heat transfer system with 25 m^3 of PHT, that runs at a maximum temperature of 310°C and a maximum pressure of 6 barg. The company produces basic chemical products and the heat transfer system is dated in 1997. The system has an expansion tank and pumps are sealed. The degraded PHT is drummed and sent to a waste processor to be disposed.

Figure 7. Air sample point in Site S-05

Site S-06 is an energy producer that operates a heat transfer system composed of a biomass heater and an ORC turbine. The system contains 18 m^3 of PHT and it is in operation since 2014, running at a maximum temperature of 305°C and a pressure of 7 barg. Installation includes an expansion tank, pumps and valves with mechanical seals, and a collection vessel. All the vent points are collected to the heater to burn the low boiling components. As previously mentioned, a leak of PHT was detected at this site in the course of the environmental monitoring.

Figure 8. Air sample point in Site S-06

Figure 9. PHT leakage and leakage point at Site S-06



Site S-07 is dedicated to the manufacture of basic chemical products. The site runs three heat transfer systems operating for more than 30 years. The volume of PHT used in circulation within the system varies from 50 to 190 m^3, depending on the system. The operating temperature range is 285-315°C and the pressure range is 2-4 barg. All of the systems have collection and expansion vessels, and centrifugal pumps with mechanical seals for fluid circulation. Low boiling components are vented in closed loops to process vents collection networks, that deliver the vents to furnaces for incineration. Finally, the disposed PHT is collected in closed-drain systems and then sent for incineration along with liquid organic wastes from the plant.

Figure 10. Air sample point in Site S-07

Site S-08 is operated by an energy producer. It includes a single heat transfer system composed of a biomass heater and an ORC turbine. The system contains 18 m^3 of PHT and it has been active for 5 years, running at a maximum temperature of 305°C and a pressure of 6 barg. It has an expansion tank, pumps and valves with mechanical seals, and a collection vessel. All the vent points are collected to the heater to burn the low boiling components.

Figure 11. Air sample point in Site S-08

No specific information about the heat transfer systems has been received from Site S-09 (basic chemicals producer).

Site S-10 is a PET producer that is operating a heat transfer system with a volume of PHT of 100 m^3 and an operating age of 24 years. The system is running at a maximum temperature of 333°C and a pressure range of 5 to 7 barg. All PHT returning from the different sub-loops is collected in an expansion vessel. From this, the PHT is pumped into the furnace coils and subsequently discharged to the main supply header. The expansion tank, main-loop-pumps, sub-loop-pumps, and drain-tank are all equipped with dams in order to collect any spills of PHT. Finally, the low boilers are removed batch-wise with the aid of a low-boiler removal skid. Therefore, the system can be considered completely closed.

Figure 12. Air sample point in Site S-10

Site S-11 is dedicated to the production of plastics machinery components (mainly conveyor belts). The site is operating a single heat transfer system with two heaters and four pumps connected each one to a different distribution line to the user's machines. The system contains 10 m^3 of PHT and it is operating since 1998, running at a maximum temperature of 300°C and a pressure of 3.5 barg. Installation includes a collection vessel, pumps and valves with mechanical seals, and an expansion tank. The low boilers are collected and treated by an external maintenance company.

Figure 13. Air sample point in Site S-11 (pumps)

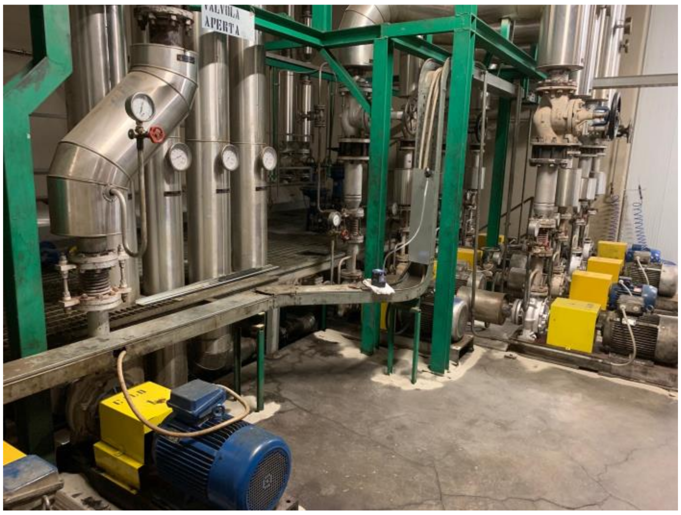
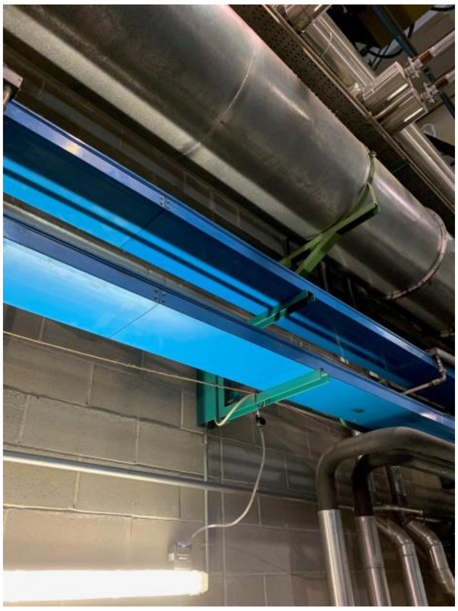


Figure 14. Air sample point in Site S-11 (transport pipes)



Site S-12 is a producer of PET resin that operates a single primary heat transfer system that feeds to other four smaller secondary systems. The overall equipment contains 70 m^3 of PHT and it is in operation since 2005, working at a pressure of 5 barg with a maximum temperature of 335°C. The system includes one storage tank and an expansion tank where low boilers are vented and later collected in a separate tank. These degraded products of PHT are disposed by authorized disposal companies with the required permits.

Site S-13 is an energy producer that operates a single heat transfer system composed of a biomass heater and an ORC turbine. The system is operating for 14 years with a volume of PHT of 65 m^3, at a maximum temperature of 310°C and a pressure of 3 bargs. It includes an expansion tank and a collection vessel, in which the low boilers are collected and disposed.

Figure 15. Air sample point in Site S-13

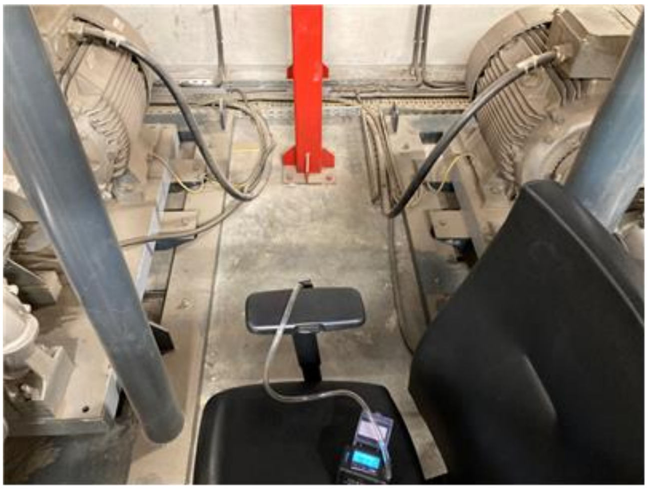


Table 26 shows a summary of the main characteristics of the monitoring sites:

Table 26. Summary of the monitoring sites

Site	Number of heat transfer systems measured	Age of the heat transfer systems (years old)	Volume of PHT (m^3)	Operating Temperature (°C)	Operating Pressure (barg)
S-01	3	36, 24, 14	60	220 - 310	7
S-02	2	42, 21	1,300	280 - 340	18
S-03	1	3	250	330	13,5
S-04	1	40	230	328	3 - 9
S-05	1	24	25	310	6
S-06	1	7	18	305	7
S-07	3	30	50 - 190	285 - 315	2 - 4
S-08	1	5	18	305	6
S-09	-	-	-	-	-
S-10	1	24	100	333	5 - 7
S-11	1	24	10	300	3.5
S-12	1	17	70	335	5
S-13	1	14	65	310	3

B.9.4. Use 2: Laboratory analysis

B.9.4.1. General information

PHT is used as HTF at multiple industrial and professional sites. At all sites samples are taken on a regular basis (once a year) to be analysed by the company selling the HTF. As a worst-case assumption 1 500 sites within the EU are assumed of which each site provides one 1 L sample for analysis per year. Specific information on the releases to the environment of PHT during analysis of HTF samples is obtained in the Exposure & Release Questionnaire (2018).

B.9.4.2. Exposure estimation

Table 27 shows the exposure estimation from the laboratory use.

Table 27. Exposure Estimation from use in laboratories

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.02%		
Total tonnage used in laboratory analysis	1.5	tonnes per year	Based on the assumption that each site within the EU sends a 1 L sample for analysis
Number of emission days	20 - 100	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 Exposure & Release Questionnaire (2018)
Daily amount of PHT used at a site (local scenario)	0.015 - 0.075	tonnes per day	Exposure & Release Questionnaire (2018)
Fraction released to air	0.001		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0 - 0.05		Exposure & Release Questionnaire (2018): No wastewater is produced during quality control operations on taken HTF samples. Wastewater which is generated during equipment cleaning is incinerated. Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.00025		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	1.5	kg per year	
Estimated release to wastewater	0 - 75	kg per year	
Estimated release to industrial soil	0.38	kg per year	
Estimated amount to solid waste for disposal	n.a.	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 28**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 28. Estimated EU releases to the environment from laboratory analysis in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	1.50	7.85
Water	0	5.67
Agricultural soil via application of sludge	0.38	63.36
Total	**1.88**	**76.87**

B.9.4.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.4.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.4.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 29**.

Table 29. Estimated indirect local exposure of human via the environment from laboratory analysis in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	6.44E-11	2.71E-4	mg/kg bw/d
Fraction of total dose through intake of drinking water	8.90E-6	0.0002	
Daily dose through intake of fish	1.96E-10	0.0045	mg/kg bw/d
Fraction of total dose through intake of fish	2.71E-5	0.0040	
Daily dose through intake of leaf crops	2.19E-6	1.09E-5	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.3027	9.71E-6	
Daily dose through intake of root crops	2.64E-7	1.113	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0365	0.9910	
Daily dose through intake of meat	3.01E-6	3.36E-3	mg/kg bw/d
Fraction of total dose through intake of meat	0.4161	0.0030	
Daily dose through intake of milk	1.77E-6	1.98E-3	mg/kg bw/d
Fraction of total dose through intake of milk	0.2447	0.0018	
Local total daily intake of humans	7.23E-6	1.12	mg/kg bw/d
Man via environment - inhalation (systemic effects)	1.14E-6	4.85E-6	mg/m^3
Man via environment - oral	7.24E-6	1.123	mg/kg bw/d

B.9.4.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 30**.

Table 30. Estimated environmental local exposure from laboratory analysis in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	2.3E-11	9.61E-3	mg/L
$PEClocal_{freshwater\ sediment}$	7.27E-7	303.8	mg/kg dw
$PEClocal_{marinewater}$	4.53E-12	9.61E-4	mg/L
$PEClocal_{marinewater\ sediment}$	1.43E-7	30.38	mg/kg dw
$PEClocal_{STP}$	0	0.142	mg/L
$PEClocal_{air}$	1.14E-6	4.85E-6	mg/m^3
$PEClocal_{agricultural\ soil}$	1.4E-5	60.31	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	1.19E-6	13.69	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	2.36E-7	1.369	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	2.36E-6	2.741	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	3.91E-5	164.5	mg/kg ww

B.9.5. Use 3: Use as HTF at professional sites

B.9.5.1. General information

PHT is used as HTF at multiple industrial and professional sites. Specific information on the releases to the environment of PHT during its use as HTF is obtained in the Exposure & Release Questionnaire (2018).

B.9.5.2. Exposure estimation

Table 31. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	17.94%		
Total tonnage used as HTF at prof. sites	1340	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use	335	tonnes per year	
Number of emission days	365	days per year	
Daily amount of PHT used at a site (local scenario)	10	tonnes per day	Worst-case assumption for prof. sites
Fraction released to air	0.002 - 0.05		Exposure & Release Questionnaire (2018) Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0 - 0.05		Exposure & Release Questionnaire (2018)

Input factor/assumption	**Value**	**Unit**	**Comment**
			Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.05		Exposure & Release Questionnaire (2018) Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	No solid waste is generated during the use of PHT as HTF		
Estimated release to air	20 – 500	kg per year	
Estimated release to wastewater	0 – 500	kg per year	
Estimated release to industrial soil	0 – 500	kg per year	
Estimated amount to solid waste for disposal	0	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 32**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 32. Estimated EU releases to the environment from professional use as HTF in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	20	542.33
Water	0	37.77
Agricultural soil via application of sludge	0	919.9
Total	**20**	**1 500**

B.9.5.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.5.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.5.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 33**.

Table 33. Estimated indirect local exposure of human via the environment from professional use as HTF in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	2.36E-8	3.60E-2	mg/kg bw/d
Fraction of total dose through intake of drinking water	1.14E-4	0.0002	
Daily dose through intake of fish	5.64E-5	11	mg/kg bw/d
Fraction of total dose through intake of fish	2.71E-1	0.0683	
Daily dose through intake of leaf crops	3.96E-5	0.023	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.1905	0.0001	
Daily dose through intake of root crops	2.54E-5	1.48E+2	mg/kg bw/d
Fraction of total dose through intake of root crops	0.1222	0.9266	
Daily dose through intake of meat	5.44E-5	0.477	mg/kg bw/d
Fraction of total dose through intake of meat	0.2616	0.0030	
Daily dose through intake of milk	3.21E-5	0.281	mg/kg bw/d
Fraction of total dose through intake of milk	0.1544	0.0018	
Local total daily intake of humans	2.08E-4	1.60E+2	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.06E-5	1.20E-2	mg/m^3
Man via environment - oral	2.08E-4	160.2	mg/kg bw/d

B.9.5.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 34**.

Table 34. Estimated environmental local exposure from professional use as HTF in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$\text{PEClocal}_{\text{freshwater}}$	6.6E-6	1.281	mg/L
$\text{PEClocal}_{\text{freshwater sediment}}$	0.209	4.05E+4	mg/kg dw
$\text{PEClocal}_{\text{marinewater}}$	8.45E-7	0.128	mg/L
$\text{PEClocal}_{\text{marinewater sediment}}$	0.027	4.05E+3	mg/kg dw
$\text{PEClocal}_{\text{STP}}$	0	18.88	mg/L
$\text{PEClocal}_{\text{air}}$	2.06E-5	0.012	mg/m^3
$\text{PEClocal}_{\text{agricultural soil}}$	1.37E-3	8.04E+3	mg/kg dw
$\text{PEClocal}_{\text{predators' prey (freshwater)}}$	0.343	3.33E+4	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (marine water)}}$	0.044	3.33E+3	mg/kg ww
$\text{PEClocal}_{\text{top predators' prey (marine water)}}$	0.439	6.66E+3	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (terrestrial)}}$	0.084	2.19E+4	mg/kg ww

B.9.6. Use 4: Formulation of adhesives and sealants

B.9.6.1. General information

PHT is used as plasticiser in adhesives and sealants. No specific information on the releases to the environment of PHT from formulation of adhesives/sealants is available. However, a FEICA / EFCC SpERC (FEICA / EFCC SPERC 2.1a.v3) is applicable for the refinement of the default assumptions.

B.9.6.2. Exposure estimation

Table 35. Assumptions for Exposure Estimations

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	6.42%		
Total tonnage used for formulation of adhesives/sealants	480	tonnes per year	
Number of emission days	100 - 300	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 FEICA / EFCC SPERC 2.1a.v3
Daily amount of PHT formulated at a site (local scenario)	1.6 - 4.8	tonnes per day	Estimate – assumes all of the tonnage is formulated at one site as a worst case
Fraction released to air	0.0008 - 0.025		FEICA / EFCC SPERC 2.1a.v3 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.0002 - 0.02		FEICA / EFCC SPERC 2.1a.v3 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.0001		FEICA / EFCC SPERC 2.1a.v3 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.002		FEICA / EFCC SPERC 2.1a.v3
Estimated release to air	384 – 12 000	kg per year	
Estimated release to wastewater	96 – 9 600	kg per year	
Estimated release to industrial soil	0 - 48	kg per year	
Estimated amount to solid waste for disposal	960	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 36**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 36. Estimated EU releases to the environment from formulation of adhesives/ sealants in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	392.13	12 812.64
Water	7.25	725.18
Agricultural soil via application of sludge	80.62	8 110.08
Total	**480**	**21 647.90**

B.9.6.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.6.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.6.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 37**.

Table 37. Estimated indirect local exposure of human via the environment from formulation of adhesives or sealants in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	2.32E-5	6.95E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.25E-4	0.0002	
Daily dose through intake of fish	5.76E-3	0.576	mg/kg bw/d
Fraction of total dose through intake of fish	5.59E-2	0.0197	
Daily dose through intake of leaf crops	5.62E-4	0.018	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0055	0.0006	
Daily dose through intake of root crops	9.50E-2	28.5	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9221	0.9735	
Daily dose through intake of meat	1.06E-3	0.11	mg/kg bw/d
Fraction of total dose through intake of meat	0.0103	0.0038	
Daily dose through intake of milk	6.22E-4	0.065	mg/kg bw/d
Fraction of total dose through intake of milk	0.0060	0.0022	
Local total daily intake of humans	1.03E-1	2.93E+1	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.93E-4	9.14E-3	mg/m^3
Man via environment - oral	1.03E-1	29.27	mg/kg bw/d

B.9.6.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 38**.

Table 38. Estimated environmental local exposure from formulation of adhesives/sealants in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	8.2E-4	0.246	mg/L
$PEClocal_{freshwater\ sediment}$	25.93	7.78E3	mg/kg dw
$PEClocal_{marinewater}$	8.2E-5	0.025	mg/L
$PEClocal_{marinewater\ sediment}$	2.593	777.8	mg/kg dw
$PEClocal_{STP}$	0.012	3.626	mg/L
$PEClocal_{air}$	2.93E-4	9.14E-3	mg/m^3
$PEClocal_{agricultural\ soil}$	5.151	1.54E3	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	17.52	1.75E3	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	1.752	175.2	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	3.509	350.9	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	14.04	4.21E3	mg/kg ww

B.9.7. Use 5: Use of adhesives and sealants at industrial sites

B.9.7.1. General information

PHT is used as plasticiser in adhesives and sealants. No specific information on the releases to the environment of PHT from the industrial use of adhesives/sealants is available. However, a FEICA SpERC (FEICA SPERC 5.1a.v3) is applicable for the refinement of the default assumptions.

B.9.7.2. Exposure estimation

Table 39. Assumptions for Exposure Estimation

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	5.14%		
Total tonnage used in adhesives/sealants at ind. sites	384	tonnes per year	
Number of emission days	20 - 300	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 FEICA SPERC 5.1a.v3
Daily amount of PHT used at a site (local scenario)	0.128 - 1.92	tonnes per day	Estimate – assumes 10% of the total use occurs at a large site
Fraction released to air	0.017 - 0.5		FEICA SPERC 5.1a.v3 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0 - 0.5		FEICA SPERC 5.1a.v3 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.01		FEICA SPERC 5.1a.v3 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0		FEICA SPERC 5.1a.v3
Estimated release to air per site (10 sites assumed in total)	652.8 – 19 200	kg per year	
Estimated release to wastewater (10 sites assumed in total)	0 – 19 200	kg per year	
Estimated release to industrial soil (10 sites assumed in total)	0 – 384	kg per year	
Estimated amount to solid waste for disposal (10 sites assumed in total)	0	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 40**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater

Table 40. Estimated EU releases to the environment from industrial use of adhesives/ sealants in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	6 528	208 253
Water	0	14 504
Agricultural soil via application of sludge	0	165 082
Total	**6 528**	**387 838**

B.9.7.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.7.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.7.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 41**.

Table 41. Estimated indirect local exposure of human via the environment from industrial use of adhesives/sealants in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	2.84E-8	6.90E-2	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.81E-6	0.0002	
Daily dose through intake of fish	6.42E-8	1.153	mg/kg bw/d
Fraction of total dose through intake of fish	6.35E-6	0.004	
Daily dose through intake of leaf crops	9.57E-4	0.029	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.09	0.0001	
Daily dose through intake of root crops	1.17E-4	285	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0116	0.9907	
Daily dose through intake of meat	1.31E-3	0.896	mg/kg bw/d
Fraction of total dose through intake of meat	0.1295	0.0031	
Daily dose through intake of milk	7.73E-3	0.528	mg/kg bw/d

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Fraction of total dose through intake of milk	0.7643	0.0018	
Local total daily intake of humans	1.01E-2	287.67	mg/kg bw/d
Man via environment - inhalation (systemic effects)	4.99E-4	1.50E-2	mg/m^3
Man via environment - oral	3.16E-3	287.6	mg/kg bw/d

B.9.7.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 42**.

Table 42. Estimated environmental local exposure from industrial use of adhesives/sealants in the EU

Compartment	Lower estimate	Upper estimate	Unit
PEClocal$_{\text{freshwater}}$	7.52E-9	2.46	mg/L
PEClocal$_{\text{freshwater sediment}}$	2.38E-4	7.78E4	mg/kg dw
PEClocal$_{\text{marinewater}}$	8.48E-9	0.246	mg/L
PEClocal$_{\text{marinewater sediment}}$	2.68E-4	7.78E3	mg/kg dw
PEClocal$_{\text{STP}}$	0	36.26	mg/L
PEClocal$_{\text{air}}$	4.99E-4	0.015	mg/m^3
PEClocal$_{\text{agricultural soil}}$	6.18E-3	1.54E4	mg/kg dw
PEClocal$_{\text{predators' prey (freshwater)}}$	3.91E-4	3.5E13	mg/kg ww
PEClocal$_{\text{predators' prey (marine water)}}$	4.41E-4	351.4	mg/kg ww
PEClocal$_{\text{top predators' prey (marine water)}}$	4.41E-3	711.3	mg/kg ww
PEClocal$_{\text{predators' prey (terrestrial)}}$	0.017	4.21E4	mg/kg ww

B.9.8. Use 6: Use of adhesives and sealants by professionals

B.9.8.1. General information

PHT is used as plasticiser in adhesives and sealants. No specific information on the releases to the environment of PHT from the professional use of adhesives/sealants is available. However, a FEICA SpERC (FEICA / EFCC SPERC 8f.1a.v2) is applicable for the refinement of the default assumptions.

B.9.8.2. Exposure estimation

Table 43. Assumptions for Exposure Estimations

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	1.28%		
Total tonnage used in adhesives/sealants at prof. sites	96	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use	96	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of PHT used at a site (local scenario)	5.28E-5	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	0 - 0.15		FEICA / EFCC SPERC 8f.1a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.015 - 0.05		FEICA / EFCC SPERC 8f.1a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.005		FEICA / EFCC SPERC 8f.1a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.04		FEICA / EFCC SPERC 8f.1a.v2
Estimated release to air	0 – 14 400	kg per year	
Estimated release to wastewater	1 440 – 4 800	kg per year	
Estimated release to industrial soil	0 - 480	kg per year	
Estimated amount to solid waste for disposal	38 4000	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 44**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 44. Estimated EU releases to the environment from professional use of adhesives/ sealants in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	121.90	14 806
Water	108.78	362.59
Agricultural soil via application of sludge	1 209.31	4 511
Total	**1 439.99**	**19 679.59**

B.9.8.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.8.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.8.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 45**.

Table 45. Estimated indirect local exposure of human via the environment from professional use of adhesives/sealants in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	5.73E-8	1.92E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.24E-4	0.0002	
Daily dose through intake of fish	1.85E-5	6E-5	mg/kg bw/d
Fraction of total dose through intake of fish	7.23E-2	0.0708	
Daily dose through intake of leaf crops	3.78E-7	6.50E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0015	0.0074	
Daily dose through intake of root crops	2.35E-4	7.88E-4	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9184	0.9010	
Daily dose through intake of meat	1.23E-6	1.13E-5	mg/kg bw/d
Fraction of total dose through intake of meat	0.0048	0.0129	
Daily dose through intake of milk	7.22E-7	6.65E-6	mg/kg bw/d
Fraction of total dose through intake of milk	0.0028	0.0076	
Local total daily intake of humans	2.56E-4	8.75E-4	mg/kg bw/d
Man via environment - inhalation (systemic effects)	1.97E-7	3.38E-6	mg/m^3
Man via environment - oral	2.56E-4	8.74E-4	mg/kg bw/d

B.9.8.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 46**.

Table 46. Estimated environmental local exposure from professional use of adhesives/sealants in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	2.17E-6	7.25E-6	mg/L
$PEClocal_{freshwater\ sediment}$	0.069	0.229	mg/kg dw
$PEClocal_{marinewater}$	2.19E-7	7.5E-7	mg/L
$PEClocal_{marinewater\ sediment}$	6.93E-3	0.024	mg/kg dw
$PEClocal_{STP}$	2.99E-5	9.97E-5	mg/L
$PEClocal_{air}$	1.97E-7	3.38E-6	mg/m^3
$PEClocal_{agricultural\ soil}$	0.013	0.043	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	0.06	0.201.	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	6.13E-3	0.021	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	0.19	0.073	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	0.036	0.122	mg/kg ww

B.9.9. Use 7: Service life of articles produced from use as plasticiser

B.9.9.1. General information

PHT is used as plasticiser in adhesives and sealants. No specific information on the releases to the environment of articles produced from use of adhesives and sealants containing PHT is available. However, results obtained in a leaching/migration estimation conducted by FABES (2021) are available. Please also refer to Chapter 9.9.2.4.

B.9.9.2. Exposure estimation

Table 47. Assumptions for Exposure Estimation

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	6.24%		
Total tonnage used in articles	480	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use of article	480	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of PHT used at a site (local scenario)	2.64E-4	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	n.a. - 0.0005		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7

Input factor/assumption	Value	Unit	Comment
Fraction released to wastewater	n.a. - 0.032		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	n.a. - 0.032		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	240	kg per year	
Estimated release to wastewater	15 360	Kg per year	
Estimated release to industrial soil	15 360	Kg per year	
Estimated amount to solid waste for disposal	n.a.	Kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 48**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 48. Estimated EU releases to the environment from service life of articles produced from use as plasticiser in the EU

Total EU releases following redistribution in STP	Lower estimate (kg/ per year)	Upper estimate (kg/ per year)
Air	n.a.	1 540.22
Water	n.a.	1 160.29
Agricultural soil via application of sludge	n.a.	28 259.33
Total	**n.a.**	**30 959.85**

B.9.9.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.9.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.9.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 49**.

Table 49. Estimated indirect local exposure of human via the environment from service life of articles produced from use as plasticiser in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	n.a.	6.12E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	2E-4	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0724	
Daily dose through intake of leaf crops	n.a.	8.76E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0032	
Daily dose through intake of root crops	n.a.	2.51E-3	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9129	
Daily dose through intake of meat	n.a.	1.96E-5	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0071	
Daily dose through intake of milk	n.a.	1.15E-5	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0042	
Local total daily intake of humans	n.a.	2.75E-3	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	4.56E-6	mg/m^3
Man via environment - oral	n.a.	2.75E-3	mg/kg bw/d

B.9.9.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 50**.

Table 50. Estimated environmental local exposure from service life of articles produced from use as plasticiser in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$PEClocal_{freshwater}$	n.a.	2.32E-5	mg/L
$PEClocal_{freshwater\ sediment}$	n.a.	0.735	mg/kg dw
$PEClocal_{marinewater}$	n.a.	2.36E-6	mg/L
$PEClocal_{marinewater\ sediment}$	n.a.	0.075	mg/kg dw
$PEClocal_{STP}$	n.a.	3.19E-4	mg/L
$PEClocal_{air}$	n.a.	4.56E-6	mg/m^3
$PEClocal_{agricultural\ soil}$	n.a.	0.136	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	n.a.	0.646	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	n.a.	0.067	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	n.a.	0.217	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	n.a.	0.39	mg/kg ww

B.9.9.3. Migration modelling

In addition to experimental methods, an alternative tool based on theoretical migration estimations can be applicable for verifying the leaching/migration of substances from specific matrixes. The EU introduced this option to use generally recognised diffusion models as a novel compliance and quality assurance tool for assessing food contact compliance[19].

Migration is a global term to describe a net mass transfer of a chemical substance from one material (e.g., plastic packaging) into another medium (e.g., food, water, air). Migration includes several macroscopic mass transfer mechanisms, such as:

- Mass diffusion in and through the different (polymer) materials as well as the liquid or gas phases separating the primary source from the target medium.
- Desorption/sorption at the interface between each crossed medium. When it involves fluid phases, migration may also cover an additional transport or mixing effect by advection.

Migration modelling is an abstract process aiming at calculating the maximum number of substances which might be transferred to the medium in contact, with various simplifications and assumptions. It is important to note that the migration modelling used for the purpose of this proposal does not seek to reproduce all the details of the real mechanisms; instead, the objective is to provide an estimate of potential migration for getting an indication of potential emissions into the environment via the migration path of plasticizers used in coatings, sealants, and articles.

Migration Scenario:

Estimation of Leaching/Migration of PHT from a special epoxy top coating (Fabes, 2021)[20]:

- Report No.:	7945-21
- Completion Date:	3.9.2021
- Number of Pages:	17

In this report the leaching/migration of PHT from a special epoxy topcoat, used in the aerospace & defence industry, into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach.

The coating is used to protect metallic structures. It contains a certain amount of PHT and is a three component, water-borne, glossy epoxy-coating obtained by mixing a so-called base with a hardener/catalyst and using demineralised water as thinner. Initially PHT is part of the base component (5 to 10% w/w), but after the mixing of the base with the hardener and thinner this substance is uniformly distributed in the topcoat. This is most likely also the case when the topcoat dries after several hours.

In principle, it can be assumed that the molecules of PHT ("the migrant") are most likely not firmly bound, trapped and cross linked (for example by strong covalent or ionic bounds) in the dry coating. Thus, the PHT molecules exhibit a certain mobility (diffusivity) in the network of the free-volumes of the polymeric topcoat. That means that in the presence of a PHT concentration gradient (which acts as a driving force) inside the coating, the molecules of the migrant can diffuse/move towards regions with lower concentrations of this substance. The rate of this internal diffusion in the coating is controlled mainly by the mobility (diffusion coefficient - Dp) of the PHT molecules and the magnitude of the migrant concentration gradient inside the dry topcoat. It is well known that the service time of the metallic aerospace

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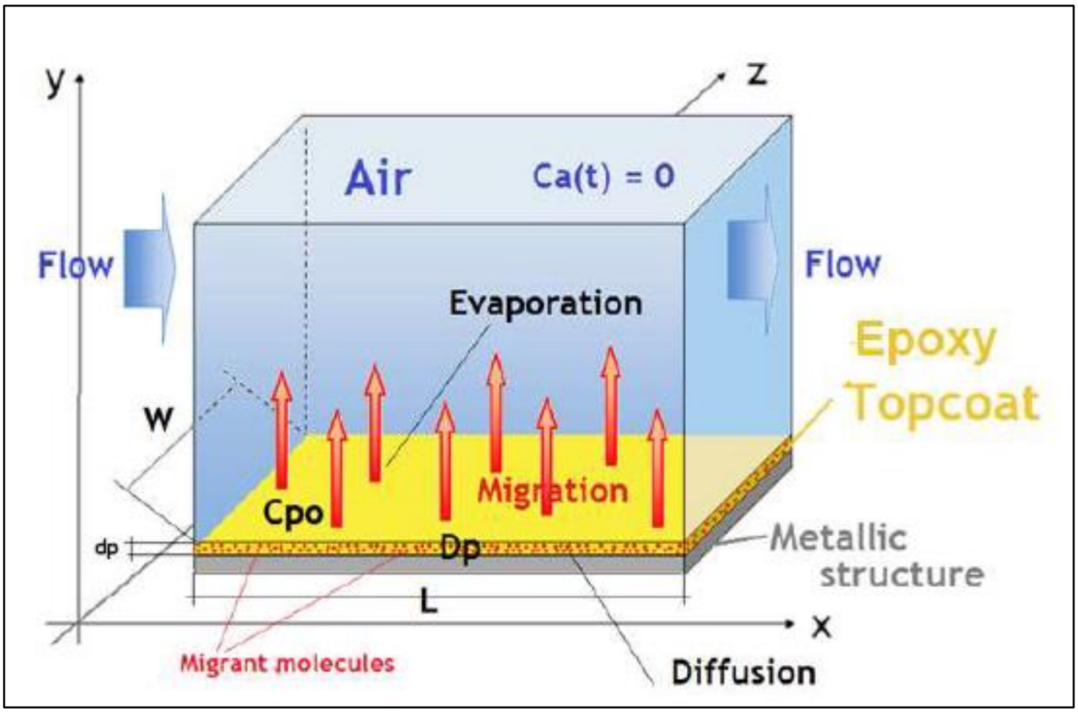
[19] JRC Publications Repository - Practical guidelines on the application of migration modelling for the estimation of specific migration (europa.eu)

[20] Fabes (2021): Estimation of Leaching/Migration of hydrogenated Terphenyl from a special epoxy top coating.-

structures coated with this coating may extend over several decades. During this time the topcoat may be exposed to temperatures that may range from low, two digits sub-zero levels to high two digits positive levels. From basic physical-chemical principles it is logic to assume that PHT molecules, which are situated in the top-coating just underneath its surface in contact with the surrounding atmosphere (air) and accumulate enough energy, may leach from the coating, evaporate, and diffuse into the air. The higher the temperature (T), the more energy is accumulated by PHT molecules and consequently the more leaching from the coating takes place. Once some part of the PHT molecules leave the "air-contact surface" of the coating, a migrant concentration gradient between this region and the "core" of the paint layer results. This gradient determines the internal diffusion of PHT molecules from the "core" of the paint layer towards its "air-contact surface". The whole process of PHT molecules diffusion in and leaching from the topcoat will be further called "the migration" of PHT from the coating into air. Theoretically, this process lasts until mobile PHT molecules still exist in the topcoat. Schematically this process is presented in **Figure 16**. A migration/leaching process cannot take place in the opposite direction because the metals coated with the coating can be considered as perfectly impermeable to any migrant molecule.

Figure 16. Schematic diagram of the migration of PHT from a topcoat layer into the surrounding atmosphere (flow of air) (Source: Fabes Report No. 7945-21, 2021, Fig. 1)



The rate of migration/leaching of PHT molecules from the topcoat into air depends, in principle, on the diffusion rate of PHT in the dry epoxy coating and on the evaporation rate of this migrant into air. Obviously, both processes are temperature dependent; the higher the temperature, the higher the diffusion rate and the evaporation rate.

Because in this migration scenario it is assumed that a flow of air always sweeps the painted metallic structure, an accumulation (till saturation) of PHT molecules in air never takes place. This means that the concentration of PHT in the air surrounding the sealant sample can be zero for any migration time. For the mathematical quantification of this migration process, it is important to know the relative magnitudes of the diffusion rate and evaporation rate processes. If the diffusion rate is significantly greater than the evaporation rate, this would mean that the migration process is predominantly "evaporation controlled". In case the evaporation rate is significantly greater than the diffusion rate, the migration process is "diffusion controlled". If both are similar, the migration process depends on both phenomena and it is "diffusion-evaporation controlled". To assess this problem for the migration scenario shown in **Figure 16**. it was the first necessary to specify the temperature/s during the migration process. As already mentioned, metallic structures of aerospace devices may be exposed (for shorter or longer periods) to severe sub-zero °C-temperatures but also to two digits positive °C temperatures.

It is well documented in the literature[21,22] that the diffusion/evaporation rate processes in discussion depend exponentially on the temperature.

Thus, PHT molecules in a coating may have diffusion and evaporation rates varying many orders of magnitude. Even more (because of the different activation energies) it might be that at low temperatures diffusion rate is greater than evaporation rate and at high temperature the opposite situation is true. Therefore, a realistic assessment of when the migration of the PHT molecules from the topcoat is diffusion or evaporation controlled would require the knowledge of the "real time-temperature scenario" to which the aerospace device is exposed during its service time. But such information is difficult if not impossible to obtain. Because of that in a first approximation a very simple "time-temperature scenario", i.e., a thin layer of dry topcoat is kept at constant T=20°C for a service time of t = 10 or 20 years, in a steadily flowing flux of air. For this "time-temperature scenario" the migration was assessed. Further calculations and input-parameters (incl. physical-chemical data of PHT and the coating) are available in the Fabes Report No. 7945-21, 2021.

For the theoretical estimation of a migration process like the one discussed above, the information about the mobility (Dp) of the migrant molecules in the matrix of the topcoat and of the partitioning at equilibrium of the migrant at the boundary between this material and air (KPa) are indispensable and very important information. As already mentioned, in principle these coefficients can be determined experimentally but such a process might be challenging.

To estimate the amount of PHT migration at 20°C from the topcoat into air in 10 and 20 years, the software MIGRATEST®-Runner2020[23] was used. **Figure 17** and **Figure 18** show the calculated results for a service time of 10 and 20 years.

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[21] 5.2C: Diffusion - Biology LibreTexts

[22] Fick's laws of diffusion - Wikipedia

[23] Software | FABES Forschungs-GmbH (fabes-online.de)

Figure 17. Time dependent amount of PHT migrated, at 20°C in 10 years, from the coating into a flow of air (Source: Fabes Report No. 7945-21, 2021, Fig. 4)

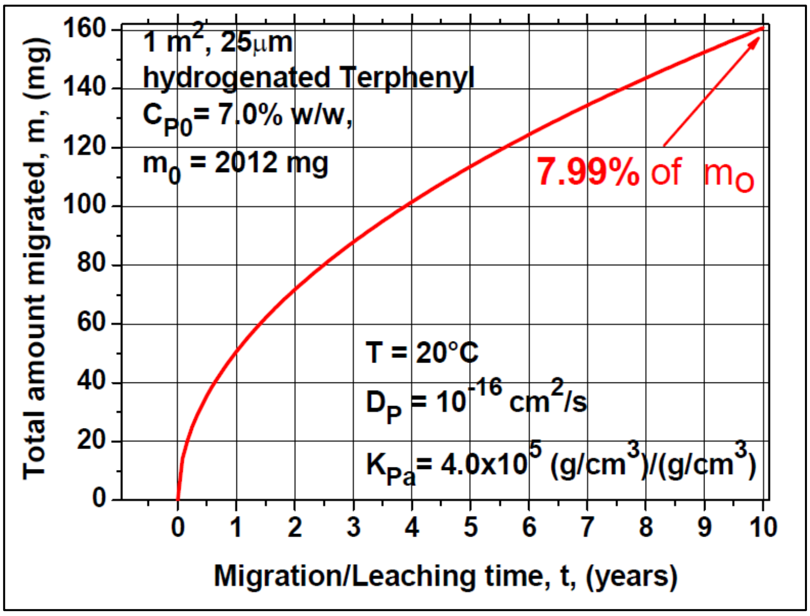
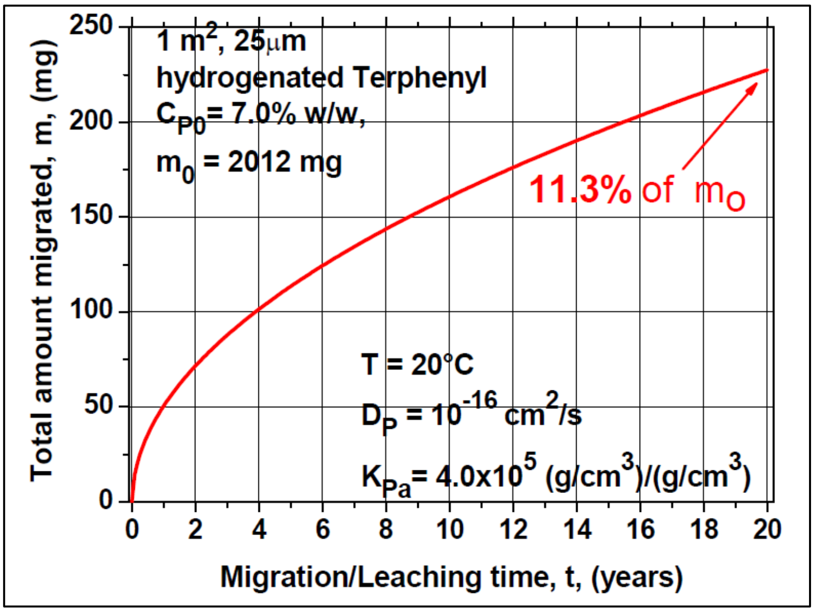


Figure 18. Time dependent amount of PHT migrated, at 20°C in 20 years, from the coating into a flow of air (Source: Fabes Report No. 7945-21, 2021, Fig. 5)



In conclusion, during a service life of 10 years ca. 8% of PHT used as a plasticizer in a coating for airplanes would migrate into the surrounding air. For a service life of 20 years, the loss of PHT would increase to ca. 11%.

As discussed under **Annex A** (Manufacture and Use), the annual volume in the EU of aerospace coatings in 2018 is assumed to be 250 tonnes year (no volume increase over time considered). As a result, within a service life of 10 years potentially **200 tonnes** out of the 2.500 t within the **10-years** range consumed could enter the environment. Considering a service life of **20 years** and 5 000 tonnes of coating used (250 tonnes year * 20 years), **550 tonnes** of PHT could potentially migrate from the top-coating into the environment. However, since airplanes travel globally, the potential loss of PHT to the environment cannot be localized to the EU only. Anyhow, since non-EU planes will be using the same coatings and are in service in the EU too, the Dossier Submitter finds it reasonable to use these numbers as worst-case releases.

Migration Scenario:

Estimation of Migration of PHT from a plasticiser use in joint seals for underground cables (FABES, 2021)[24]

- Report No.: 8053-21
- Completion Date: 3.12.2021
- Number of Pages: 17

In this report the migration of PHT from a special cable joint sealant into the soil and groundwater surrounding a high voltage cable joint is estimated by means of a theoretical modelling approach.

The polymer modified bitumen (PmB) is used as a sealant to insulate special high voltage cables. These cable joints are then buried in the soil with potential groundwater contact.

No further details about the chemical nature of the PmB materials were disclosed, but information is available that the polymer used is polyurethane (PU) and that the PmB material contains between 5 and 10% w/w of PHT.

In principle, it can be assumed that the molecules of PHT ("the migrant") are most likely not firmly bound, trapped and cross linked (for example by strong covalent or ionic bounds) in the PmB material. Thus, the PHT molecules exhibit a given mobility (diffusivity) in the network of the free-volumes of this sealant material. That means that in the presence of a PHT concentration gradient (which acts as a driving force) inside the PmB sealant, the molecules of the migrant can diffuse/move towards regions with lower concentrations of this substance. The rate of this internal diffusion in the sealant is controlled mainly by the mobility (diffusion coefficient DP) and the magnitude of the migrant concentration gradient inside the PmB material. Once the high voltage cables are buried in the soil this PmB coating/insulation will come into contact with the surrounding soil (which may or may not contain a given amount of water). Even more, in some cases the buried high voltage cables may come into contact with the groundwater. In such situations, from basic physical-chemical principles, it is logic to assume that PHT molecules, situated just underneath the contact surface of the PmB sealant and which accumulate enough energy may leach from the sealant and diffuse into the surrounding soil or ground water.

The higher the temperature T, the more energy is accumulated by the PHT molecules and consequently the more leaching from the PmB sealant takes place. Once some part of the PHT molecules "leave" the surface of the PmB coating/insulation a migrant concentration gradient between this region and the "core" of the sealant layer results. This gradient determines the internal diffusion of PHT molecules from the "core" towards the "contact surface" of the sealant layer. The whole process of PHT molecules diffusion in and leaching from the PmB material will be further called "the migration" of PHT from the sealant into the soil or groundwater. Theoretically, this process lasts until mobile PHT molecules still exist in the PmB material. Schematically this process is presented in **Figure 19**.

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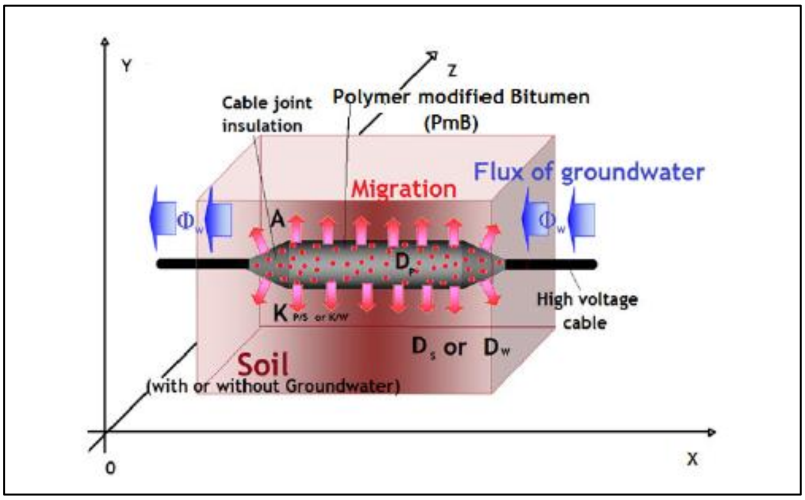
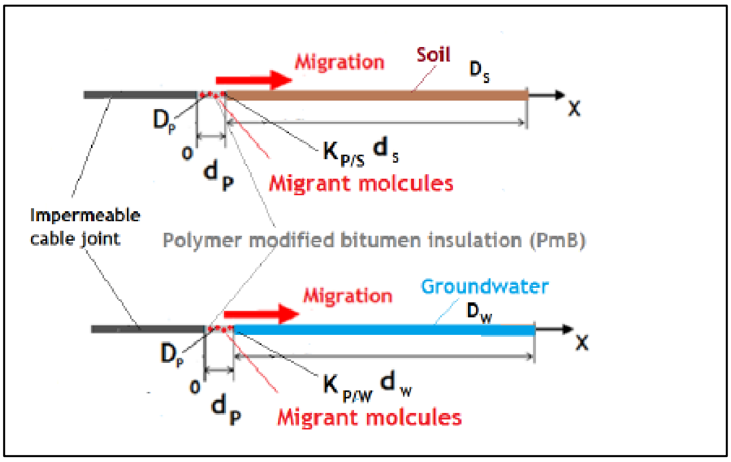
[24] Fabes (2021): Estimation of Migration of hydrogenated Terphenyl from a special Cable Joint made of a Polymer modified Bitumen Sealant.-

Figure 19. Schematic diagram of the migration of PHT from the insulation of a high voltage cable joint into surrounding soil (Source: Fabes Report No. 8053-21, 2021, Fig. 2)



The calculation/estimation of the migration process has been conducted according to the previously described migration scenarios and is illustrated in **Figure 20**.

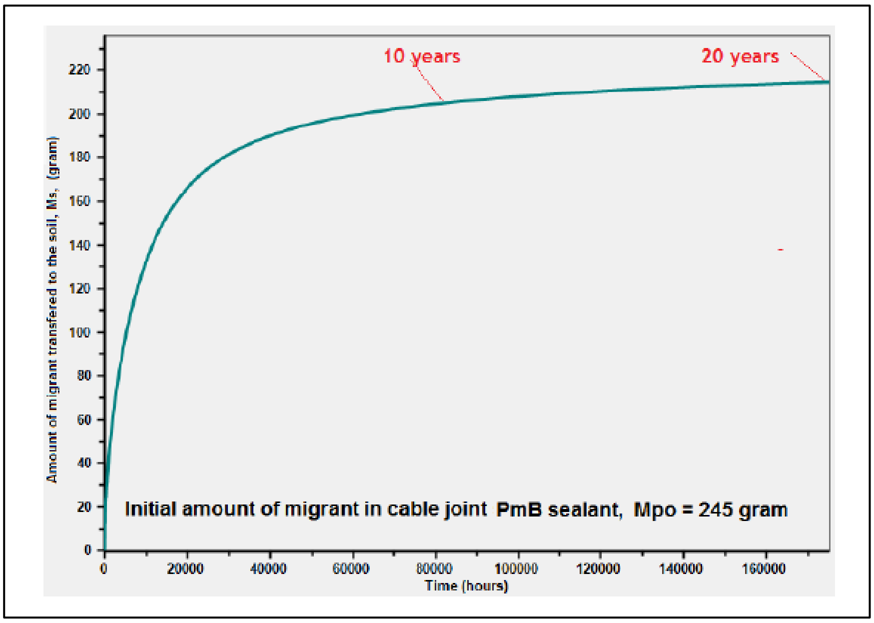
Figure 20. Schematic diagram Schematic presentation of the migration/leaching from a polymer modified bitumen (PmB) insulation of a special cable joint into the soil and groundwater (Source: Fabes Report No. 8053-21, 2021, Fig. 3)



In the migration modelling it was estimated that the total initial amount of PHT in the PMB sealant (m_{p0}) is 245 g, reflecting a cable joint with a length of 270 cm.

The calculated time dependent increase of the migrated/leached PHT amount from the biggest cable joint PmB sealant into a stagnant soil surrounding the cable joint in a 1 m radius is shown in **Figure 21**. Note, that M_{p0} is the total amount (in g) of PHT found initially in the PMB layer insulation the cable joint (at 10% w/w).

Figure 21. Time dependent amount of PHT migrated from the PMB insulation of the biggest cable joint into a 1 m thick stagnant soil layer surrounding the cable (Source: Fabes Report No. 8053-21, 2021, Fig. 4)



The temperature during the migration process was assumed to be 10°C and the migration rates were calculated for 10 and 20 years. According to the modelling, after 10 years > 80% and after 20 years > 85% of PHT migrated from the sealant into the soil. Assuming, that this application consumes 10 tonnes year within the EU, it can be concluded that ca. **80 tonnes** in total could be migrating within **10 years** into the environment, in **20 years** approximately **85 tonnes** could have been leached into the cable surrounding soil.

The migration of PHT into a flux of groundwater was modelled as well but the amounts of leached PHT into the groundwater were considerably lower compared to the migration into the soil, due to the very low water solubility of PHT.

B.9.10. Use 8: Formulation of coatings/inks

B.9.10.1. General information

PHT is used as plasticiser in coatings and inks. No specific information on the releases to the environment of PHT from formulation of coatings/inks is available. However, a CEPE SpERC (CEPE SPERC 2.1c.v2) is applicable for the refinement of the default assumptions.

B.9.10.2. Exposure estimation

Table 51. Assumptions for Exposure Estimation

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	3.40%		
Total tonnage for formulation of coatings/inks	254	tonnes per year	
Number of emission days	100 - 225	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 CEPE SpERC 2.1c.v2
Daily amount of PHT formulated at a site (local scenario)	1.129 - 2.54	tonnes per day	Estimate – assumes all of the tonnage is formulated at one site as a worst case
Fraction released to air	9.5E-5 - 0.025		CEPE SpERC 2.1c.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to Wastewater	5E-5 – 0.02		CEPE SpERC 2.1c.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.0001		CEPE SpERC 2.1c.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.01		CEPE SpERC 2.1c.v2
Estimated release to air	24.13 – 6 350	kg per year	
Estimated release to wastewater	12.70 – 5 080	kg per year	
Estimated release to industrial soil	0 – 25.40	kg per year	
Estimated amount to solid waste for disposal	2 540	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 52**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 52. Estimated EU releases to the environment formulation of coatings/inks in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	25.21	6 780.02
Water	0.96	383.74
Agricultural soil via application of sludge	10.67	4 291.58
Total	**36.83**	**11 455.35**

B.9.10.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.10.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.10.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 53**.

Table 53. Estimated indirect local exposure of human via the environment from formulation of coatings/inks in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	4.08E-6	3.68E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	0.0002	0.0002	
Daily dose through intake of fish	7.62E-4	0.31	mg/kg bw/d
Fraction of total dose through intake of fish	0.0424	0.0197	
Daily dose through intake of leaf crops	3.53E-5	9.31E-3	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0020	0.0006	
Daily dose through intake of root crops	1.70E-2	1.51E+1	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9466	0.9735	
Daily dose through intake of meat	9.87E-05	0.058	mg/kg bw/d
Fraction of total dose through intake of meat	0.0055	0.0037	
Daily dose through intake of milk	5.82E-05	0.034	mg/kg bw/d
Fraction of total dose through intake of milk	0.0032	0.0022	
Local total daily intake of humans	1.80E-2	1.55E+1	mg/kg bw/d
Man via environment - inhalation (systemic effects)	1.84E-5	4.84E-3	mg/m^3
Man via environment - oral	0.018	15.49	mg/kg bw/d

B.9.10.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 54**.

Table 54. Estimated environmental local exposure from formulation of coatings/inks in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	1.45E-4	0.13	mg/L
$PEClocal_{freshwater\ sediment}$	4.574	4.12E+3	mg/kg dw
$PEClocal_{marinewater}$	1.45E-5	0.013	mg/L
$PEClocal_{marinewater\ sediment}$	0.457	411.6	mg/kg dw
$PEClocal_{STP}$	2.13E-3	1.919	mg/L
$PEClocal_{air}$	1.84E-5	4.84E-3	mg/m^3
$PEClocal_{agricultural\ soil}$	0.908	817.1	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	2.318	927.3	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	0.232	92.73	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	0.464	185.6	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	2.477	2.23E+3	mg/kg ww

B.9.11. Use 9: Direct use for industrial coatings and inks applications

B.9.11.1. General information

PHT is used as plasticiser in coatings and inks. No specific information on the releases to the environment of PHT from the industrial use of coatings and inks is available. However, a CEPE SpERC (CEPE SPERC 5.1a.v2) is applicable for the refinement of the default assumptions.

B.9.11.2. Exposure estimation

Table 55. Assumptions for Exposure Estimation

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7,471	tonnes per year	
Share of total volume	2.73%		
Total tonnage used in coatings/inks at ind. sites	204	tonnes per year	
Number of emission days	20 - 225	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 CEPE SPERC 5.1a.v2
Daily amount of PHT used at a site (local scenario)	0.091 – 1.02	tonnes per day	Estimate – assumes 10% of the total use occurs at a large site
Fraction released to air	0.015 - 0.5		CEPE SPERC 5.1a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0 - 0.5		CEPE SPERC 5.1a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0 - 0.01		CEPE SPERC 5.1a.v2

Input factor/assumption	Value	Unit	Comment
			Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.52		CEPE SPERC 5.1a.v2
Estimated release to air per site (10 sites assumed in total)	306 – 10 200	kg per year	
Estimated release to wastewater per site (10 sites assumed in total)	0 – 10 200	kg per year	
Estimated release to industrial soil per site (10 sites assumed in total)	0 - 204	kg per year	
Estimated amount to solid waste for disposal per site (10 sites assumed in total)	10 608	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 56**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 56. Estimated EU releases to the environment from industrial coatings and inks applications in the EU

Total EU releases following redistribution in STP	Lower estimate (kg per year)	Upper estimate (kg per year)
Air	3 060	110 634
Water	0	7705
Agricultural soil via application of sludge	0	87 700
Total	**3 060**	**206 039**

B.9.11.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.11.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.11.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 57**.

Table 57. Estimated indirect local exposure of human via the environment from industrial coatings and inks applications in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	1.33E-8	3.39E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	8.98E-6	0,0004	
Daily dose through intake of fish	3.01E-8	8.097	mg/kg bw/d
Fraction of total dose through intake of fish	2.03E-5	0.9931	
Daily dose through intake of leaf crops	4.49E-4	0.015	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.3032	0.0018	
Daily dose through intake of root crops	5.47E-5	1.84E-3	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0369	0.0002	
Daily dose through intake of meat	6.15E-4	0.023	mg/kg bw/d
Fraction of total dose through intake of meat	0.4153	0.0028	
Daily dose through intake of milk	3.62E-4	0.013	mg/kg bw/d
Fraction of total dose through intake of milk	0.2445	0.0016	
Local total daily intake of humans	1.48E-3	8.15	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.34E-4	7.81E-3	mg/m^3
Man via environment - oral	1.48E-3	8.153	mg/kg bw/d

B.9.11.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 58**.

Table 58. Estimated environmental local exposure from industrial coatings and inks applications in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$\text{PEClocal}_{\text{freshwater}}$	3.52E-9	17.29	mg/L
$\text{PEClocal}_{\text{freshwater sediment}}$	1.11E-4	5.47E5	mg/kg dw
$\text{PEClocal}_{\text{marinewater}}$	3.98E-9	1.73	mg/L
$\text{PEClocal}_{\text{marinewater sediment}}$	1.26E-4	5.47E+4	mg/kg dw
$\text{PEClocal}_{\text{STP}}$	0	0	mg/L
$\text{PEClocal}_{\text{air}}$	2.34E-4	7.81E-3	mg/m^3
$\text{PEClocal}_{\text{agricultural soil}}$	2.9E-3	0.098	mg/kg dw
$\text{PEClocal}_{\text{predators' prey (freshwater)}}$	1.83E-4	2.46E+4	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (marine water)}}$	2.07E-4	2.46E+3	mg/kg ww
$\text{PEClocal}_{\text{top predators' prey (marine water)}}$	2.07E-3	4.93E+3	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (terrestrial)}}$	8.17E-3	1.467	mg/kg ww

B.9.12. Use 10: Direct use for professional coatings/inks applications

B.9.12.1. General information

PHT is used as plasticiser in coatings and inks. No specific information on the releases to the environment of PHT from the professional use of coatings/inks is available. However, a CEPE SpERC (CEPE SPERC 8f.3a.v2) is applicable for the refinement of the default assumptions. Thereby, the release to soil is higher using the SpERC than the default release factor as indicated in ECHA Guidance R.16.

B.9.12.2. Exposure estimation

Table 59. Assumptions for Exposure Estimation

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7,471	tonnes per year	
Share of total volume	0.68%		
Total tonnage used in adhesives/sealants at prof. sites	51	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use	51	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of PHT used at a site (local scenario)	2.81E-5	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	0 - 0.15		CEPE SPERC 8f.3a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.02 - 0.05		CEPE SPERC 8f.3a.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.005 – 0.02		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7 CEPE SPERC 8f.3a.v2
Fraction released to solid waste	0.3		CEPE SPERC 8f.3a.v2
Estimated release to air	0 – 7 650	kg per year	
Estimated release to wastewater	1 020 – 2 550	kg per year	
Estimated release to industrial soil	255 – 1 020	kg per year	
Estimated amount to solid waste for disposal	15 300	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in

Table 60. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 60. Estimated EU releases to the environment from professional coatings and inks application in the EU

Total EU releases following redistribution in STP	Lower estimate (kg per year)	Upper estimate (kg per year)
Air	86.34	7 865.86
Water	77.05	192.63
Agricultural soil via application of sludge	1 111.6	3 161.49
Total	**1 274.99**	**11 219.97**

B.9.12.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.12.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.12.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 61**.

Table 61. Estimated indirect local exposure of human via the environment from professional coatings and inks applications in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	4.07E-08	1.02E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.23E-04	2.19E-4	
Daily dose through intake of fish	1.32E-05	3.29E-5	mg/kg bw/d
Fraction of total dose through intake of fish	0.0722	0.0706	
Daily dose through intake of leaf crops	5.76E-07	3.68E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0031	0.0079	

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of root crops	1.67E-04	4.19E-4	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9132	0.8997	
Daily dose through intake of meat	1.29E-06	6.31E-6	mg/kg bw/d
Fraction of total dose through intake of meat	0.0071	0.0135	
Daily dose through intake of milk	7.61E-07	3.72E-6	mg/kg bw/d
Fraction of total dose through intake of milk	0.0042	0.0080	
Local total daily intake of humans	1.83E-04	4.66E-4	mg/kg bw/d
Man via environment - inhalation (systemic effects)	3E-7	1.92E-6	mg/m^3
Man via environment - oral	1.83E-4	4.65E-4	mg/kg bw/d

B.9.12.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 62**.

Table 62. Estimated environmental local exposure from professional coatings and inks applications in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
PEClocal$_{\text{freshwater}}$	1.54E-6	3.86E-6	mg/L
PEClocal$_{\text{freshwater sediment}}$	0.049	0.122	mg/kg dw
PEClocal$_{\text{marinewater}}$	1.57E-7	3.99E-7	mg/L
PEClocal$_{\text{marinewater sediment}}$	4.97E-3	0.013	mg/kg dw
PEClocal$_{\text{STP}}$	2.12E-5	5.3E-5	mg/L
PEClocal$_{\text{air}}$	3E-7	1.92E-6	mg/m^3
PEClocal$_{\text{agricultural soil}}$	9.04E-3	0.023	mg/kg dw
PEClocal$_{\text{predators' prey (freshwater)}}$	0.043	0.107	mg/kg ww
PEClocal$_{\text{predators' prey (marine water)}}$	4.43E-3	0.011	mg/kg ww
PEClocal$_{\text{top predators' prey (marine water)}}$	0.014	0.04	mg/kg ww
PEClocal$_{\text{predators' prey (terrestrial)}}$	0.026	0.065	mg/kg ww

B.9.13. Use 11: Service life of articles produced from use of coatings and inks

B.9.13.1. General information

PHT is used as plasticiser in coatings and inks. No specific information on the releases to the environment of articles produced from use of coatings and inks containing PHT is available.

However, results obtained in a leaching/migration estimation conducted by FABES (2021) are available. Please also refer to Chapter 9.13.2.4.

B.9.13.2. Exposure estimation

Table 63. Assumptions for Exposure Estimations

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	3.40%		
Total tonnage used in articles	254	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use of article	254	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of PHT used at a site (local scenario)	1.4E-4	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	0.0005		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.032		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.032		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	n.a. - 25.50	kg per year	
Estimated release to wastewater	n.a. - 163.20	kg per year	
Estimated release to industrial soil	n.a. - 163.20	kg per year	
Estimated amount to solid waste for disposal	n.a.	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 64**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 64. Estimated EU releases to the environment from service life of articles produced from use of coatings and inks in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	n.a.	39.31
Water	n.a.	12.33
Agricultural soil via application of sludge	n.a.	300.26
Total	**n.a.**	**351.90**

B.9.13.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.13.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.13.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 65**.

Table 65. Estimated indirect local exposure of human via the environment from service life of articles produced from use of coatings and inks in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	n.a.	3.24E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	1.05E-4	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0721	
Daily dose through intake of leaf crops	n.a.	4.64E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0032	
Daily dose through intake of root crops	n.a.	1.33E-3	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9132	
Daily dose through intake of meat	n.a.	1.04E-5	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0071	

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of milk	n.a.	6.10E-6	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0042	
Local total daily intake of humans	n.a.	1.46E-3	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	2.41E-6	mg/m^3
Man via environment - oral	n.a.	1.46E-3	mg/kg bw/d

B.9.13.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 66**.

Table 66. Estimated environmental local exposure from service life of articles produced from use of coatings and inks in the EU

Compartment	Lower estimate	Upper estimate	Unit
$\text{PEClocal}_{\text{freshwater}}$	n.a.	1.23E-5	mg/L
$\text{PEClocal}_{\text{freshwater sediment}}$	n.a.	0.389	mg/kg dw
$\text{PEClocal}_{\text{marinewater}}$	n.a.	1.25E-6	mg/L
$\text{PEClocal}_{\text{marinewater sediment}}$	n.a.	0.04	mg/kg dw
$\text{PEClocal}_{\text{STP}}$	n.a.	1.69E-4	mg/L
$\text{PEClocal}_{\text{air}}$	n.a.	2.41E-6	mg/m^3
$\text{PEClocal}_{\text{agricultural soil}}$	n.a.	0.072	mg/kg dw
$\text{PEClocal}_{\text{predators' prey (freshwater)}}$	n.a.	0.342	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (marine water)}}$	n.a.	0.035	mg/kg ww
$\text{PEClocal}_{\text{top predators' prey (marine water)}}$	n.a.	0.115	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (terrestrial)}}$	n.a.	0.206	mg/kg ww

B.9.13.3. Migration modelling

In addition to experimental methods, an alternative tool based on theoretical migration estimations can be applicable for verifying the leaching/migration of substances from specific matrixes. The EU introduced this option to use generally recognised diffusion models as a novel compliance and quality assurance tool for assessing food contact compliance[25].

Migration is a global term to describe a net mass transfer of a chemical substance from one material (e.g., plastic packaging) into another medium (e.g., food, water, air). Migration includes several macroscopic mass transfer mechanisms including:

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[25] JRC Publications Repository - Practical guidelines on the application of migration modelling for the estimation of specific migration (europa.eu)

- Mass diffusion in and through the different (polymer) materials as well as the liquid or gas phases separating the primary source from the target medium.
- Desorption/sorption at the interface between each crossed medium. When it involves fluid phases, migration may also cover an additional transport or mixing effect by advection.

Migration modelling is an abstract process aiming at calculating with various simplifications and assumptions the maximum amount of substances which might be transferred to the medium in contact. It is important to note that the migration modelling used for the purpose of this proposal does not seek to reproduce all the details of the real mechanisms but to provide an estimate of potential migration for getting an indication of potential emissions into the environment via the migration path of plasticizers used in coatings, sealants, and articles.

Migration Scenario:

Estimation of Migration of PHT from a special polysulfide sealant (FABES, 2021)[26]

- Report No.: 7946-21
- Completion Date: 7.9.2021
- Number of Pages: 17

In this report the migration of PHT from a sample plate made of polysulfide sealant into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach.

The polysulfide sealant is used in the aerospace industry as integral fuel tank and aircraft body sealant. The two-component polysulfide sealant is obtained by the mixing of a base component and a catalyst. Initially PHT is part of the catalyst component (30 to 45% w/w), but in the freshly mixed sealant (which is a thixotropic paste) PHT is uniformly distributed. This is most likely also the case after several hours with the cured sealant. In principle one can assume that the molecules of PHT (“the migrant”) are most likely not firmly bound, trapped and cross linked (for example by strong covalent or ionic bounds) in the cured polysulfide sealant. Thus, the PHT molecules exhibit a certain mobility (diffusivity) in the network of the free-volumes of this polysulfide sealant. That means that in the presence of a PHT concentration gradient (which acts as a driving force) inside the cured polysulfide sealant, the molecules of the migrant can diffuse/move towards regions with lower concentrations of this substance. The rate of this internal diffusion in the sealant is controlled mainly by the mobility (Dp) and the magnitude of the migrant concentration gradient inside the cured polysulfide sealant. It is well known that the service time of aircraft and aerospace structures may extend over several decades. During this time the temperature to which the cured sealant mass is exposed may range from low two digits sub-zero °C levels to high two digits positive ones. From basic physical-chemical principles it is logic to assume that PHT molecules, situated in the polysulfide sealant just underneath its “air-contact surface”, which accumulate enough energy may leach from the sealant, evaporate, and diffuse into the air. The higher the temperature, T, the more energy is accumulated by the PHT molecules and consequently the more leaching from the sealant takes place. Once some part of the PHT molecules leave the “air-contact surface” of the polysulfide sealant, a migrant concentration gradient between this region and the “core” of the sealant results. This gradient determines the internal diffusion of PHT molecules from the “core” towards the “air-contact surface” of the sealant material. The whole process of PHT molecules diffusion in and leaching from the polysulfide sealant will be further called “the migration” of PHT from the sealant into air. Theoretically, this process lasts until mobile PHT molecules still exist in the polysulfide sealant.

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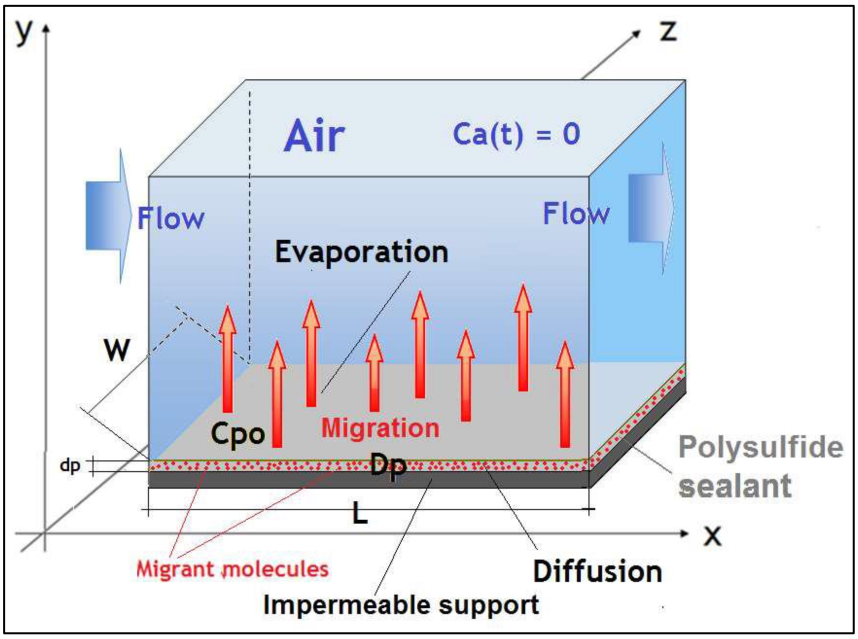
[26] Fabes (2021): Estimation of Migration of hydrogenated Terphenyl from a special polysulfide sealant.-

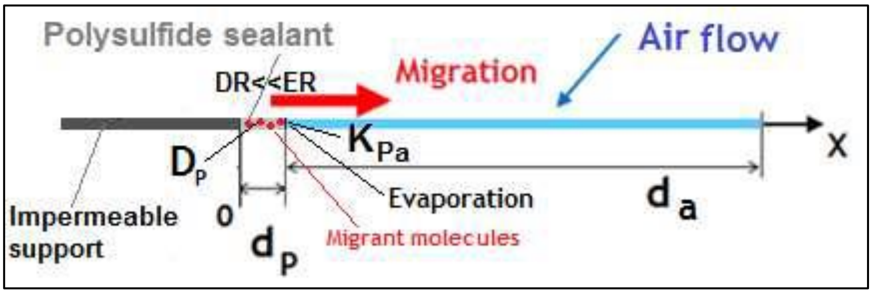
Schematically this process is presented in **Figure 22**. A migration of PHT cannot take place in the opposite direction because fuel tank and fuselage parts of an aerospace device can be considered as perfectly impermeable to any migrant molecule.

Figure 22. Schematic diagram of the migration of PHT from a from a plate made of a polysulfide sealant into air (Source: Fabes Report No. 7946-21, 2021, Fig. 1)



The calculation/estimation of a migration process has been conducted according to the previously described migration scenario and is illustrated in **Figure 23**.

Figure 23. 1D migration/leaching diagram from thin dry polysulfide sealant into an air flow (Source: Fabes Report No. 7946-21, 2021, Fig. 3)



The calculated time dependent increase of the migrated/leached PHT amount from the 100 cm² (10x10 cm) and 1.0 cm thick polysulfide sealant. Further calculations and input-parameters (incl. physical-chemical data of PHT and the coating) are available in the Fabes Report No. 7946-21, 2021. **Figure 24** and **Figure 25** are showing the calculated results for a service time of 10 and 20 years.

Figure 24. Time dependent amount of PHT migrated, at 20°C in 10 years, from the polysulfide sealant into a flow of air (Source: Fabes Report No. 7946-21, 2021, Fig. 4)

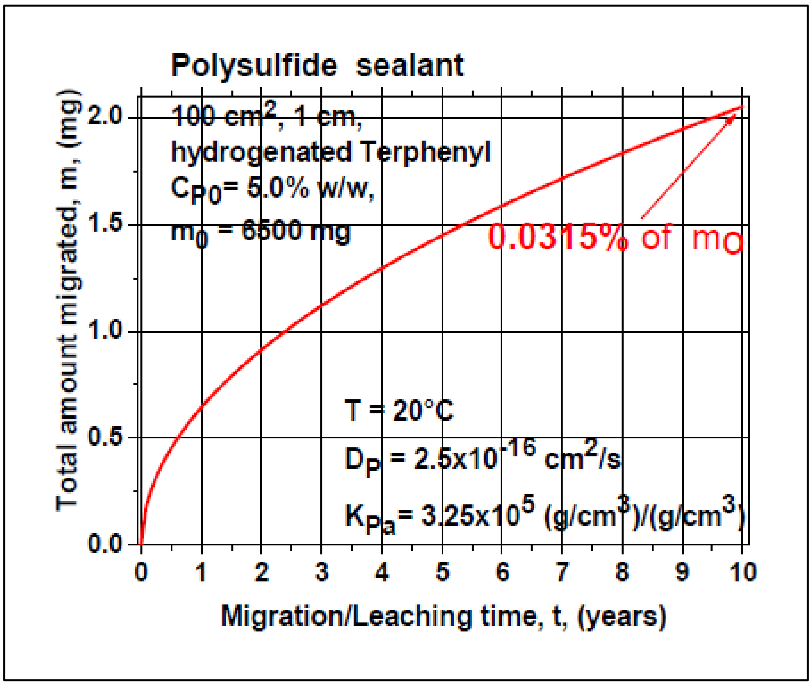
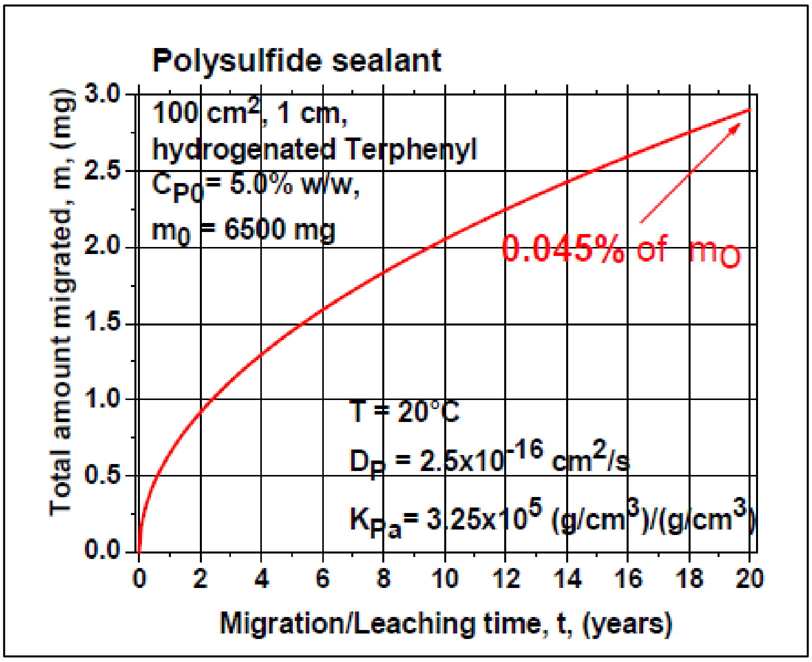


Figure 25. Time dependent amount of PHT migrated, at 20°C in 20 years, from the polysulfide sealant into a flow of air (Source: Fabes Report No. 7946-21, 2021, Fig. 5)



In conclusion, during a service life of 10 years ca. 0.031% of PHT used as a plasticizer in a polysulfide sealant for airplanes would migrate into the surrounding air. For a service life of 20 years, the loss of PHT would increase to ca. 0.045%.

The difference from the migration between Scenarios 1 and 2 are due to the differences in surface area and thicknesses between the coating and the sealant scenarios.

As discussed under **Annex A** (Manufacture and Use), the annual volume in the EU of aerospace sealants in 2018 is assumed to be 180 tonnes year (no volume increase/decrease over time was included). As a result, within a service life of 10 years potentially **0.5 tonnes** out of the 1.800 tonnes within the **10-years** range consumed could enter the environment. Considering a service life of **20 years** and 3 600 t of sealant used (180 tonnes year * 20 years), **1.6 tonnes** of PHT could potentially migrate from the polysulfide sealant into the environment. However, since airplanes do travel globally, the potential loss of PHT to the environment cannot be localized to the EU only. Anyhow, since non-EU planes will be using the same coatings and are in service in the EU too, the Dossier Submitter finds it reasonable to use these numbers as worst-case releases.

B.9.14. Use 13: Formulation - use as additive in plastic applications

B.9.14.1. General information

The "Formulation - use as additive in plastic applications" is already sufficiently covered by the following uses:

- Formulation of coatings/inks
- Formulation of adhesives and sealants

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.14.2. Exposure estimation

The "Formulation - use as additive in plastic applications" is already sufficiently covered by the following uses:

- Formulation of coatings/inks
- Formulation of adhesives and sealants

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.15. Use 14: Use as additive in plastic application

B.9.15.1. General information

The "Use as additive in plastic application" is already sufficiently covered by the following uses:

- Direct use for industrial coatings/inks applications
- Use of adhesives and sealants at industrial sites

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.15.2. Exposure estimation

The "Use as additive in plastic application" is already sufficiently covered by the following uses:

- Direct use for industrial coatings/inks applications
- Use of adhesives and sealants at industrial sites

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.16. Use 15: Service life of plastics

B.9.16.1. General information

The "Service life of plastics" is already sufficiently covered by the following uses:

- Service life of articles produced from use of coatings and inks
- Service life of articles produced from use as plasticiser

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.16.2. Exposure estimation

The "Service life of plastics" is already sufficiently covered by the following uses:

- Service life of articles produced from use of coatings and inks
- Service life of articles produced from use as plasticiser

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.17. Use 15: Formulation, transfer and repackaging of substances in preparations and mixtures

B.9.17.1. General information

A minor amount of PHT is used as solvent/process medium by the industry or as laboratory chemical by professional. The formulation, transfer and repacking of PHT used as solvent/

process medium by the industry or as laboratory chemical by professional is covered by this scenario. No specific information on the releases to the environment is available.

B.9.17.2. Exposure estimation

Table 67. Assumptions for Exposure Estimations

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.49%		
Total tonnage used for solvent/processing aid and laboratory chemical formulations	36.5	tonnes per year	
Number of emission days	10	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of PHT formulated at a site (local scenario)	3.65	tonnes per day	Estimate – assumes all of the tonnage is formulated at one site as a worst case
Fraction released to air	0.025		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.02		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.0001		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	n.a. - 912.5	kg per year	
Estimated release to wastewater	n.a. - 730	kg per year	
Estimated release to industrial soil	n.a. - 3.65	kg per year	
Estimated amount to solid waste for disposal	n.a.	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 68**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 68. Estimated EU releases to the environment from formulation, transfer and repackaging of substances in preparations and mixtures in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	n.a.	974.29
Water	n.a.	55.14
Agricultural soil via application of sludge	n.a.	616.70
Total	n.a.	**1 646.14**

B.9.17.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.17.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.17.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 69**.

Table 69. Estimated indirect local exposure of human via the environment from formulation, transfer and repackaging of substances in preparations and mixtures in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	n.a.	5.28E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	0.04	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0020	
Daily dose through intake of leaf crops	n.a.	1.37E-3	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0001	
Daily dose through intake of root crops	n.a.	2.17E+1	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9928	
Daily dose through intake of meat	n.a.	0.067	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0031	
Daily dose through intake of milk	n.a.	0.039	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0018	
Local total daily intake of humans	n.a.	2.18E+1	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	6.95E-4	mg/m^3
Man via environment - oral	n.a.	21.83	mg/kg bw/d

B.9.17.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 70**.

Table 70. Estimated environmental local exposure from formulation, transfer and repackaging of substances in preparations and mixtures in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	n.a.	0.187	mg/L
$PEClocal_{freshwater\ sediment}$	n.a.	5.91E+3	mg/kg dw
$PEClocal_{marinewater}$	n.a.	0.019	mg/L
$PEClocal_{marinewater\ sediment}$	n.a.	591.4	mg/kg dw
$PEClocal_{STP}$	n.a.	2.757	mg/L
$PEClocal_{air}$	n.a.	6.95E-4	mg/m^3
$PEClocal_{agricultural\ soil}$	n.a.	1.17E+3	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	n.a.	133.2	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	n.a.	13.32	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	n.a.	26.68	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	n.a.	3.2E3	mg/kg ww

B.9.18. Use 16: Use as solvent/or process medium

B.9.18.1. General information

A minor amount of PHT is used as solvent/process medium by the industry. No specific information on the releases to the environment is available. However, an ESVOC SpERC (ESVOC SPERC 4.1.v2) is applicable for the refinement of the default assumptions.

B.9.18.2. Exposure estimation

Table 71. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.47%		
Total tonnage used as solvent/process medium at ind. sites	35	tonnes per year	
Number of emission days	20 - 300	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 ESVOC SPERC 4.1.v2
Daily amount of PHT used at a site (local scenario)	0.012 - 0.175	tonnes per day	Estimate – assumes 10% of the total use occurs at a large site
Fraction released to air	0.00001 - 1		ESVOC SPERC 4.1.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.00001 - 1		ESVOC SPERC 4.1.v2

Input factor/assumption	Value	Unit	Comment
			Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.0001 - 0.05		ESVOC SPERC 4.1.v2 Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.05		ESVOC SPERC 4.1.v2
Estimated release to air per site (10 sites assumed in total)	0.04 – 3 500	kg per year	
Estimated release to wastewater per site (10 sites assumed in total)	0.04 – 3 500	kg per year	
Estimated release to industrial soil per site (10 sites assumed in total)	0.35 - 175	kg per year	
Estimated amount to solid waste for disposal per site (10 sites assumed in total)	175	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 72**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 72. Estimated EU releases to the environment from use as solvent/process medium in the EU.

Total EU releases following redistribution in STP	Lower estimate (kg per year)	Upper estimate (kg per year)
Air	0.38	37 963
Water	2.64E-2	2 644
Agricultural soil via application of sludge	3.79	31 143
Total	**4.2**	**71 750**

B.9.18.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.18.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.18.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 73**.

Table 73. Estimated indirect local exposure of human via the environment from use as solvent/process medium in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	8.79E-10	1.30E-2	mg/kg bw/d
Fraction of total dose through intake of drinking water	3.86E-04	0.0002	
Daily dose through intake of fish	2.10E-06	2E-1	mg/kg bw/d
Fraction of total dose through intake of fish	9.22E-01	0.0040	
Daily dose through intake of leaf crops	5.27E-08	5.22E-3	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0231	0.0001	
Daily dose through intake of root crops	7.68E-09	5.20E+01	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0034	0.9907	
Daily dose through intake of meat	7.28E-08	0.163	mg/kg bw/d
Fraction of total dose through intake of meat	0.0320	0.0031	
Daily dose through intake of milk	4.29E-08	0.096	mg/kg bw/d
Fraction of total dose through intake of milk	0.0188	0.0018	
Local total daily intake of humans	2.28E-06	5.24E+01	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.75E-8	2.68E-3	mg/m^3
Man via environment – oral	2.28E-6	52.44	mg/kg bw/d

B.9.18.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 74**.

Table 74. Estimated environmental local exposure from use as solvent/process medium in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$PEClocal_{freshwater}$	3.08E-7	0.448	mg/L
$PEClocal_{freshwater\ sediment}$	9.74E-3	1.42E-4	mg/kg dw
$PEClocal_{marinewater}$	3.08E-8	0.045	mg/L
$PEClocal_{marinewater\ sediment}$	9.74E-4	1.42E3	mg/kg dw
$PEClocal_{STP}$	4.53E-6	6.61	mg/L
$PEClocal_{air}$	2.65E-8	2.68E-3	mg/m^3

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$PEClocal_{agricultural\ soil}$	4.08E-7	2.81E+3	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	6.41E-3	640.4	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	6.42E-4	64.06	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	1.31E-3	129.6	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	5.31E-6	7.68E+3	mg/kg ww

B.9.19. Use 17: Use as laboratory chemical by professionals

B.9.19.1. General information

A very small amount of PHT is used as laboratory chemical by professional. No specific information on the releases to the environment is available.

B.9.19.2. Exposure estimation

Table 75. Assumptions for Exposure Estimation.

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.02%		
Total tonnage used as laboratory chemical at prof. sites	1.5	tonnes per year	
Share of volume used outdoor	0		Reasonable worst-case assumption
Total tonnage – outdoor use	0	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of PHT used at a site (local scenario)	8.25E-7	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	0.05		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.05		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	n.a. – 75	kg per year	
Estimated release to wastewater	n.a. – 75	kg per year	
Estimated release to industrial soil	0	kg per year	

Input factor/assumption	**Value**	**Unit**	**Comment**
Estimated amount to solid waste for disposal	n.a.	kg per year	

The estimated total EU releases following redistribution in a STP are summarised in **Table 76**. These values include any direct release to air and soil and take into account the redistribution in the STP for emissions to wastewater.

Table 76. Estimated EU releases to the environment from professional use as laboratory chemical in the EU

Total EU releases following redistribution in STP	**Lower estimate (kg per year)**	**Upper estimate (kg per year)**
Air	n.a.	91.35
Water	n.a.	5.67
Agricultural soil via application of sludge	n.a.	62.99
Total	n.a.	**150**

B.9.19.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.19.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.19.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 77**.

Table 77. Estimated indirect local exposure of human via the environment from professional use as laboratory chemical in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	n.a.	2.99E-9	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	1E-6	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0717	
Daily dose through intake of leaf crops	n.a.	4.62E-8	mg/kg bw/d

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Fraction of total dose through intake of leaf crops	n.a.	0.0034	
Daily dose through intake of root crops	n.a.	1.23E-5	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9128	
Daily dose through intake of meat	n.a.	1.00E-7	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0074	
Daily dose through intake of milk	n.a.	5.91E-8	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0044	
Local total daily intake of humans	n.a.	1.35E-5	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	2.41E-8	mg/m^3
Man via environment – oral	n.a.	1.34E-5	mg/kg bw/d

B.9.19.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 78**.

Table 78. Estimated environmental local exposure from professional use as laboratory chemical in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$\text{PEClocal}_{\text{freshwater}}$	n.a.	1.13E-7	mg/L
$\text{PEClocal}_{\text{freshwater sediment}}$	n.a.	3.58E-3	mg/kg dw
$\text{PEClocal}_{\text{marinewater}}$	n.a.	1.15E-8	mg/L
$\text{PEClocal}_{\text{marinewater sediment}}$	n.a.	3.64E-4	mg/kg dw
$\text{PEClocal}_{\text{STP}}$	n.a.	1.56E-6	mg/L
$\text{PEClocal}_{\text{air}}$	n.a.	2.41E-8	mg/m^3
$\text{PEClocal}_{\text{agricultural soil}}$	n.a.	6.65E-4	mg/kg dw
$\text{PEClocal}_{\text{predators' prey (freshwater)}}$	n.a.	3.13E-3	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (marine water)}}$	n.a.	3.13E-4	mg/kg ww
$\text{PEClocal}_{\text{top predators' prey (marine water)}}$	n.a.	1.04E-3	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (terrestrial)}}$	n.a.	1.9E-3	mg/kg ww

B.9.20. Other sources (for example natural sources, unintentional releases)

There are no known natural sources of PHT.

B.9.21. Overall environmental exposure assessment

B.9.21.1. Summary exposure assessment

The exposure assessment shows that the largest source of PHT emission to the environment in the EU is attributed to the use in adhesives/sealants. Regarding the high emission scenario the "use of adhesives and sealants at industrial sites" contribute significantly to the overall emission (share of total: approximately 41%). Moreover the use of coatings and inks at industrial sites as well as the use as HTF at industrial sites have a share of approximately 22 and 19%, respectively, of the total emissions.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately 67% of the total emissions followed by the industrial use of sealants and adhesives (approximately 14%).

Table 79. Emission sources of PHT

Scenario	**Share of total (%) – Low emission scenario**	**Share of total (%) – High emission scenario**
Manufacture*	0	0
Formulation of coatings/inks	0.08	2.27
Direct use for industrial coatings/inks applications	6.66	21.59
Direct use for professional coatings/inks applications	2.77	1.18
Service life of articles produced from use of coatings and inks	0.77	0.04
Use as HTF at industrial sites	0	18.86
Laboratory analysis	4.08E-3	0.01
Use as HTF at professional sites	0.04	0.16
Formulation of adhesives and sealants	1.04	2.27
Use of adhesives and sealants at industrial sites	14.21	**40.63**
Use of adhesives and sealants by professionals	3.13	2.06
Service life of articles produced from use as plasticiser	**67.37**	3.24
Formulation, transfer and repackaging of substances in preparations and mixtures	3.58	0.17
Use as solvent/process medium	0.01	7.52
Use as laboratory chemical by professionals	0.33	0.02

*Please notice that there is no manufacture taking place within the EEA.

Additionally, the share of total emissions is evaluated based on the market sector (please refer to the following **Table 80**). Thereby the following market sectors are differentiated:

- Use in coatings/inks
- Use as HTF
- Use in adhesives/sealants
- Misc uses (i.e. general formulation, use as solvent and use as lab chemical by professionals)

The analysis showed that the adhesives/sealants have by far the largest share of the total emission. In the high emission scenario, the share is estimated to be approximately 48% whereas the share in the low emission scenario is even higher (approximately 86%).

Table 80. Emission sources of PHT based on market sector

Scenario	Share of total (%) Low emission scenario	Share of total (%) High emission scenario
Coatings/inks	10.28	25.07
HTF	0.05	19.02
Adhesives/sealants	**85.76**	**48.21**
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.92	7.71

In the **Table 81** the emissions for each compartment (air, water, and soil) is displayed. These include the sum of estimated releases to the air, water, and soil. However, the redistribution in the STP is not taken into account for emissions to wastewater.

Regarding the low emission scenario approximately the same amount is released to the water and soil compartment (approximately 42 and 37%, respectively) whereas the release to air is lower (approximately 22%).

For the high emission scenario approximately 40% is released to the air as well as the water compartment. Only approximately 21% is released to the soil.

In general, no major route of emission can be determined.

Table 81. Estimated total EU releases for PHT

Environmental compartment	Estimated EU emissions based on data on volume for 2021		
	Low (kg per year)	High (kg per year)	Share of total (%)
Air	14 000	710 000	21.64 – 39.80
Water	26 900	706 000	41.58 – 39.57
Soil	23 800	368 000	36.79 – 20.63
All / Total	64 700	1 784 000	100

Emission to wastewater treatment plant (WWTP) taking into account the redistribution of emission to wastewater in STP are displayed in the **Table 82**.

Taking into account the redistribution of the emission via wastewater the major route of exposure with a share of approximately 72% of the total emissions for the low emission scenario is clearly the soil compartment. The share of the total volume of the soil compartment is lower (approximately 54%) for the high emission scenario. The share of air compartment on the total emissions is approximately 25 and 43% for the low and the high emission scenario, respectively. The share on the total emission of the water compartment is by far the lowest with only approximately 3% for both, the low and high emission scenario.

Table 82. Estimated total EU releases for PHT following redistribution in STP

Environmental compartment	**Estimated EU emissions based on data on volume for 2021**		
	Low (kg per year)	**High (kg per year)**	**Share of total (%)**
Air	16 277	769 763	25.16 – 43.15
Water	2 032	53 331	3.14 – 2.99
Soil	46 391	960 899	71.70 – 53.86
All / Total	64 700	1 783 993	100

The estimated regional PECs for PHT in the EU are summarised in **Table 83**.

Table 83. Estimated regional PECs for PHT in the EU

Environmental compartment	**Lower estimate**	**Upper estimate**	**Unit**
Fresh water	3.51E-6	6.12E-4	mg/L
Sediment (freshwater)	0.222	38.65	mg/kg dw
Marine water	4.41E-7	6.82E-5	mg/L
Sediment (marine water)	0.028	4.286	mg/kg dw
Air	1.01E-5	3.29E-4	mg/m³
Agricultural soil	6.73E-4	0.022	mg/kg dw
Man via environment - inhalation (systemic effects)*	1.01E-5	3.29E-4	mg/m³
Man via environment (oral)**	3.75E-4	0.057	mg/kg bw/d

*expressed as concentration in air
**expressed as exposure via food consumption

In general, the high emission scenario represents a worst-case assumption whereby e.g. the default release factors as indicated in ECHA Guidance R.16 are used. Hence, the high emission scenario has to be regarded as a very conservative approach overestimating the actual exposure. The low emission scenario takes into account information from e.g., SpERC and information obtained in a survey. Hence it is regarded a more realistic emission estimation. Also, the findings are proven by comparable results of the modelling conducted by FABES as well as the monitoring data.

B.9.21.2. Environmental monitoring data

PHT is a very persistent substance and will have a very long residence time in the environment. It could build up over time and can be widespread in various environmental media. The substance has not been widely found in the environment so far. However, this should not be interpreted as the substance not yet having entered the environment, but that it has previously not been measured in environmental samples. Only a few international measurements of PHT in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with PHT, while Sturaro et al. (1995) detected PHT as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by the NILU and the NIVA (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including PHT.

Table 84 summarises the concentrations found in the NILU study.

Table 84. Summary of PHT concentrations found in environmental samples (NILU, 2018)

Sample Type	Number of Samples	Detection Details	Concentration
Surface Water	9	Dimension Range Average Detection Frequency	ng/l -- -- 0
Wastewater	7	Dimension Range Average Detection Frequency	ng/l 3 – 150 119 100%
Sediment	5	Dimension Range Average Detection Frequency	ng/g 1 – 430 113 100%
Biota	15	Dimension Range Average Detection Frequency	ng/g -- -- 0
Indoor Air	24	Dimension Range Average Detection Frequency	ng/m^3 0.10 – 13 3.8 100%

The substance was found in the 100 ng/g range in marine sediments, which corresponds to a factor of 60 lower, compared to the PNEC in the REACH Dossier. However, it was recommended that the chemical should consequently be studied in more detail.

PHT was not found in surface waters. Compared to surface water the detection frequency for PHTs were found in all sediment samples, still in low concentrations. Composite river sediment samples were collected a few meters upstream from the river sampling sites at Brubak and Kværnerbyen using a sediment core sampler. Each composite sample consisted of five separate grab samples of the upper two centimeters of the sediments. Marine sediment was collected at two stations, one sample at Hovedøya and two samples at Storøyodden by means of a van Veen grab (0.15 m^2) from RV Trygve Braarud. Three samples of the top layer (0-2 cm with undisturbed surface were prepared in grab samples of four individual grabs each.

PHT was analysed as well in waste (sewage) water and biota. In all wastewater samples PHT could be found in concentrations ranging from 3 – 510 ng/l. Regarding samples taken in biota (gull eggs and blue mussel), all concentrations were below the detection limit (< 5 – 15 ng/g ww). The wastewater samples were collected as time-integrated composite samples (50 mL sub-samples every 10 min). Household wastewater samples were collected from a manhole downstream of the residential area during dry weather conditions only with the flowmeter mounted in the 300 mm pipeline entering the same manhole. Industry-influenced wastewater samples were collected from a manhole situated downstream of the industrial areas during both dry weather conditions and at the beginning of heavy rain events.

B.9.22. Human exposure assessment

B.9.22.1. General

Generally, exposure can occur through 1) workers exposure, 2) consumer exposure and 3) indirect exposure of humans via the environment. However, the exposure through workers and consumer exposure is not considered in this dossier, as the restriction dossier is based on the established vPvB properties of PHT, hence, the assessment of human health effects is not conducted. Only the assessment of the exposure to PHT through indirect exposure of humans via the environment is carried out.

In principle, exposure can either be estimated by 1) calculating the external dose by multiplying measured or modelled concentrations of PHT from different sources (e.g. food, air and drinking water) with exposure factors (e.g. inhalation rate or volume/amount consumed), or 2) assessing the internal dose by measuring concentrations of the substance in biological matrix (e.g. blood, hair, fat tissue or breast milk), which further can be used to calculate the body burden based on the knowledge of toxicokinetic behaviour. Information on internal concentrations is normally obtained via human biomonitoring data, however no such data exist for PHT. The fact that human biomonitoring data for PHT are not available was also stated in a recent report of the Health Council of the Netherlands providing Health-based recommendation on occupational exposure limits on hydrogenated terphenyl (HCN, 2020).

Information on accumulation in biological matrices is limited to measurements in biota. As given under B.9.21.2. Environmental monitoring data, PHT samples were taken in biota gull eggs and blue mussel. The measurements revealed that all concentrations were below the detection limit (< 5 – 15 ng/g w/w). Due to the limited data, this result can provide an indication that no accumulation of PHT is to be expected in biological matrices.

Due to the lack of human biomonitoring data, in this section exposure to PHT has primarily been described by available measurements of PHT in indoor and outdoor environments, as given in more detail in the following chapter. The assessment of indirect exposure of humans via the environment is then conducted using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). Please refer to the corresponding chapters under B.9.1-B.9.21.

B.9.22.2. Detected/measured levels regarding consumers exposure

A screening programme conducted in 2018 by the NILU and the NIVA (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including PHT.

Table 85 summarises the concentrations found in the NILU study (NILU, 2018).

Table 85. Summary of PHT concentrations found in environmental samples (NILU, 2018)

Sample Type	Number of Samples	Detection Details	Concentration
Indoor Air	24	Dimension Range Average Detection Frequency	ng/m^3 0.10 – 13 3.8 100%

In addition, PHT was measured in buildings in house dust. Screening of indoor environments was performed by collecting settled floor dust samples and passive air samples from 16 residential buildings and five non-residential buildings in the Oslo area. The sampling locations also includes sites that represent different levels of population density, from the urban center of Oslo to the semi-rural areas around Oslo. The non-residential buildings included offices, a school, and one veterinary clinic. Passive air samples were collected using two types of samplers: i) polyurethane foam passive air samplers (PUF-PAS), and ii) XAD resin PAS (XAD-PAS). Analytical data shows in general a much lower concentration in non-residential buildings. However, there is one single case of extreme air concentration (13 ng/m^3).

According to the dossier submitters interpretation, these concentration levels are likely resulting from the use of PHT in plasticiser applications, e.g., from plastics in building materials or plasticiser applications in electronics. We do not share the interpretation of the study authors that the concentrations in indoor air are resulting from the use as HTF. It is assumed that other uptake routes are more relevant than inhalation.

Figure 26. Comparison of air concentrations of the sum of all measured PHTs in residential and non-residential indoor environments (NILU, 2018)

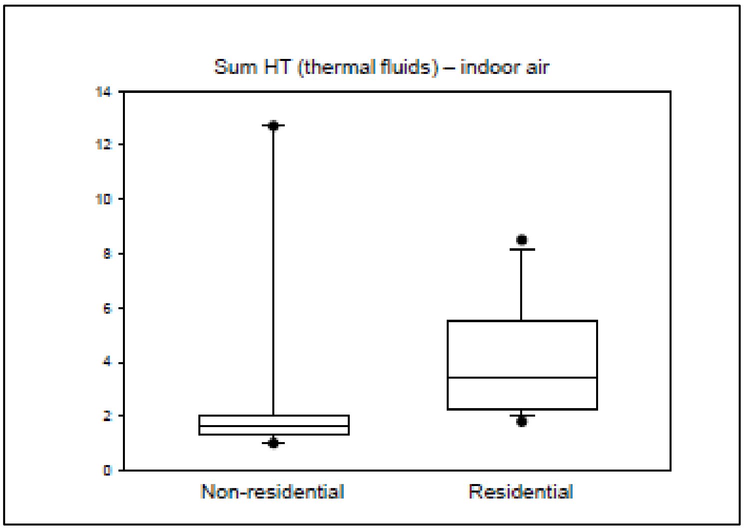
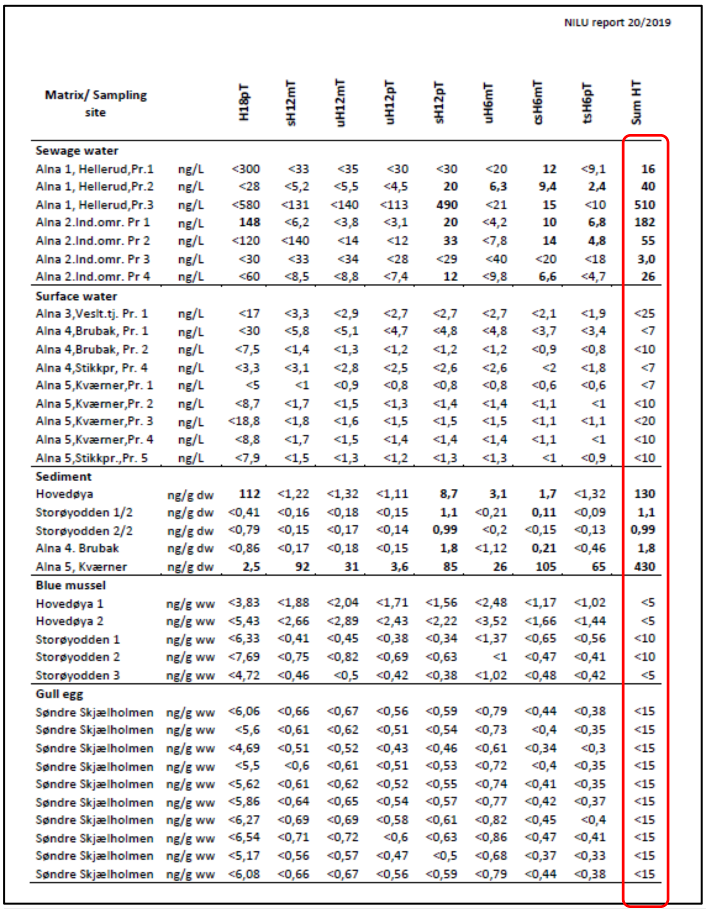


Figure 27 provides a full copy of the analytical results table from the NILU study (NILU, 2018).

Figure 27. Analytical results table from the NILU study (NILU, 2018)*

* Please note that commas separate decimal values



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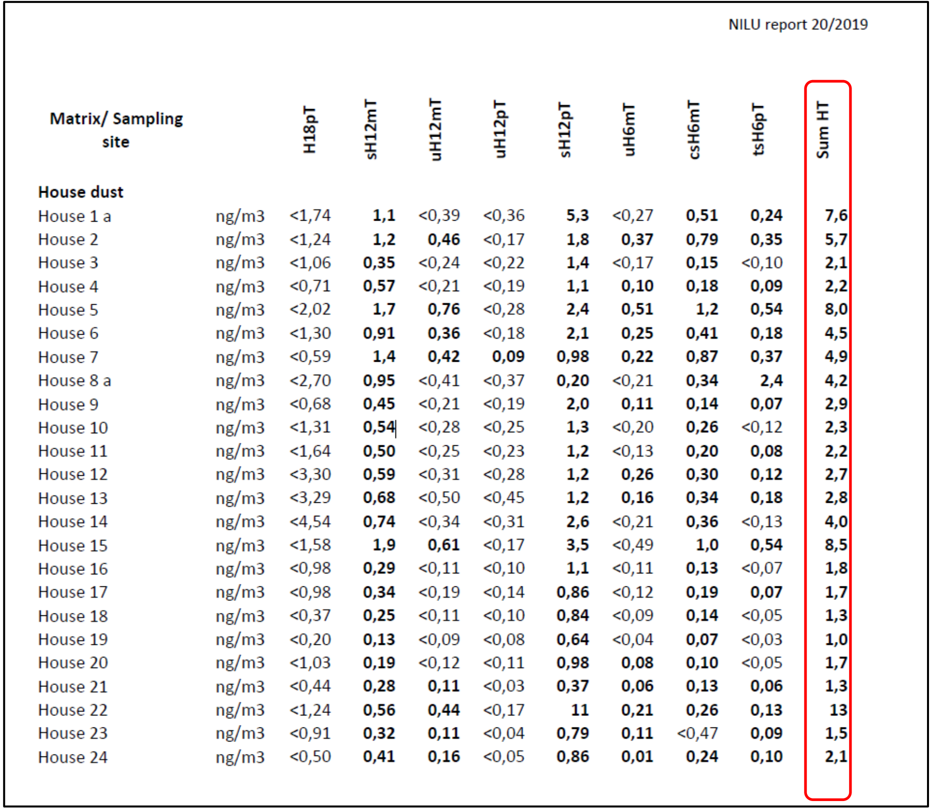
Matrix/ Sampling site		H18pT	sH12mT	uH12mT	uH12pT	sH12pT	uH6mT	csH6mT	tsH6pT	Sum HT
Sewage water										
Alna 1, Hellerud,Pr.1	ng/L	<300	<33	<35	<30	<30	<20	**12**	<9,1	**16**
Alna 1, Hellerud,Pr.2	ng/L	<28	<5,2	<5,5	<4,5	**20**	**6,3**	**9,4**	**2,4**	**40**
Alna 1, Hellerud,Pr.3	ng/L	<580	<131	<140	<113	**490**	<21	**15**	<10	**510**
Alna 2.Ind.omr. Pr 1	ng/L	**148**	<6,2	<3,8	<3,1	**20**	<4,2	**10**	**6,8**	**182**
Alna 2.Ind.omr. Pr 2	ng/L	<120	<140	<14	<12	**33**	<7,8	**14**	**4,8**	**55**
Alna 2.Ind.omr. Pr 3	ng/L	<30	<33	<34	<28	<29	<40	<20	<18	**3,0**
Alna 2.Ind.omr. Pr 4	ng/L	<60	<8,5	<8,8	<7,4	**12**	<9,8	**6,6**	<4,7	**26**
Surface water										
Alna 3,Veslt.tj. Pr. 1	ng/L	<17	<3,3	<2,9	<2,7	<2,7	<2,7	<2,1	<1,9	<25
Alna 4,Brubak, Pr. 1	ng/L	<30	<5,8	<5,1	<4,7	<4,8	<4,8	<3,7	<3,4	<7
Alna 4,Brubak, Pr. 2	ng/L	<7,5	<1,4	<1,3	<1,2	<1,2	<1,2	<0,9	<0,8	<10
Alna 4,Stikkpr, Pr. 4	ng/L	<3,3	<3,1	<2,8	<2,5	<2,6	<2,6	<2	<1,8	<7
Alna 5,Kværner,Pr. 1	ng/L	<5	<1	<0,9	<0,8	<0,8	<0,8	<0,6	<0,6	<7
Alna 5,Kværner,Pr. 2	ng/L	<8,7	<1,7	<1,5	<1,3	<1,4	<1,4	<1,1	<1	<10
Alna 5,Kværner,Pr. 3	ng/L	<18,8	<1,8	<1,6	<1,5	<1,5	<1,5	<1,1	<1,1	<20
Alna 5,Kværner,Pr. 4	ng/L	<8,8	<1,7	<1,5	<1,4	<1,4	<1,4	<1,1	<1	<10
Alna 5,Stikkpr.,Pr. 5	ng/L	<7,9	<1,5	<1,3	<1,2	<1,3	<1,3	<1	<0,9	<10
Sediment										
Hovedøya	ng/g dw	**112**	<1,22	<1,32	<1,11	**8,7**	**3,1**	**1,7**	<1,32	**130**
Storøyodden 1/2	ng/g dw	<0,41	<0,16	<0,18	<0,15	**1,1**	<0,21	**0,11**	<0,09	**1,1**
Storøyodden 2/2	ng/g dw	<0,79	<0,15	<0,17	<0,14	**0,99**	<0,2	<0,15	<0,13	**0,99**
Alna 4. Brubak	ng/g dw	<0,86	<0,17	<0,18	<0,15	**1,8**	<1,12	**0,21**	<0,46	**1,8**
Alna 5, Kværner	ng/g dw	**2,5**	**92**	**31**	**3,6**	**85**	**26**	**105**	**65**	**430**
Blue mussel										
Hovedøya 1	ng/g ww	<3,83	<1,88	<2,04	<1,71	<1,56	<2,48	<1,17	<1,02	<5
Hovedøya 2	ng/g ww	<5,43	<2,66	<2,89	<2,43	<2,22	<3,52	<1,66	<1,44	<5
Storøyodden 1	ng/g ww	<6,33	<0,41	<0,45	<0,38	<0,34	<1,37	<0,65	<0,56	<10
Storøyodden 2	ng/g ww	<7,69	<0,75	<0,82	<0,69	<0,63	<1	<0,47	<0,41	<10
Storøyodden 3	ng/g ww	<4,72	<0,46	<0,5	<0,42	<0,38	<1,02	<0,48	<0,42	<5
Gull egg										
Søndre Skjælholmen	ng/g ww	<6,06	<0,66	<0,67	<0,56	<0,59	<0,79	<0,44	<0,38	<15
Søndre Skjælholmen	ng/g ww	<5,6	<0,61	<0,62	<0,51	<0,54	<0,73	<0,4	<0,35	<15
Søndre Skjælholmen	ng/g ww	<4,69	<0,51	<0,52	<0,43	<0,46	<0,61	<0,34	<0,3	<15
Søndre Skjælholmen	ng/g ww	<5,5	<0,6	<0,61	<0,51	<0,53	<0,72	<0,4	<0,35	<15
Søndre Skjælholmen	ng/g ww	<5,62	<0,61	<0,62	<0,52	<0,55	<0,74	<0,41	<0,35	<15
Søndre Skjælholmen	ng/g ww	<5,86	<0,64	<0,65	<0,54	<0,57	<0,77	<0,42	<0,37	<15
Søndre Skjælholmen	ng/g ww	<6,27	<0,69	<0,69	<0,58	<0,61	<0,82	<0,45	<0,4	<15
Søndre Skjælholmen	ng/g ww	<6,54	<0,71	<0,72	<0,6	<0,63	<0,86	<0,47	<0,41	<15
Søndre Skjælholmen	ng/g ww	<5,17	<0,56	<0,57	<0,47	<0,5	<0,68	<0,37	<0,33	<15
Søndre Skjælholmen	ng/g ww	<6,08	<0,66	<0,67	<0,56	<0,59	<0,79	<0,44	<0,38	<15



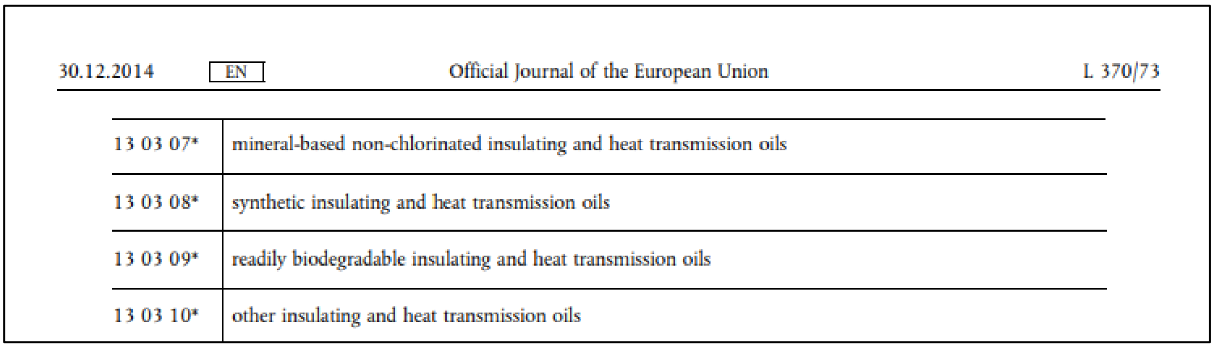
NILU report 20/2019

Matrix/ Sampling site		H18pT	sH12mT	uH12mT	uH12pT	sH12pT	uH6mT	csH6mT	tsH6pT	Sum HT
House dust										
House 1 a	ng/m3	<1,74	**1,1**	<0,39	<0,36	**5,3**	<0,27	**0,51**	**0,24**	**7,6**
House 2	ng/m3	<1,24	**1,2**	**0,46**	<0,17	**1,8**	**0,37**	**0,79**	**0,35**	**5,7**
House 3	ng/m3	<1,06	**0,35**	<0,24	<0,22	**1,4**	<0,17	**0,15**	<0,10	**2,1**
House 4	ng/m3	<0,71	**0,57**	<0,21	<0,19	**1,1**	**0,10**	**0,18**	**0,09**	**2,2**
House 5	ng/m3	<2,02	**1,7**	**0,76**	<0,28	**2,4**	**0,51**	**1,2**	**0,54**	**8,0**
House 6	ng/m3	<1,30	**0,91**	**0,36**	<0,18	**2,1**	**0,25**	**0,41**	**0,18**	**4,5**
House 7	ng/m3	<0,59	**1,4**	**0,42**	**0,09**	**0,98**	**0,22**	**0,87**	**0,37**	**4,9**
House 8 a	ng/m3	<2,70	**0,95**	<0,41	<0,37	**0,20**	<0,21	**0,34**	**2,4**	**4,2**
House 9	ng/m3	<0,68	**0,45**	<0,21	<0,19	**2,0**	**0,11**	**0,14**	**0,07**	**2,9**
House 10	ng/m3	<1,31	**0,54**	<0,28	<0,25	**1,3**	<0,20	**0,26**	<0,12	**2,3**
House 11	ng/m3	<1,64	**0,50**	<0,25	<0,23	**1,2**	<0,13	**0,20**	**0,08**	**2,2**
House 12	ng/m3	<3,30	**0,59**	<0,31	<0,28	**1,2**	**0,26**	**0,30**	**0,12**	**2,7**
House 13	ng/m3	<3,29	**0,68**	<0,50	<0,45	**1,2**	**0,16**	**0,34**	**0,18**	**2,8**
House 14	ng/m3	<4,54	**0,74**	<0,34	<0,31	**2,6**	<0,21	**0,36**	<0,13	**4,0**
House 15	ng/m3	<1,58	**1,9**	**0,61**	<0,17	**3,5**	<0,49	**1,0**	**0,54**	**8,5**
House 16	ng/m3	<0,98	**0,29**	<0,11	<0,10	**1,1**	<0,11	**0,13**	<0,07	**1,8**
House 17	ng/m3	<0,98	**0,34**	<0,19	<0,14	**0,86**	<0,12	**0,19**	**0,07**	**1,7**
House 18	ng/m3	<0,37	**0,25**	<0,11	<0,10	**0,84**	<0,09	**0,14**	<0,05	**1,3**
House 19	ng/m3	<0,20	**0,13**	<0,09	<0,08	**0,64**	<0,04	**0,07**	<0,03	**1,0**
House 20	ng/m3	<1,03	**0,19**	<0,12	<0,11	**0,98**	**0,08**	**0,10**	<0,05	**1,7**
House 21	ng/m3	<0,44	**0,28**	**0,11**	<0,03	**0,37**	**0,06**	**0,13**	**0,06**	**1,3**
House 22	ng/m3	<1,24	**0,56**	**0,44**	<0,17	**11**	**0,21**	**0,26**	**0,13**	**13**
House 23	ng/m3	<0,91	**0,32**	**0,11**	<0,04	**0,79**	**0,11**	<0,47	**0,09**	**1,5**
House 24	ng/m3	<0,50	**0,41**	**0,16**	<0,05	**0,86**	**0,01**	**0,24**	**0,10**	**2,1**

PHT as a substance is not included in the European Pollutant Release and Transfer Register (E-PRTR), which is based on Regulation (EC) No 166/2006[27] and COM Implementing Decision 2019/1741.[28] E-PRTR is a Europe-wide register of environmental release data from industrial facilities in European Economic Area (EEA) Member States[29] established under Regulation (EC) No 166/2006. It contains data reported annually from 2007 onwards by some 30.000 industrial facilities covering 65 economic activities across Europe, including information concerning the amounts of pollutant releases to air, water and land as well as off-site transfers of waste and pollutants in wastewater. Release and transfer data are reported on 91 key pollutants (Annex II to Regulation (EC) No 166/2006) including heavy metals, pesticides, greenhouse gases, and organic chemicals. Industrial facilities that undertake one or more of the activities specified in Annex I to Regulation (EC) No 166/2006 must annually report release and transfer data (unless they stay below the capacity thresholds).

Synthetic HTFs, like PHT, can be captured by a specific waste code. A standard coding system classifies and describes the type of waste. These are called EWC Codes (European Waste Codes) as specified in the EU Waste Legislation[30].

Figure 28. Waste codes of synthetic HTFs. Waste marked with an asterisk (*) in the list of wastes shall be considered as hazardous waste



30.12.2014 EN Official Journal of the European Union L 370/73

13 03 07*	mineral-based non-chlorinated insulating and heat transmission oils
13 03 08*	synthetic insulating and heat transmission oils
13 03 09*	readily biodegradable insulating and heat transmission oils
13 03 10*	other insulating and heat transmission oils

B.9.22.3. Indirect exposure of humans via the environment

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier

B.9.22.4. Combined human exposure assessment

Generally, the combined human exposure assessment considers exposure from all sources. However, this restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

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[27] European Industrial Emissions Portal (europa.eu)

[28] EUR-Lex - 32019D1741 - EN - EUR-Lex (europa.eu)

[29] The EEA includes EU countries and also Iceland, Liechtenstein and Norway.

[30] EU Waste Framework Directive 2008/98.

B.10. Risk characterisation

It is not relevant to perform quantitative risk assessments of vPvB substances, due to the uncertainties regarding long-term exposure and effects. Therefore, the risks of vPvB substances, such as PHT, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim for vPvB substances is to minimise the exposures and emissions to humans and the environment (REACH Regulation, Annex I, section 6.5):

"For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, RMMs which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or IU".

Annex C: Justification for action on a Union-wide basis

PHT has been identified as an SVHC based on its vPvB properties according to Article 57(e) of the REACH Regulation. In addition, on 14 April 2021 ECHA has recommended the substance for the inclusion in Annex XIV to REACH (List of Substances subject to Authorisation). This 10th ECHA Recommendation[31] is based on the inherent properties (vPvB), the volume and the wide dispersiveness of uses (industrial sites, professional workers and use in articles).

As outlined before, PHT is chemically very stable in various environmental compartments with minimal or no abiotic degradation and is very bioaccumulative, which means that environmental stock may increase over time upon continued releases. For vPvB substances a safe concentration level in the environment cannot be established with sufficient reliability and for this reason, vPvB substances are treated as non-threshold substances for the purpose of risk management under REACH. For these substances, for which it is not possible to establish a safe level of exposure, RMMs should always be taken to minimise exposure and emissions, as far as technically and practically possible (recital 70 of the REACH Regulation). Due to this fact, even small levels of environmental emissions of this kind of substances could be considered sufficient to demonstrate their risk.

When PHT is used as an HTF, it is constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated under "**Annex B.9**.: Exposure Assessment". During operation, special attention needs to be paid to the interfaces of the closed system to the atmosphere, such as closed draining, separation points (joints, mechanical seals, flanges, valves, etc.) and rotary transmission equipment (pumps, etc.). Potential emissions to the environment are prevented by the implementation of stringent containment measures and control during the design stage of the closed system. Other exposure and emission sources of PHT when used as HTF are related to transport, loading and refilling operations, replacement or topping-up of the HTF, industrial cleaning operations, and disposal of the HTF.

When PHT is used as a plasticiser it is released into the environment during the various life cycle steps. The LR has conducted a comparative risk assessment for the two main uses, HTF and plasticiser (Solutia, 2018). The calculation clearly showed that the plasticiser use is far more critical for risk management than the HTF use.

The estimated local and regional overall release associated with the use as a plasticiser is up to 10-times higher than the local and regional overall release associated with the use as an HTF, respectively. It was shown that the total environmental emissions based on the use of PHT as an HTF are significantly lower than the total releases from the plasticiser uses. The use of the substance as a plasticiser is more critical for risk management regarding the emissions to the environment than the use as an HTF within a closed system.

These results have been confirmed by the Environmental Monitoring program at HTF sites and migration modelling studies on plasticiser uses, conducted by the LR (see **Annex B.9.**: Exposure Assessment).

Moreover, for the plasticiser use PHT will be incorporated into/onto an article. At the end of the service life of the article, it has to be disposed. During the disposal at a WWTP the PHT may be released into the environment as well. Consequently, the end of the article's service life leads to the generation of waste containing the substance and the final disposal may lead to additional releases to the environment. As shown in **Annex A** (Manufacture and Uses), in total more than 12 000 articles containing PHT have been notified to the SCIP database. Most entries are related to the use in polymers, rubber, and elastomers (> 60%), sealants (> 25%), inks (> 5%), sensors (< 1%), paper (> 1%) and a few others. In summary it can be concluded that close to 85% of PHT use in articles is related to plasticiser uses. Therefore,

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[31] Submitted recommendations - ECHA (europa.eu)

there is also significant potential for release of PHT to the environment from waste disposal activities (see Annex B.9.: Exposure assessment”). The dossier submitter assumes, that at the waste life-cycle stage of articles, the operational conditions and risk management measures are not sufficient and effective enough to control the risks of PHT.

PHT has not been widely found in the environment so far. However, this should not be interpreted as the substance not yet having entered the environment, but that it has previously not been measured in environmental samples. Only a few international measurements of PHT in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with PHT, while Sturaro et al. (1995) detected PHT as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by the NILU and the NIVA (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including PHT. The substance was found in the 100 ng/g range in marine sediments, and it was recommended that the chemical should consequently be studied in more detail. Compared to surface water the detection frequency for hydrogenated terphenyls were found in all samples, still in low concentrations. In addition, PHT was measured in buildings. Analytical data shows in general a much lower concentration in non-residential buildings. However, there is one single case of extreme air concentration which might be due to leakage from technical installations in this building.

Since PHT persists in the environment for a very long time and it has the potential to accumulate in humans and wildlife, effects of current emissions may be observed or only become apparent in future generations. Avoiding effects will then be difficult due to the irreversibility of exposure. The main benefits to society from a partial restriction of PHT will be the avoidance of these potential transgenerational impacts on the environment and human health in the future, through proportionate reductions in emissions and exposure to this substance.

It is therefore desirable to go ahead with a Restriction under REACH in order to benefit from an early implementation of emission reduction. Consequently, an EU Restriction will be an important step to reduce the emissions and risks from PHT within the EU internal market.

National regulatory actions are not considered adequate to manage the risks – in particular the risk on the plasticizer uses. Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to actions undertaken by individual Member States.

A description of the proposed Union-wide Restriction Option (RO) that has the potential to reduce emissions of PHT to the environment is presented in **Annex E.1.** (Risk Management Options). A corresponding EU-wide restriction will prevent and reduce the releases of the substance and is considered to be the most efficient and appropriate way to limit the risks (due to further releases into the environment) for human health and the environment on an EU level.

Annex D: Baseline

D.1. Introduction

The baseline scenario is the situation in the absence of the proposed restriction or any further RMM, or interventions implemented to reduce the environmental risks from manufacture, import and use of PHT. The baseline is a projection of future PHT volumes used in the EU and the corresponding projected releases of PHT into the environment. The projections consider other external factors that could affect the market, such as implementation of new legislations/regulations or changes to existing ones that may affect the releases of PHT. The baseline scenario describes the "business as usual" situation.

The baseline was developed based on the data gathered on manufacture, import and use of PHT within the EU as presented in **Annex A** (Manufacture and Uses) and the Exposure Assessment as outlined in **Annex B.9**.

The period from which the baseline is derived was chosen to be 2025 – 2044 as 2025 is considered the earliest, realistic Entry into Force (EiF) for a potential REACH restriction on PHT and 20 years is the analytical period commonly used for most restriction proposals.

The tonnage and releases report in **Annex A** (Manufacture and Uses) and **Annex B.9.** (Exposure Assessment) are the starting point for the baseline in this analysis and the assumptions related to future trends of the use of PHT. The baseline scenario is compared to the proposed restriction scenario in the Impact Assessment (**Annex E**) in terms of both costs and benefits.

D.2. Existing Regulations affecting the Manufacture and Use of PHT

There is currently no regulation at EU level which is significantly affecting the manufacture and use of PHT. There are some indications that SVHC identification could affect the baseline, mainly for their use in non-HTF applications.

According to personal communication with representatives from the adhesives & sealants industry (use as a plasticiser), SVHC listing makes additives less attractive for mid- to long-term formulation developments, due to the perceived threat they could become subject to REACH Authorisation at any time. The decreasing participation in the SEA questionnaires from 2018 to 2020 and 2021 (see **Annex E**: Impact Assessment) suggests as well that the industry involved in the plasticiser use has started the reformulation/ substitution process already.

Moreover, it should be noted that Annex I of REACH obliges registrants of PBT/vPvB substances to implement or recommend to downstream user RMMs that minimise the releases of substances to environmental compartments and the workplace throughout the life cycle of the substance. Use of a PBT/vPvB substances in a consumer product that has a "widely dispersed" use (either released to the atmosphere or to wastewater), is unlikely to be consistent with the concept of minimisation. Therefore, it could be argued that the identification of PHT as SVHC is sufficient justification itself for producers to reformulate sealants & adhesives products.

The current version of the CLP Regulation, which implements the GHS, does not include the possibility of classifying a substance as PBT/vPvB, since these categories are not part of the GHS. However, CLP Regulation is currently being updated and PBT/vPvB are likely to be included as hazard classes in the future.

The EU Water Framework Directive (Directive 2000/60/EC)[32] provides a framework for the

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[32] Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy.

protection of inland surface waters, transitional waters, coastal waters and groundwater. The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment are controlled by national measures including environmental permits. The Water Framework Directive manages surface water pollutants by identifying and regulating those of greatest concern across the EU known as "Priority Substances" and further requiring Member States to identify substances of national or local concern (river basin specific pollutants). Measures must be taken to reduce the emissions, discharges and losses of the Priority Substances (PS) and to phase out those deemed the most harmful ones ("Priority Hazardous Substances", PHS). Environmental Quality Standards (EQS) are set in the Environmental Quality Standards Directive (2008/105/EC)[33] for PS and PHS[34]. Member States must ensure that the EQS for the Priority Substances are met in order to achieve "good chemical status" in accordance with Water Framework Directive Article 4 and Annex V 1.4.3[35]. The Priority Substances list was replaced in 2013 via Directive 2013/39/EU[36], which also includes EQS and other provisions for chemical pollutants. The provisions involve improving the efficiency of monitoring and the clarity of reporting with regard to certain PBT substances. Terphenyl, hydrogenated is currently not identified as a PS or PHS.

The Industrial Emissions Directive (2010/75/EU)[37] establishes the main principles for permitting and control large industrial installations based on an integrated approach and the application of Best Available Techniques (BAT) to achieve a high level of environmental protection.

The manufacture and some uses of PHT are covered by the Industrial Emissions Directive (IED). However, as no BAT reference documents[38] related to the use of PHT are available, the IED is considered of limited applicability for the risk management of the substance.

From an EU policy standpoint, the COM's new Circular Economy Action Plan announces initiatives along the entire life cycle of products. It targets their design and promotes circular economy processes to stimulate sustainable consumption. It also aims to ensure that the resources used are kept in the EU economy for as long as possible, thus reducing waste.

The Waste Framework Directive (2008/98/EC) sets out measures addressing the adverse impacts of the generation and management of waste on the environment and human health, as well as to improve the efficient use of resources. An amendment[39] to the Waste Framework Directive prescribes that from 5 January 2021 suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit to ECHA information via the SCIP Database, thus providing waste operators information about hazardous substances in the waste processed.

D.3. Current Situation on Volumes and Baseline Volumes

To be able to estimate the expected impact of the restriction proposal, it is important to know the current situation in terms of the use of PHT in the EU and to describe the expected trends that would occur without the introduction of any new regulatory measure.

From 2025 to 2044, it is expected that developments in the volume of PHT used as HTF in the EU will be dominated by the market trends. As shown before, PHT plays a significant role

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[33] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy.

[34] http://ec.europa.eu/environment/water/water-dangersub/index.htm

[35] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0060-20141120

[36] Directive 2013/39/EU of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

[37] Directive 2010/75/EU of the European Parliament and the Council on industrial emissions.

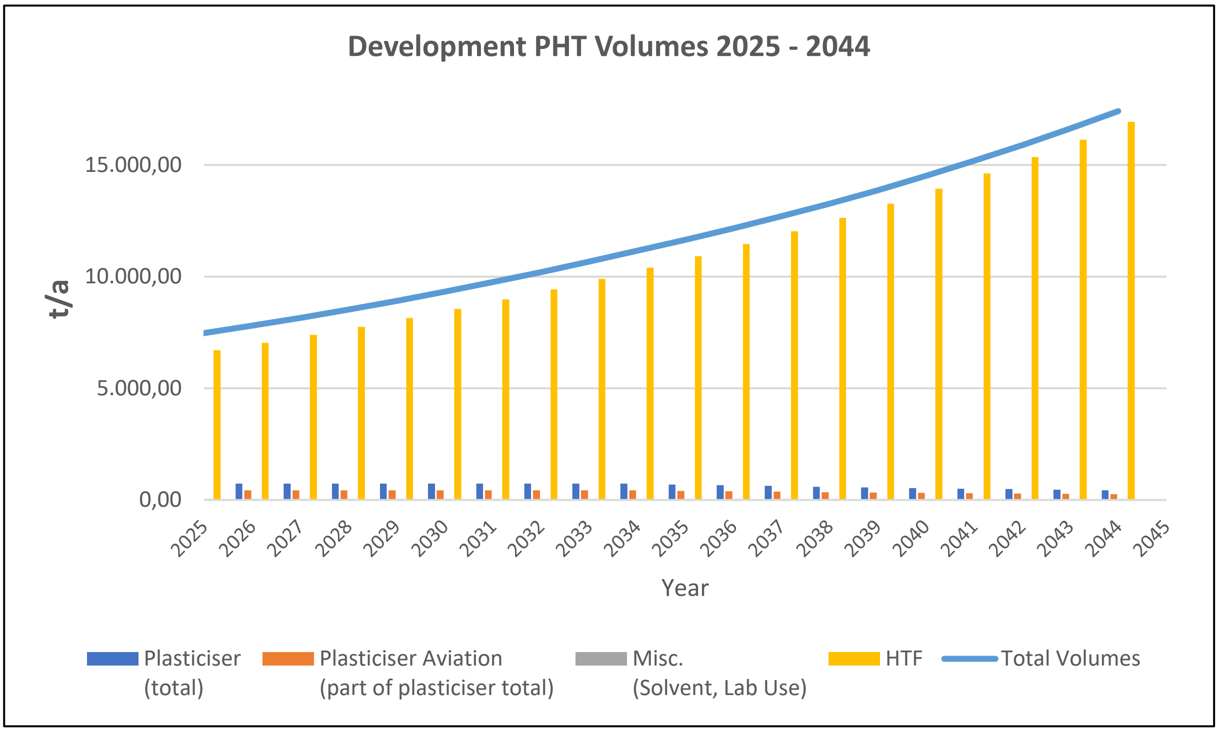
[38] BAT reference documents | Eippcb (europa.eu)

[39] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste.

as HTF in alternative energy technology (ORC and solar) supporting the EU's Green Deal[40]. Moreover, chemical recycling of PET and other polymers is increasing following the EU's Circular Economy action plan[41]. The dossier submitter therefore assumes, that the growth trend as shown will continue in the next 20 years, but slightly levelled due to the SVHC listing. In addition and due to the feedback from the different questionnaires, the demand for PHT was higher than the available production capacity in the last 5 years, therefore new production plants have been installed in China and the Middle East.

This resulted in growth rates of up to 30% in the last 3 years globally as well as on EU level. It is reasonable to assume that this growth rate will flatten as more capacity has been installed globally and a continued volume increase of 5% annually for HTF use is assumed by the Dossier Submitter, resulting in a predicted volume for HTF use of ca. 16 931 tonnes per year by end of 2044. **Figure 29** below shows the estimated volume development in the EU between 2025 and 2044, based on the aforementioned growth rates.

Figure 29. Estimated trend of volume development of PHT in the EU from 2025 – 2044



The plasticiser use is assumed to be stagnant from 2025 – 2035. Beyond 2035, the uncertainty in any projection increases and makes it difficult to identify the driving factors for the plasticiser use. The Dossier Submitter assumes, that due the SVHC listing the reformulation will kick in, resulting in a drop of the plasticiser use in the EU. It is expected that the decrease in volume as of 2036 will be 5% per annum. On the other hand, it is very likely that the production of articles including PHT as a plasticiser will be relocated outside the EU and that the volume of imported articles containing PHT into EU will increase. The high number of articles containing PHT notified to the SCIP Database shows evidence for that. Consequently, for the Baseline Scenario a stagnant plasticiser emission is assumed. The non-HTF and non-plasticiser use is assumed to be stagnant, too.

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[40] Delivering the European Green Deal | European Commission (europa.eu)
[41] Circular economy action plan (europa.eu)

D.4. Current Releases of PHT and Baseline Emissions

The current emissions of PHT to the environment from various sources in 2021 were derived in **Annex B.9.** (Exposure Assessment). The environmental releases are based on the default release factors in accordance with ECHA Guidance R.16. In case other information on the releases was available to the Dossier Submitter and applicable for PHT, e.g., SpERCs or OECD Emission Scenario Documents, this information was used in preference to the default release factors as indicated in the ECHA Guidance R.16 (ECHA, 2016). Additionally, specific information was collected via the Exposure & Release Questionnaire (2018) by the LR, which was initiated to update the Exposure Assessment of the Registration Dossier.

The main objective for the approach of the environmental exposure assessment was to present a realistic assessment. The default release factors represent a worst-case approach, overestimating the actual emissions to the environment. Hence, the default release factors give an indication of the relative release potential from the various processes but do not take into account the physico-chemical properties of the substance or any RMM that is used during the process.

Using more specific information, if available, instead of the default release factors guarantees a more realistic exposure assessment, which is based on actual emissions. However, if no other information was available the default release factors as indicated in ECHA Guidance R.16 were used. The default release factors are described in **Table 16**. in **Annex B.9.** (Exposure Assessment).

The share of the total emissions was evaluated based on the market sector and summarised in **Table 86**. The exposure assessment shows that in the "high emission scenario" the largest source of PHT emission to the environment in the EU is attributed to the use in adhesives/sealants. Regarding the high emission scenario, the "use of adhesives and sealants at industrial sites" contribute significantly to the overall emission (approximately 41%). The use of coatings/inks at industrial sites as well as the use as HTF at industrial sites have a share of approximately 25 and 19%, respectively, of the total emissions.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately 67% of the total emissions followed by the industrial use of sealants and adhesives (approximately 14%).

The following market sectors were considered:

- Use in coatings/inks
- Use as HTF
- Use in adhesives/sealants
- Miscellaneous uses (i.e., general formulation, use as solvent and use as laboratory chemical by professionals)

The analysis showed that the adhesives/sealants represent by far the largest share of the total emissions. In the high emission scenario, the share is estimated at approximately 48% whereas the share in the low emission scenario is even higher (approximately 86%).

Table 86. Sources of Emission of PHT by market sectors

Scenario	Share of total (%) Low emission scenario	Share of total (%) High emission scenario
Adhesives and sealants	85.76	48.21
Coatings and inks	10.28	25.07
HTF	0.05	19.02
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.92	7.71

In **Table 87** the emissions for each compartment (air, water and soil) are displayed. These include the sum of estimated releases to air, water and soil. However, the redistribution in STP is not taken into account for emissions to waste water.

Regarding the low emission scenario approximately the same amount is released to water and soil (approximately 42 and 37%, respectively) whereas the release to air is lower (approximately 22%). For the high emission scenario, approximately 40% is released to air as well as to water. Only approximately 21% is released to soil.

In general, no major route of emission can be determined.

Table 87. Estimated total release for PHT in EU in 2021

Environmental compartment	Estimated EU emissions based on data on volume for 2021		
	Low (kg per year)	High (kg per year)	Share of total (%)
Air	14 000	710 000	21.64 – 39.80
Water	26 900	706 000	41.58 – 39.57
Soil	23 800	368 000	36.79 – 20.63
All / Total	**64 700**	**1 784 000**	**100**

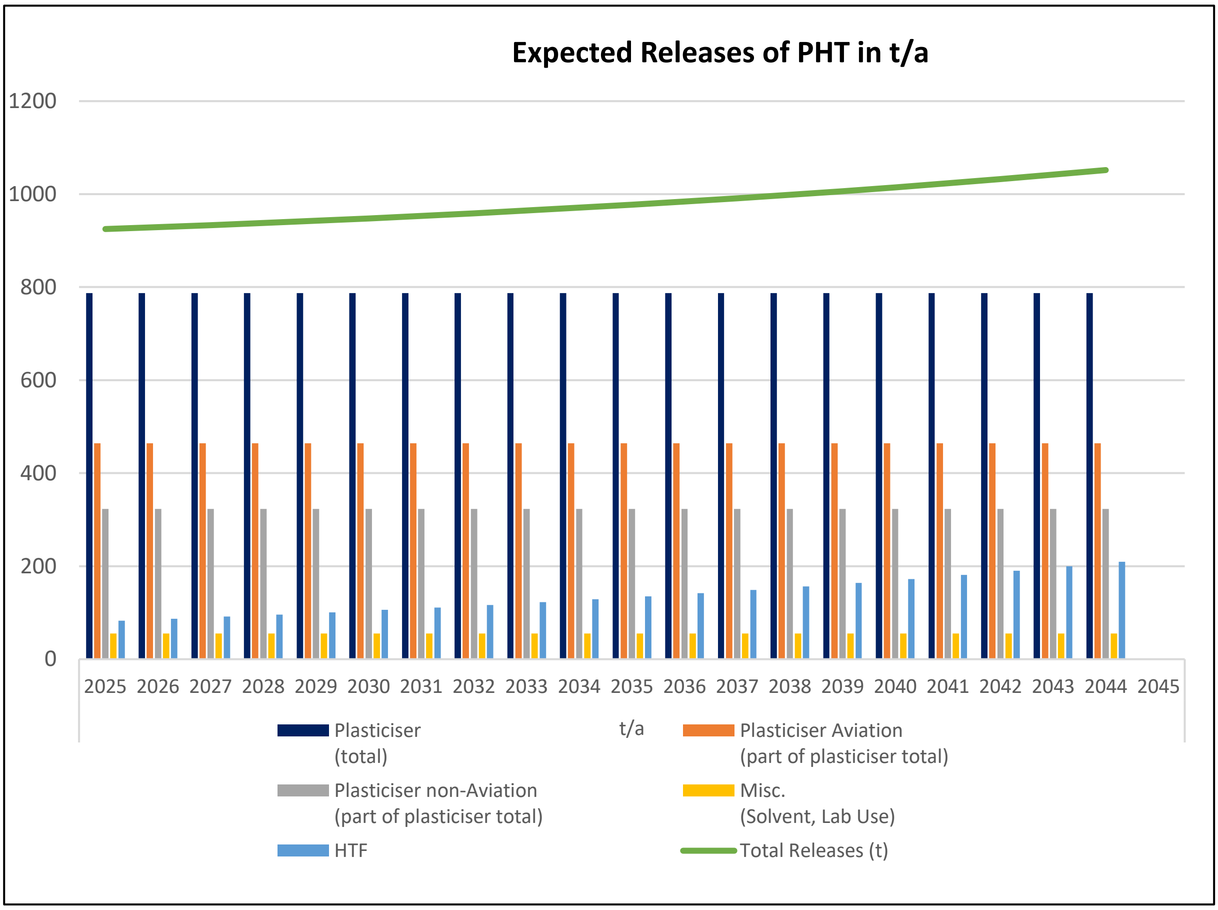
Table 88 shows the estimated total release for PHT in EU by market sector in 2021. For the Baseline calculations, the below averaged release shares (average between low and high emission scenario) have been used. The high and low volume emission scenarios were averaged to an estimated PHT release of 925 t in 2021.

Table 88. Estimated total release for PHT based on market sector in EU in 2021 based on average release shares and average total volume

Market SU	Release Share (average in%)	Volume of total releases, average (tonnes per year)	Release, average, (tonnes per year)
Plasticiser Adhesives and Sealants	67	**925**	620
Plasticiser Coatings and Inks	18		167
HTF	9		83
Miscellaneous	6		55

This means that the plasticiser applications, representing ca. 10% of the volumes used in the EU are responsible for 85% of the releases of the 2021 volumes. The HTF use, representing 90% of the volume account for approximately 9% of the releases and the remaining non-HTF and non-plasticiser applications (< 1% of the volume used) sum up for 6% of the emissions. In addition, it needs to be considered that PHT will be entering the EU via articles containing PHT as a plasticiser and will be released during service life.

Figure 30. Estimation of expected PHT releases on an annual basis from 2025 – 2044



The worst-case cumulative releases of PHT from 2025 to 2044 have been estimated with a total volume of 19 584 tonnes, which corresponds to an average annual release of 979 tonnes. From 2025 to 2044 the annual releases increase from 925 to 1 052 tonnes, as illustrated in **Table 89**.

Table 89. Cumulated and averaged expected releases from 2025 – 2044 per use

	Tonnes per year						
Expected releases	**2025**	**2030**	**2035**	**2040**	**2044**	**Cumulated releases 20 years in tonnes**	**Average annual release in tonnes per year**
Plasticiser (Total)	787	787	787	787	787	15 740	787
Plasticiser Aviation	464	464	464	464	464	9 280	464
Plasticiser non-Aviation	323	323	323	323	323	6 460	323
Miscellaneous (Solvent, Lab. Use)	55	55	55	55	55	1 100	55
HTF	83	106	135	173	210	2 744	137
Total Releases (tonnes)	**925**	**948**	**977**	**1 015**	**1 052**	**19 584**	**979**

Since the emissions from plasticiser uses will be stagnating as outlined before, but the HTF volume is increasing significantly over the next 20 years by a factor of 2.5, the HTF emissions will proportionately increase from 83 tonnes in 2025 to 210 tonnes in 2044, resulting in a doubling of emission share of HTF uses from 9% to ca. 20% of total PHT emissions. However, it should be noted that this is a very conservative and worst-case approach and most likely a significant overestimation. In particular since on-site exposure measurements (see Chapter B.9.3.3. Exposure measurements) did only identify negligible releases.

Over the examined 20 years, the whole plasticiser releases account on average for ca. 80% of the emissions and the non-HTF uses in sum for 86%. Resulting in a 14% contribution of HTF uses to the total averaged releases.

Annex E: Impact Assessment

The basis for the impact assessment were mainly the findings and results from stakeholder interactions and responses to questionnaires as well as comments submitted during public consultations (see as well “**Annex G**: Stakeholder Consultation”). Within the public consultations in the SVHC identification and the ECHA prioritization process, a call for information on Socio Economic Impacts by the COM was included. In the framework of this call, the COM asked for submission of information on the possible economic, social, health and environmental impacts (costs and benefits) of possible inclusion into REACH Annex XIV. The questionnaire template is included as Appendix 3.

Comments during the public consultation on ECHA’s Draft 10th recommendation were analysed as well, since they mostly include responses on impacts for industry too.[42]

Furthermore, the Dossier Submitter had several telephone interviews with the Lead- and Member Registrants as well as individual users of the substance via its consultant.

In early 2018, the LR of PHT conducted a simplified socio-economic impact analysis for PHT, in the context of the process to identify PHT as SVHC. It was based on responses to a questionnaire (see template in Appendix 2) addressed to their downstream users. 24 completed questionnaires were received from SMEs and large companies, including HTF uses in different industrial sectors (aluminium, polymers, chemicals, ORC) and plasticiser users (sealants, coatings, adhesives). This information was used for the preparation of the Risk Management Option Analysis of the Dossier Submitter in 2020 (ISS, 2021).

In the course of the restriction proposal preparation, the Dossier Submitter launched, between the 21 of June and the 30 of September 2021, a SEA Questionnaire (see template in Appendix 4) to the PHT value chain, including manufacturers, importers, downstream users, article manufacturers and equipment manufacturers (e.g., boiler makers) via its technical consultant. In addition, some relevant industry associations were contacted. In total about 250 questionnaires were sent and 30 replies were received from different industry sectors.

In summary, 135 responses were analysed for getting a better understanding of impacts for industry and society. **Table 90** is providing an overview.

Several individuals/companies responded to all or some of the requests. Removing duplicate responses leads to a total of 96 individual replies of which 89 are from individual companies and 7 from industry associations.

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[42] https://echa.europa.eu/documents/10162/b0b07eaa-b59a-4df5-42d5-cd89ca50e021

Table 90. Responses reviewed related to impacts on industry

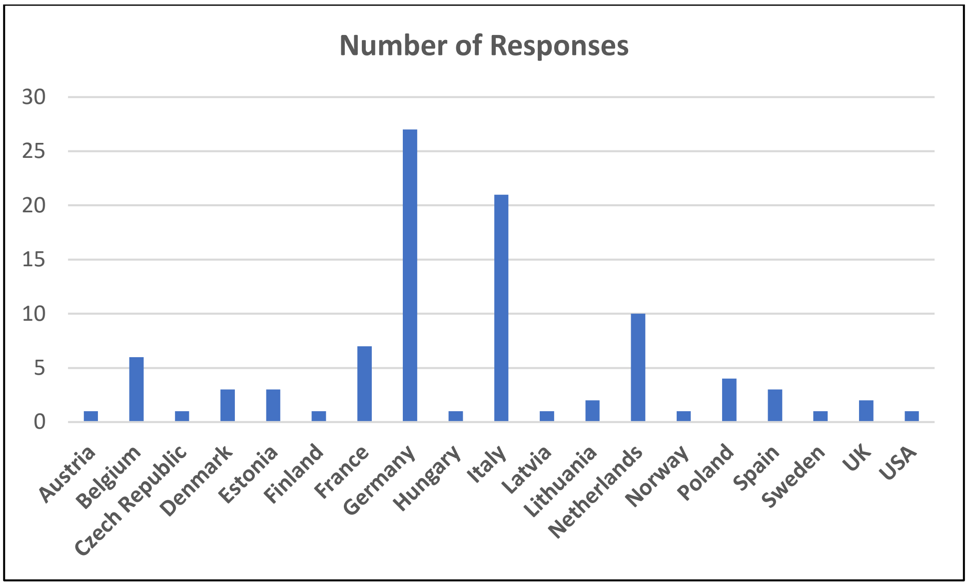
Type of Request/Response	Number of Responses
LR - SEA Questionnaire, 2018	24
COM - Socio-Economic Impact Questionnaire, 2020	26
ECHA - Responses to 10th Recommendation, 2020	55
Dossier Submitter - SEA Questionnaire, 2021	30
Total	**135**
Individuals (removing duplicate responses)	96
Individual companies	89
Industry Associations	7

Analysing the number of responses per country it can be determined that unsurprisingly most of the responses came from EU countries, where PHT has the highest installed base (see **Annex A** – Manufacture and Uses). **Table 91** does show the responses per country and **Figure 31** does illustrate these numbers in a schematic diagram.

Table 91. Responses by Country

Country	No of Responses
Austria	1
Belgium	6
Czech Republic	1
Denmark	3
Estonia	3
Finland	1
France	7
Germany	27
Hungary	1
Italy	21
Latvia	1
Lithuania	2
Netherlands	10
Norway	1
Poland	4
Spain	3
Sweden	1
UK	2
USA	1

Figure 31. Schematic diagram to illustrate the number of responses per country



E.1. Risk Management Options

Information to justify why a restriction is required at EU wide level is provided in **Annex C** (Justification for action on a Union-wide basis). Section E.1 therefore focuses on what the scope of such a restriction might be. In **Annex E.1.1.** three different ROs (RO1, RO2 and RO3) are reviewed, which are included in the SEA. Each of the ROs vary in terms of the scope (and severity of impacts) of the possible restriction.

RO1 presents the proposed restriction which is subject to comments from stakeholders, the Risk Assessment Committee (RAC) and the Committee for Socio-Analysis Committee (SEAC). However, it is important to note that a SEA has also been carried out on RO2 and RO3. Therefore, stakeholders and the two committees can also comment on the proportionality of all three ROs. Further details on all three options can be found in **Annex E.3.** Restriction scenario(s), **Annex E.8.** Proportionality and comparison of ROs, and **Annex F** Assumptions, uncertainties, and sensitivities.

E.1.1. Proposed option(s) for restriction

E.1.1.1. Proposed RO: RO1 – Derogation for HTF Use and Use as Plasticiser in Production of Aircrafts

RO1:

- A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.
- A derogation shall apply for the use and placing on the market for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.
- A derogation shall apply for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts from EiF + 5 years.

E.1.1.2. Justification for the selected scope of the proposed RO

RO1 is the RO with the most balanced scenario between socio-economic impacts and the potential for emission reduction (kg avoided emissions of PHT). Under RO1 there is a general derogation for HTF use, provided that such sites implement strictly controlled closed systems with technical containment measures to prevent environmental emissions.

These minimum requirements are described under Chapter E. 3.

Exposure measurements on facilities using PHT as HTFs demonstrated that emissions from HTF plants are negligible (see **Annex B.9.**: Exposure Assessment) if certain design standards are met. Moreover, this substance is critical to many industrial processes and alternatives do not exist for high temperature, non-pressurised HTF applications. The most common alternative substances are expected to have similar vPvB/PBT properties, therefore replacement would result in significant costs and regrettable substitution. Since substitution is not feasible, a ban of PHT would lead to significant negative socio-economic impacts, potentially resulting in relocation outside of the EU of some industrial users of PHT.

Furthermore, RO1 includes a derogation for the use of PHT in plasticisers in the production of aircrafts and their spare parts from EiF + 5 years. PHT is used in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations for which it was reported that there are currently no alternatives available. PHT is used due to their ease of application, ease of field repair, flexibility, solvent and chemical resistance, low moisture permeability, and adherence to many metals, composite, and coated substrates. The aerospace industry needs time to develop alternative formulations. To test them against performance requirements, to qualify and validate their use can take several years. It was therefore deemed to be appropriate to provide a derogation for 5 years after EiF. Considering the date of inclusion in the Candidate List in June 2018 and timeline of the restriction process, the overall timeframe for reformulation was > 10 years.

With RO1 it is still expected to reduce the majority of the emissions of PHT, as the proposed derogation on plasticiser use in the aviation sector is time limited. The analysis and comparison of the ROs in **Annex E.8.** "Proportionality" shows, that RO1 is the most proportionate and cost-effective option and shows, that the need for derogations for both uses is justified.

E.1.1.3. Other RO 1: RO2 – Derogation for HTF Use

RO2:

- A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.
- A derogation shall apply for the use and placing on the market for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

E.1.1.4. Justification for the selected scope of the other RO 1

The socio-economic impact on society would be higher and proportionality is lower compared to RO1. The benefits are clearly outweighing the risks. The costs per kg avoided emissions is not justifying the direct ban on plasticiser uses in the aerospace industry. As outlined under RO1, the aviation sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. New materials or design changes can only be introduced on the aircraft if testing and compliance demonstrations has been approved. Therefore, the Practicality (implementability, enforceability, manageability) of this option was considered worse to the proposed option RO1, the transitional period (EiF + 18 months) would not be sufficient for the aviation industry to reformulate.

In addition, it needs to be taken into account, that aerospace supply chains are complex with many actors involved at different levels involving a significant number of SMEs, which increases complexity and timing for substitution.

Monitorability of the restriction is expected to be similar to the proposed restriction RO1. This option **RO2 was overall discarded** as it would be less net beneficial to society than the proposed restriction.

E.1.1.5. Other RO 2: RO3 – Total Ban

RO3:

- A restriction on the manufacture, use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months

E.1.1.6. Justification for the selected scope of the other RO 2

RO3 is the RO with the highest risk reduction potential and thus the option that would give over long time the highest environmental benefits related to reduced risks associated with the use of PHT. Under this RO, no derogations would be granted which would mean that all uses of PHT must cease by the end of the transition period (EiF + 18 months).

The impact on the aviation industry is the same as under RO2. The impact on the HTF sector would be tremendously higher. All ca. 1,300 existing systems using PHT as HTF in the EU would need to either shut down their plants or retrofit their plants for using alternative HTF (potentially leading to regrettable substitution) or alternative technologies. This would not only result in much higher costs and socio-economic impacts but could as well result in higher emissions, since all plants would need to be emptied and the PHT waste to be disposed of. The installed volume of about 25 000 t in the EU would become hazardous waste.

Therefore, RO3 was discarded as disproportionate. The Practicality (implementability, enforceability, manageability) of this option is considered the worse of all ROs. Monitorability of the restriction is expected to be worse too, compared to the proposed restriction. It will be difficult to monitor at closed HTF systems, if PHT has been replaced.

E.1.2. Discarded ROs

Actors or Sectors that would be heavily impacted by a restriction have a vested interest in putting forward evidence that a derogation for their use is needed. Since few stakeholders outside the HTF and Aviation sector provided such information, this would indicate that a restriction on PHT would not result in disproportionate costs for their uses/sectors.

Therefore, it is concluded that derogations are not needed in any other sectors. ROs with derogations for uses outside the HTF and Aerospace sectors have therefore not been considered. It remains a risk that there are actors with critical uses of PHT, who did not respond to the stakeholder consultations, but in the absence of any such evidence, increasing the risk to the environment by choosing a more lenient RO is not justified.

E.1.3. Other Union-wide risk management options than restriction

PHT itself is not currently regulated by other legislation in the EU. Other EU legislation related to PBT/vPvB substances is mentioned below. This section gives a short description of other Union-wide legislative options that have the potential to influence emissions of PHT to the environment. In most cases where a concern related to a substance has been identified, there will be several options for addressing this concern. All the additional legislative measures that may be used have different strengths and weaknesses which will vary depending on the case. The Dossier Submitter prepared an Regulatory Management Option Analysis (RMOA) (ISS 2021) on PHT in 2021, which was discussed at the RIME+ Meeting in October 2020 and submitted to ECHA in 2021[43]. The aim of a systematic analysis of the Regulatory Management Options (RMOs) is to facilitate the identification and choice of the most appropriate measure (or combination of measures) for the case at hand.

The EU CLP Regulation, which implements the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), does not include the possibility of classifying a substance as PBT/vPvB, since these categories are not part of the GHS. However, the classification 'hazardous for the aquatic environment' includes "ready degradability" and "potential to bioaccumulate" as criteria to consider, meaning that some aspects of persistence are taken into account. Moreover, it is expected that PBT and vPvB properties will be included in the future in CLP.

The EU Water Framework Directive (Directive 2000/60/EC)[44] provides a framework for the protection of inland surface waters, transitional waters, coastal water, and groundwater. The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment are controlled by national measures including environmental permits. The Water Framework Directive manages surface water pollutants by identifying and regulating those of greatest concern across the EU known as "Priority Substances" and by requiring Member States to identify substances of national or local concern (river basin specific pollutants). Measures must be taken to reduce the emissions, discharges, and losses of the Priority Substances (PS) and to phase out those deemed the most harmful ("Priority Hazardous Substances" (PHS)). Environmental Quality Standards (EQS) are set in the Environmental Quality Standards Directive (2008/105/EC) for PS and PHS[45].

Member States must ensure that the EQS for the Priority Substances are met in order to achieve "good chemical status" in accordance with Water Framework Directive Article 4 and Annex V 1.4.3. The Priority Substances list was replaced in 2013 via Directive 2013/39/EU, which also includes EQS and other provisions for chemical pollutants. The provisions involve improving the efficiency of monitoring and the clarity of reporting with regard to certain PBT substances. PHT is not currently identified as a PS or PHS.

The Industrial Emissions Directive (2010/75/EU)[46] establishes the main principles for permitting and control of large industrial installations based on an integrated approach and the application of Best Available Techniques (BAT) to achieve a high level of environmental protection. The manufacture and some uses of PHT are covered by the Industrial Emissions Directive (IED). However, as no BAT reference documents related to the use of PHT are available, the IED is considered of limited applicability for the risk management of PHT.

From an EU policy standpoint, the COM's new Circular Economy Action Plan (European Commission, 2020) announces initiatives along the entire life cycle of products. It targets their design and promotes circular economy processes to stimulate sustainable consumption.

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[43] Assessment of regulatory needs list - ECHA (europa.eu)

[44] WFD Directive. Consolidated version 20/11/2014. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02000L0060-20141120&qid=1632903621154

[45] http://ec.europa.eu/environment/water/water-dangersub/index.htm

[46] IED Directive. Consolidated version 06/01/2011. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0075-20110106&qid=1632903943515

It also aims to ensure that the resources used are kept in the EU economy for as long as possible, thus reducing waste.

The Waste Framework Directive (2008/98/EC)[47] sets out measures addressing the adverse impacts of the generation and management of waste on the environment and human health, and for improving efficient use of resources. An amendment[48] to the Waste Framework Directive prescribes that from 5 January 2021 suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA thus providing waste operators with information about hazardous substances in the waste they are processing. As already mentioned in previous sections, the SCIP Database includes > 12 000 Articles containing PHT.

In the above mentioned RMOA of the Dossier Submitter, **Authorisation** and Restriction under REACH were compared as potential risk management options (see **Table 92**).

The analysis of Authorisation as RMO – against the key criteria - demonstrates that the Restriction route would be the most appropriate option to deal with the potential risks derived from the manufacture and use of PHT in the EU. In contrast, authorisation would be a disproportionate, less practical, and less effective provision due to the lack of suitable alternatives for the vast majority of the volume used; and therefore, it should not be selected as a RMO for this substance. The main use of PHT in the EU (approximately 90% of the volume) is as a high temperature, non-pressurised HTF. This use takes place in closed systems from which low emissions are, in principle expected. However, situations may arise in which releases could be possible (e.g., top-up, sampling, transport, cleaning and maintenance or final disposal). Because of the properties of PHT as a vPvB substance, those situations could lead to an unacceptable risk of PHT reaching environmental compartments. Furthermore, it is not clear whether industry is currently using the best available technologies to guarantee that emissions during normal operations are adequately controlled. For this reason, a restriction could be based around introducing technical requirements to ensure that PHT is used and handled at industrial settings in an appropriate manner, e.g., via establishing specific technical requirements aimed at granting tight engineering controls on the equipment where PHT is used.

A restriction could also better address risks derived from other uses that may lead to significantly higher exposure compared to the HTF use. For uses where risk is considered to be unacceptable, a ban on the use of the substance could apply. Finally, it is very likely that articles containing PHT are imported into the EU (see **Annex A**: Manufacture and Use). In order to avoid that such articles would reach consumers, volumes of PHT introduced in the Community would be included in the restriction proposal to grant that such articles would not lead to unexpected emissions of PHT.

Table 92. Comparison of the identified RMO against the key criteria (Source ISS, 2021)

Criterion	**Restriction**	**Authorisation**
Risk Reduction Capacity	++	+
Proportionality	++	--
Practicality (implementability, enforceability, manageability)	+	-

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[47] Directive 2008/98/EC. Consolidated version 05/07/2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705&qid=1632904019685

[48] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste

Monitorability	+	+
Regulatory Consistency	++	+

E.2. Alternatives

This section identifies and analyses potential alternatives to PHT in terms of hazards, technical feasibility, economic feasibility, and availability.

Section E.2.1. sets out the functions and corresponding IU of PHT.

Section E.2.2 presents the different alternative substances to PHT and the sources of this information.

The assessment of hazards, technical feasibility, economic feasibility, and availability of each alternative are presented in Section E.2.3., whilst the conclusions from the assessment of alternatives are summarised in Section E.2.4.

E.2.1. Description of the use and function of the restricted substance(s)

As mentioned before, ca. 90% of PHT is used as a HTF, with about 10% of its use being in other applications, such as:

- Additive in plastics (plasticisers);
- Additive in coatings, paints, inks;
- Additive in sealants and adhesive applications;
- Solvent or process medium;
- Laboratory chemicals.

HTFs are used in situations where precise temperature control is needed, such as in the manufacture and processing of synthetic fibres, plastics, rubber, and other chemicals. HTF can be used in non-pressurised or pressurised liquid phase systems. HTFs (or heat transfer media) are of great importance for many industrial processes in which heat needs to be transported or transformed. The most important requirements are:

- low vapor pressure
- high heat capacity
- low viscosity
- high thermal stability and
- low corrosivity

A HTF is a liquid or gas which is specifically manufactured for the transmission of heat. HTFs can be used by many sectors for any single- or multiple-station heat-using system. Thus, they are primarily used as an auxiliary fluid to transfer heat from a heat source to other areas of a process with heat demands. The HTF is a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source (heater). Selection of the most suitable HTF is based on the type of industrial applications, stable temperature range for safe operation and lifetime of the HTF. Synthetic HTFs like PHT do not require pressurizing at temperatures up to 350°C. Another advantage of using a mineral or synthetic fluid, as opposed to water, is that it generally has a lower freezing point. Lastly, HTFs also tend to be less reactive and corrosive to pipes and other parts of the system than water.

Synthetic HTF systems allow fuel and energy consumption to be reduced by 20 to 25% compared with steam heating systems, making thermal fluid an efficient solution, both environmentally and economically. In an indirect heating system using steam overall efficiency of 65 – 70% is obtained, i.e., over 30% of the fuel's energy is lost, representing an increase in energy costs and lower efficiency of the heating system. The same process heated with HTF has an efficiency of 90% (Pirobloc, 2021a).

Non-pressurised liquid phase systems are generally the simplest to design and operate. HTFs can be used in this type of system as long as the operating temperature is below its boiling range. When the operating temperature of the HTF is above its boiling range a pressurised system is needed. A pressurised inert gas (nitrogen) is used to maintain HTF in the liquid phase in these systems.

PHT is specifically used as a HTF in closed manufacturing systems, including those for polymers, waste heat recovery, oil and gas, petrochemicals, and renewable energy. PHT can be used as an HTF with high operating temperature range of 325-350°C in non-pressurised liquid phase heat transfer systems, because it has a boiling point of 342°C at the standard atmospheric pressure (101.325 kPa). At temperatures above 350°C heat transfer systems containing PHT need to be pressurised.

E.2.2. Identification of potential alternative substances and techniques fulfilling the function

This section describes the approach to identify, compare, and select potential alternatives to PHT. The overall goal is to support informed decisions regarding the advantages and disadvantages of different alternatives to PHT.

The alternative to PHT would need to be technically and economically feasible, but also have a favourable hazard profile to avoid regrettable substitution and subsequent regulatory action on the alternative. Considering these conditions, this identification process can be divided in three general steps:

- Screening of information sources
- Assessment on the technical suitability of the alternatives
- Assessment of the hazard profile of the alternatives

In the analysis of the second step, the uses of the substance will be considered separately.

E.2.2.1. Screening of information sources

This screening step has mainly consisted in the review of the different information sources in which alternative substances to PHT are included, such as:

- available literature and bibliography, and
- information from stakeholders and responses to the SEA questionnaires.

Technical documentation on specifications for plant construction[49] identify PHT, 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS 63231-51-6; EC 400-370-7), and dibenzyl-benzene, ar-methyl derivative (CAS 53585-53-8; EC 258-649-2) as possible HTFs (See **Figure 32**).

"The heat transfer media (HTM) will be organic oil, modified terphenyl type. The plant shall be capable of using the following HTM types without compromising on efficiency, plant lifetime and performance:

Therminol 66 from Solutia	(= PHT)
Dowtherm RP from Dow Chemical	(= 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene)
Marlotherm SH from Eastman	(= dibenzylbenzene, ar-methyl derivative)

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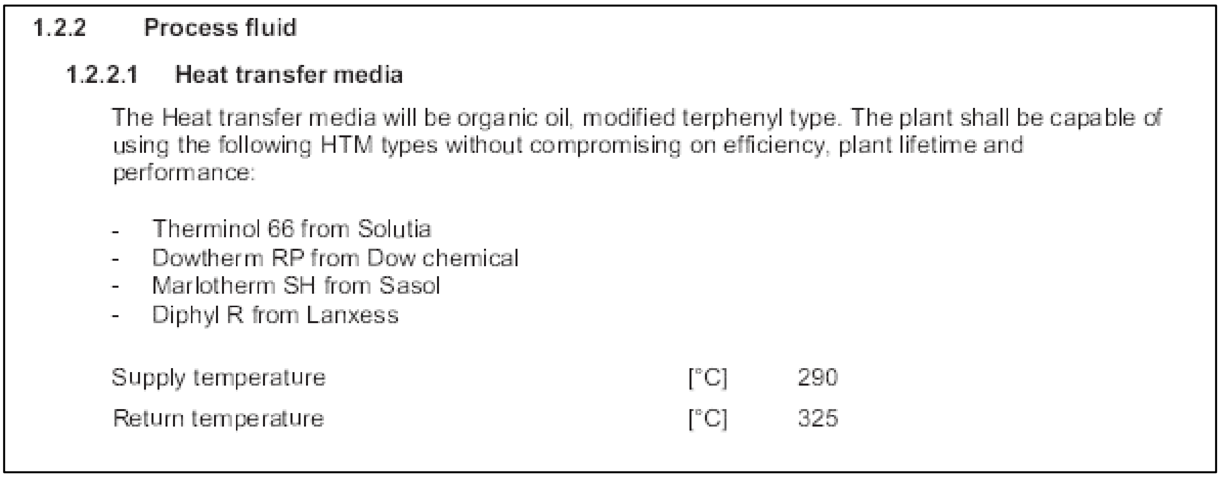
[49] Polymer Plant Specification (Source: undisclosed Technical Specification of HTF Plant)

- *Diphyl R from Lanxess."* (= PHT)

Figure 32. Polymer Plant Specification for HTF Unit



1.2.2 Process fluid

1.2.2.1 Heat transfer media

The Heat transfer media will be organic oil, modified terphenyl type. The plant shall be capable of using the following HTM types without compromising on efficiency, plant lifetime and performance:

- Therminol 66 from Solutia
- Dowtherm RP from Dow chemical
- Marlotherm SH from Sasol
- Diphyl R from Lanxess

Supply temperature	[°C]	290
Return temperature	[°C]	325

Also, these two substances (Dowtherm RP and Marlotherm SH) were included in the RMOA conducted by the Finnish Safety and Chemicals Agency (Tukes, 2020), the Finnish competent authority regarding REACH, as part of a functional grouping approach for high temperature, non-pressurised HTF, which might be used as substitutes for the SVHC-identified substance PHT.

In November 2021, the COM published a draft of the proposal for a restriction roadmap under the chemical strategy for sustainability (European Commission, 2021a), which was discussed at the 42nd CARACAL meeting. This roadmap includes an entry in Annex I (Rolling list of (groups of) substances for restriction) related to substances used as high temperature HTFs, that comprises PHT and these two potential alternatives. Furthermore, in February 2022 the Austrian competent authority published a comment[50] on this restriction roadmap, indicating that they and the Finnish competent authority had established discussions in relation to a possible cooperation for proposing further measures for these two substances. The aim of this action is to ensure an adequate risk reduction measure (possibly a restriction) for these two substances in order to avoid regrettable substitution of PHT.

In general, HTFs can be classified, according to their chemical structure, in three main types (Pirobloc, 2021b):

- Mineral
- Synthetics
- Silicones

Mineral fluids are obtained from conventional oil refining, in which the base oil is extracted directly from the distillation of petroleum. The majority of these consist of paraffinic and naphthenic hydrocarbons, to which some additives are added to give them properties that improve their performance. The general operating range is around -10°C to 315°C.

Synthetic fluids are obtained via chemical synthesis processes or other processes different to conventional refining. They consist of a benzene-based structure and include diphenyl and biphenyl oxides, diphenylethanes, dibenzyltoluenes, and terphenyls. The operating temperature range for these types of fluids is around -20°C to 400°C.

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[50] Comment of the Austrian CA on the Restrictions Roadmap: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/d9d35c5f-8c6f-4fe6-98ec-649667c55864/details

Silicone fluids are used in specialised heat transfer applications. In the comparative temperature ranges of the mineral and synthetic fluids, they are unlikely to be choices for most process applications due to performance and cost factor disadvantages.

Based on information obtained from the responses to the SEA questionnaires, the following synthetic fluids could be also considered as potential alternatives to PHT:

- Benzene, ethylenated, by-products from (CAS 68608-82-2; EC 271-802-8)
- Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl (EC 915-589-8)
- Reaction mass of m-terphenyl and o-terphenyl (EC 904-797-4)
- Diphenyl ether (CAS 101-84-8; EC 202-981-2)
- Biphenyl (CAS 92-52-4; EC 202-163-5)
- Cyclohexylbenzene (CAS 827-52-1; EC 212-572-0)
- Bicyclohexyl (CAS 92-51-3; EC 202-161-4)
- Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS 84961-70-6; EC 284-660-7)
- Benzyltoluene (CAS 27776-01-8; EC 248-654-8)
- Ditolyl ether (CAS 28299-41-4; EC 248-948-6)

It has to be noted that Bicyclohexyl (CAS 92-51-3; EC 202-161-4) is not registered under the REACH Regulation. Therefore, this substance is discarded as alternative to PHT because it cannot be legally marketed and used in EU in the required quantities (see **Annex A**).

Considering this fact, the final list of alternatives to be assessed are indicated in **Table 93**:

Table 93. List of alternatives

Alternative	Chemical name	CAS	EC
1	1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene	63231-51-6	400-370-7
2	Dibenzylbenzene, ar-methyl derivative	53585-53-8	258-649-2
3	Benzene, ethylenated, by-products from	68608-82-2	271-802-8
4	Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl	-	915-589-8
5	Reaction mass of m-terphenyl and o-terphenyl	-	904-797-4
6	Diphenyl ether	101-84-8	202-981-2
7	Biphenyl	92-52-4	202-163-5
8	Cyclohexylbenzene	827-52-1	212-572-0
9	Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues	84961-70-6	284-660-7
10	Benzyltoluene	27776-01-8	248-654-8
11	Ditolyl ether	28299-41-4	248-948-6
12	Mineral fluids	-	-

E.2.2.2. Assessment on the technical suitability of the alternatives

Regarding the use as HTF, alternatives to PHT need to have a similar boiling point (342°C) at standard atmospheric pressure (101.325 kPa) to be used without excessive thermal degradation in liquid phase, non-pressurised systems at a high temperature range of 325-350°C. As the working temperature of the non-pressurised liquid phase systems must be below the boiling range of the HTF, substances showing values of the boiling point lower than 325°C cannot be considered suitable technical alternatives to PHT, because they require the pressurization of the heat transfer system.

Synthetic HTFs generally have higher maximum operating temperatures than mineral fluids based hot oils, which are not recommended to be used above a temperature of 315-320°C (Damiani MR, 1998). Therefore, mineral fluids cannot be considered as alternative to PHT as HTF for technical reasons.

The boiling point values and the registered uses of the potential alternatives has been obtained from the information of their respective REACH registration dossiers disseminated in the webpage of ECHA (ECHA, 2021d). These values are described in **Table 94**:

Table 94. Boiling points and registered uses of the potential alternatives

Alternative	EC	Boling point (°C)	Registered uses
1	400-370-7	335-365	HTF
2	258-649-2	390.1	HTF, plasticiser, etc.
3	271-802-8	265-295	HTF, etc.
4	915-589-8	314	HTF, laboratory chemical, etc.
5	904-797-4	355	HTF
6	202-981-2	258	HTF, solvent or process medium, laboratory chemical, etc.
7	202-163-5	255	HTF, solvent or process medium, laboratory chemical, etc.
8	212-572-0	235	HTF, solvent or process medium, laboratory chemical
9	284-660-7	300.4 - 407.5	HTF, plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, laboratory chemical, etc.
10	248-654-8	283 - 287	HTF, etc.
11	248-948-6	283	HTF, etc.

Entry "etc." in the table means that other uses different to the uses defined for PHT are registered for the substance. In the case of Alternative 1, as there are not uses defined in the REACH registration dossier, the use has been extracted from the SDS of one registrant (Dow, 2017).

All the potential alternatives considered include the use as HTF in the registration dossier.

Alternatives 3, 4, 6, 7, 10 and 11 show values of the boiling point below 325°C and they cannot be considered suitable alternatives to PHT for technical reasons. This conclusion is aligned with the analysis performed on these substances in the RMOA developed by the Finnish CA (Tukes, 2020). For the same reason Alternative 8, that had not been assessed previously, cannot be considered.

Alternative 9 is a UVCB substance that shows a very wide range for the boiling point (more than 100°C). This is due to the presence of different constituents that make an exact value for this property difficult to predict. For this substance it is expected that some constituents in the lower boiling point range would undergo significant thermal degradation at high temperatures in non-pressurised systems, thus it would not qualify as direct substitution candidate for PHT in those specific conditions (Tukes, 2020).

On the contrary, Alternatives 1, 2 and 5 could be considered as suitable alternatives to PHT from the technical point of view, because all of them show values of the boiling point close to or higher than PHT.

Concerning the substitution of PHT in the other applications, e.g., in plasticiser uses in plastics, sealants and coatings, only scarce technical information is available to the dossier submitter.

According to the feedback during the Public Consultation on the SVHC Listing in early 2018 (ECHA, 2018b), the Aerospace Industry Association (AIA) commented that "*PHT is found in most polysulfide sealants. It is used as a high viscosity plasticizer to prevent phase separation of heavy constituents from settling out during storage, often found in accelerators. More importantly, the plasticizer must not fog or leach out of the cured polysulfide sealant once cured and exposed to numerous exposure environments*". According to the response, it will be difficult to replace PHT "*because the list of plasticizers compatible with polysulfides is limited and some of these can be ruled out as substitutes due to environmental and human health concerns (e.g., some phthalates, chlorinated paraffins). Polysulfide sealants are broadly used in the aerospace and defence industry because they provide flexible and chemically resistant sealing with low moisture permeability. They have excellent resistance to fuels, salt water, ozone and sunlight and exhibit resistance to impact, shock, vibration, and thermal cycling. They provide a secure, long-lasting seal to components which may be exposed to or immersed in liquids for prolonged periods of time. Other uses of PHT in polysulfides include specialty aerospace sealants for fuel tanks, window installations, sealing sandwich assemblies, self-levelling compounds, hole filling, low density, fast cure sealants, temperature-resistance, fuel, pressure and weather resistance, and pressure and environmental sealants. They are also used in potting compounds for potting of electrical connectors and potting inserts in sandwich panels. They are also found in tapes, electrical insulating coating compounds, epoxies, polyurethane potting and moulding compounds, and electric cables*". The aerospace industry claims, that "*it would be technically challenging to identify and develop equivalent or superior alternatives for these numerous uses of PHT. There are no direct replacements in many critical applications and replacement would likely involve significant redesign and requalification and recertification activities in this industry*". In conclusion, it seems that technical alternatives are available, such as phthalates or chlorinated paraffins.

Considering the registered uses of the selected potential alternatives (see **Table 94**), Alternatives 2 and 9 could be used as plasticiser; Alternatives 6, 7, 8 and 9 as solvent or process medium; Alternative 9 as additive in adhesive and sealants (together with phthalates or chlorinated paraffins); Alternatives 4, 6, 7, 8 and 9 as laboratory chemicals; and alternative 9 as additive in coatings, paints, and inks. However, no specific information about these uses has been found. It is worth noting, that in the case of Alternative 4 the use as additive in coatings, paints, and inks is a use specifically advised against in its REACH registration dossier.

As a final summary of the technical assessment, and considering all the above reasons, Alternatives 3, 10 and 11 can be discarded as substitutes of PHT.

E.2.2.3. Assessment of the hazard profile of the alternatives

The hazard profile of the list of potential alternatives will be used to screen out substances that are likely to be the focus of future regulatory actions, such as those with PBT properties or those which are carcinogenic, mutagenic, or toxic for reproduction (CMR), to avoid a situation of regrettable substitution in the selection of alternatives to PHT. These substances will be eliminated from the list. It is worth noting that the present assessment is based on how substances are classified today and not on any prediction (e.g., based on structure) of hazardous properties that might lead to further designations in the future.

The hazard profile of the potential alternatives has been obtained from the information of their respective REACH registration dossiers disseminated in the webpage of ECHA (ECHA, 2021d), and they are displayed in **Table 95**:

Table 95. Hazard profile of the potential alternatives

Alternative	EC	Hazard class	PBT properties
1	400-370-7	Aquatic Chronic 1	Under assessment as PBT
2	258-649-2	Asp. Tox. 1, Repr. 1B, Aquatic Chronic 1	Further information relevant for the PBT assessment is necessary
4	915-589-8	Skin Irrit. 2, Asp. Tox. 1, Repr. 2, STOT Rep. Exp. 2, Aquatic Chronic 4	The substance is handled as if it were a PBT/vPvB
5	904-797-4	Aquatic Acute 1, Aquatic Chronic 1	The substance is PBT/vPvB
6	202-981-2	Eye Irrit. 2A, Aquatic Acute 1, Aquatic Chronic 3	The substance is not PBT/vPvB
7	202-163-5	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1	The substance is not PBT/vPvB
8	212-572-0	Asp. Tox. 1, Aquatic Acute 1, Aquatic Chronic 1	The substance is not PBT/vPvB
9	284-660-7	Asp. Tox. 1	Under assessment as PBT

Regarding the CMR classification, Alternatives 2 (Repr. 1B) and 4 (Repr. 2) should be directly discarded because they lead to a regrettable substitution of PHT.

Considering the PBT properties, the only potential substitute that should be completely discarded is Alternative 5, because it is a declared PBT substance. However, Alternatives 1 and 9 should be considered with caution, because both are currently under assessment as potential PBT substances via the REACH CoRAP[51] process. If this fact were confirmed in the future, the substitution of PHT by these alternatives would become a regrettable substitution.

However, in general terms, all of the potential alternatives to PHT are assigned more restrictive hazardous classifications (PHT is classified as Aquatic Chronic 2). Therefore, regrettable substitution should be a concern in all of these situations.

In the case of phthalates and chlorinated paraffins (short chain chlorinated paraffins – SCCP, medium chain chlorinated paraffins – MCCP, and long chain chlorinated paraffins - LCCP), that could be potential substitutes of PHT as additive in adhesive and sealants from the technical point of view, they carry similar concerns to PHT in terms of their hazard properties and environmental behaviour.

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[51] Substance Information - ECHA (europa.eu)

SCCP has been declared as PBT/vPvB substance and it is restricted in the POPs Regulation[52]; a substance evaluation (SEv) confirms the PBT/vPvB concerns of MCCP, that are also currently involved in a restriction proposal; and LCCP may contain significant amounts of MCCP and can therefore be regarded as a PBT/vPvB containing substance. Furthermore, SCCP and MCCP have been included as an SVHC in the candidate list due to its PBT/vPvB properties, and SCCP is a potentially candidate for SVHC qualification. For this reason, they should be discarded as potential alternatives to PHT.

The most commonly known phthalates used in adhesive and sealants are Butyl-Benzyl Phthalate (BBP), Dibutyl Phthalate (DBP), Di-Isononyl Phthalate (DINP), Di-n-Octyl Phthalate (DNOP) and Di-isobutyl Phthalate (DIBP), according to the information published by COM (European Commission, 2021b). BBP, DBP and DIBP are classified as CMR substances (harmonised classification as Repr. 1B); DINP is currently not classified but its harmonised classification as Repr. 1B is under consultation; DNOP is currently not classified, but it has been notified as Repr. 2 in the C&L Inventory by 8 notifiers, however this substance is not registered under REACH and therefore it cannot be used as alternative to PHT because it cannot be legally marketed and used in EU in the required quantities. In addition, DBP is under assessment as PBT and some co-registrants of DIBP indicate that they consider this substance as PBT. Therefore, these substances should not be considered as potential alternatives to PHT related to the plasticiser uses.

E.2.2.4. Summary and shortlist of alternatives

According to the conclusions from the previous Sections, a universal alternative to PHT will likely not be available, and selection of any alternative will need to be considered on a use-by-use basis.

Table 96 below presents the shortlist of alternatives for PHT in their different uses.

Table 96. Potential alternatives to PHT

Alternative	EC	Potential uses
1	400-370-7	HTF
6	202-981-2	Solvent or process medium, laboratory chemical
7	202-163-5	Solvent or process medium, laboratory chemical
8	212-572-0	Solvent or process medium, laboratory chemical
9	284-660-7	Plasticiser, adhesive and sealants, paints and coatings, inks and toners, solvent or process medium, laboratory chemical

These functions are independent from each other and as such, some alternatives may be suitable replacements for some uses, but not for others. This is indicated in the following section E.2.3. that discusses the risk reduction, technical and economic feasibility, and availability of these potential alternatives to PHT.

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[52] Regulation (EU) 2019/1021 on persistent organic pollutants. Consolidated version 15/03/2021: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R1021-20210315&qid=1646858530383

E.2.3. Risk reduction, technical and economic feasibility, and availability of alternatives

In this section, the most relevant potential alternative substances from Section E.2.2. are shortlisted and assessed in more detail in terms of their hazard, technical and economic feasibility, and availability. Due to the limited available information in the literature and lack of information provided by stakeholders for some of the uses, technical feasibility can only be assessed in terms of proven or confirmed uses of PHT. It may therefore be the case that some of the uses of PHT are not covered in this analysis of alternatives.

The following sections, E.2.3.1 – E.2.3.5 detail the technical feasibility of alternatives that have been selected. Each section comprises the following subsections:

- Availability of alternative
- Human health risks related to alternative
- Environment risks related to alternative
- Technical and economic feasibility of alternative
- Other information on alternative
- Conclusions

Since PHT has been identified as a vPvB substance, quantitative risk characterisation is not appropriate nor meaningful. Therefore, it is not feasible to carry out a risk comparison between PHT and its alternatives. Instead, a comparison of hazard properties has been used as an indicator of potential regrettable substitutions. Short-listed alternatives were assessed qualitatively based on a comparison of available information on hazard profile, including consideration of:

- Hazard classifications notified under CLP
- On-going regulatory assessments

E.2.3.1. Assessment of 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS No. 63231-51-6; EC No. 400-370-7)

E.2.3.1.1. Availability of 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

The REACH registration tonnage band for 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene is marked confidential. Therefore, there are no references to the volume of substance available for the use as HTF (the only use considered for this substance as alternative to PHT). The available studies on the ECHA Website suggest an EU volume band of 100 – 1.000 tonnes per year. Therefore, it is questionable if the volume on the EU market could be sufficient to cover the HTF uses. According to the OECD Existing Chemicals Database[53], it is considered globally an HPV Chemical. There is currently one active registration (individual submission) for the substance.

E.2.3.1.2. Human health risks related to 1,2,3,4-Tetrahydro-5-(1-phenylethyl) naphthalene

There is no harmonised classification for 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS No. 63231-51-6; EC No. 400-370-7). The ECHA C&L Inventory does not show any entry related to the human health risks, and no human health classification is provided in the industry self-classification.

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[53] OECD's Work on Co-operating in the Investigation of High Production Volume Chemicals - Chemical Detailed Results

Therefore, based on this information, the substance seems to present a low hazard to human health.

E.2.3.1.3. Environment risks related to 1,2,3,4-Tetrahydro-5-(1-phenylethyl) naphthalene

There is no harmonised classification for 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS No. 63231-51-6; EC No. 400-370-7). The notified classifications in the ECHA C&L Inventory are summarised below (assessed October 2021):

- Aquatic Chronic 1; H410	56 notifications
- Not classified	55 notifications

The industry self-classification included in the REACH registration dossier is Aquatic Chronic 1 (H410) and Aquatic Acute 1 (H400).

The RMOA conducted by the Finnish CA on this substance (Tukes, 2020) concluded that, according to the available information, this substance fulfils the criteria for PBT according to Article 57(d) of REACH regulation. Due to its functionality, this alternative to PHT for use as a high-temperature non-pressurised HTF carries similar concerns in terms of its hazard properties and environmental behaviour. However, this alternative has not yet been subject to the same level of scrutiny applied at EU level under REACH compared to PHT.

As a result of this RMOA, 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene was included by Finland on the ECHA PACT list for RMOA assessments based on PBT concerns. Moreover, the substance was included in CoRAP for SEv. This evaluation is being performed by the Finnish CA and it is currently under development in order to clarify the PBT/vPvB concern of the substance or one or more of its constituents, therefore further assessment is needed. Due to the data gaps, experimental data (ready biodegradability, simulation testing) is needed to substantiate the persistence. If the substance fulfils the P or vP criterion, then further information on bioaccumulation (e.g., BCF test in aquatic species) and toxicity (e.g., long-term aquatic toxicity testing) potential of the substance may be needed.

E.2.3.1.4. Technical and economic feasibility of 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

This substance shows a boiling point range of 335 - 365°C (at 101.3 kPa), very close to the boiling point value of PHT (342°C) and to the operating temperature range of 325-350°C in non-pressurised liquid phase heat transfer systems. Therefore, it could be a potential alternative to PHT in the main use as HTF.

The same conclusion was obtained by the Finnish CA in the RMOA on the substance (Tukes, 2020): after an in-depth evaluation of this potential alternative to PHT the conclusion was that this substance could be used as reliable substitute for PHT at the whole temperature range of 300-350°C in non-pressurised heat transfer systems.

However, the substitution of PHT by this substance is not an easy process in technical and economic terms. According to the responses to the to the SEA questionnaires, the costs for structural alteration, replacement, and refill of the current HTF closed loop systems due to the substitution of PHT by 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene would be up to €120 000-300 000 per company. Furthermore, completely replacing PHT from existing heat transfer systems would impose significant technical challenges to industry; it is expected that plants should be stopped for 1-2 months in order to undertake substitution, and hundreds of metric tonnes of hazardous waste would be generated that could not be recovered (PHT is destroyed by incineration). The downtime cost for the temporary plant shutdown and the incineration costs are unknown and would depend on the company. All the above mentioned would trigger a loss of turnover due to Research and Development (R&D) and investment costs related to the substitution process.

E.2.3.1.5. Other information on 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

No other information available.

E.2.3.1.6. Conclusions on 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

Although the PBT status of this substance is still under assessment, there are well-founded suspicions that this behaviour will be confirmed in the near future (considering its inclusion in the restrictions roadmap and the future actions to be undertaken by the Austrian and Finnish competent authorities, as commented above). This position is aligned with the idea that substances with the same functionalities show similar hazard profiles. Therefore, the substitution of PHT by 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene when used as HTF in non-pressurised liquid phase systems could result in regrettable substitution.

E.2.3.2. Assessment of Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

E.2.3.2.1. Availability of Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

The REACH registration tonnage band for diphenyl ether is 1,000 – 10,000 tonnes per year. This is a smaller tonnage band than then one registered for PHT. However, as the uses considered for this substance as alternative to PHT (solvent or process medium, and laboratory chemical) represent less than 10% of the volume of PHT used in the EU, this volume could be sufficient to cover these uses.

E.2.3.2.2. Human health risks related to Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

There is no harmonised classification for diphenyl ether (CAS No 101-84-8; EC No 202-981-2). The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Eye Irrit. 2; H319	1 796 notifications
- Not classified	12 notifications
- Skin Irrit. 2; H315	8 notifications
- STOT SE 3; H335	7 notifications
- Acute Tox. 4; H302, H312	5 notifications
- Eye Dam. 1; H318	3 notifications
- Skin Sens. 1; H317	1 notification

The industry self-classification included in the REACH registration dossier for health effects is Eye Irrit. 2 (H319).

Based on the available data the main hazard to human health presented by diphenyl ether are related to eye irritation. However, a dossier evaluation (DEv) is in place for this substance, related with a request of information about mutagenicity, cytogenicity, and developmental toxicity endpoints. These studies should be finished in August 2023.

E.2.3.2.3. Environment risks related to Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

There is no harmonised classification for Diphenyl ether (CAS No 101-84-8; EC No 202-981-2). The notified classifications in the ECHA C&L Inventory for environmental effects are summarised below (assessed October 2021):

- Aquatic Chronic 2; H411	1 856 notifications
- Aquatic Acute 1; H400	206 notifications
- Aquatic Chronic 1; H410	124 notifications
- Aquatic Chronic 3; H412	72 notifications

The industry self-classification included in the REACH registration dossier for environmental effects is Aquatic Acute 1 (H400) and Aquatic Chronic 3 (H412).

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB. Available evidence on degradation, bioaccumulation potential, and toxicity for diphenyl ether indicates that the screening criteria for persistence (P), as well as the Annex XIII criteria for bioaccumulation potential (B), and toxicity (T) are not met.

E.2.3.2.4. Technical and economic feasibility of Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

No information about technical and economic feasibility of this alternative has been reported in the responses to the SEA questionnaires.

According to the available data (NLM, 2021), Diphenyl ether is commonly used as dye carrier (solvent or process medium). This function is also considered for PHT (GR, 2020).

E.2.3.2.5. Other information on Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

No other information available.

E.2.3.2.6. Conclusions on Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

Diphenyl ether has been assessed as a potential alternative to PHT for the use as solvent or process medium. Both materials can be used as textile dyestuff carrier. Available volumes of the substance are sufficient to cover this use. The substance shows low hazards for both human health and environment, and it is not considered a PBT substance. However, the CMR status of this substance is still under assessment. Therefore, if this status is confirmed in the near future, the substitution of PHT by diphenyl ether could result in regrettable substitution. Furthermore, the feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

E.2.3.3. Assessment of Biphenyl (CAS No 92-52-4; EC No 202-163-5)

E.2.3.3.1. Availability of Biphenyl (CAS No 92-52-4; EC No 202-163-5)

The REACH registration tonnage band for biphenyl is 1 000 – 10 000 tonnes per year. This is a smaller tonnage band than the one registered for PHT. However, as the uses considered for this substance as alternative to PHT (solvent or process medium, and laboratory chemical) represent less than 10% of the volume of PHT used in the EU, this volume could be sufficient to cover these uses.

E.2.3.3.2. Human health risks related to Biphenyl (CAS No 92-52-4; EC No 202-163-5)

Biphenyl is classified according to Annex VI, table 3.1 of CLP Regulation (harmonised classification). The classification for health effects is the following: Skin Irrit. 2 (H315), Eye Irrit. 2 (H319) and STOT SE 3 (H335). This classification has been adopted by registrants.

The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

Skin Irrit. 2; H315	1 199 notifications
Eye Irrit. 2; H319	1 199 notifications
STOT SE 3; H335	1 199 notifications
Acute Tox. 2; H330	446 notifications
Acute Tox. 3; H331	48 notifications
Asp. Tox. 1; H304	18 notifications
Acute Tox. 4; H302	1 notification

Based on the available data the main hazards to human health presented by biphenyl are related to skin, eye, and respiratory irritation.

In 2018 a testing proposal (DEv) was issued by ECHA on this substance, requiring registrants to perform a pre-natal developmental toxicity study. The results were submitted before December 2019. The evaluation is currently concluded and no changes on the classification of the substance has been observed in the last update of the registration dossier (2021). Therefore, it is assumed that the substance does not show any concern related to the potential for adverse effects on fertility or development.

E.2.3.3.3. Environment risks related to Biphenyl (CAS No 92-52-4; EC No 202-163-5)

Biphenyl is classified according to Annex VI, table 3.1 of CLP Regulation (harmonised classification). The classification for environmental effects is the following: Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). This classification has been adopted by registrants.

The notified classifications in the ECHA C&L Inventory for environmental effects are summarised below (assessed October 2021):

Aquatic Chronic 1; H410	1 200 notifications
Aquatic Acute 1; H400	1 150 notifications

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB, because it does not meet any of the P/vP, B/vB, or T criteria. The substance was included in the Community Rolling Action Plan (CoRAP) in 2013 and it was assessed by the Portuguese CA concerning its PBT properties. The conclusion of the SEv was that the substance is not PBT/vPvB.

E.2.3.3.4. Technical and economic feasibility of Biphenyl (CAS No 92-52-4; EC No 202-163-5)

No information about technical and economic feasibility of this alternative has been reported in the responses to the SEA questionnaires.

According to the bibliography (Danish EPA, 2014; GR, 2020; Sturaro et al., 1995) both biphenyl and PHT can be used as dye carriers (solvent or process medium) for textiles and copying paper, although this last use has been stopped in the case of PHT.

E.2.3.3.5. Other information on Biphenyl (CAS No 92-52-4; EC No 202-163-5)

No other information available.

E.2.3.3.6. Conclusions on Biphenyl (CAS No 92-52-4; EC No 202-163-5)

Biphenyl could be a potential alternative to PHT for its use as solvent or process medium, mainly as textile dyestuff carrier. Available volumes of the substance are sufficient to cover this use. Also, although the substance shows some human health effects and the environmental classification is more restrictive than that of PHT, biphenyl is not a PBT substance. Therefore, a case for regrettable substitution can be discarded. Feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

E.2.3.4. Assessment of Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

E.2.3.4.1. Availability of Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

The REACH registration tonnage band for cyclohexylbenzene is 100 – 1,000 tonnes per year. This is a smaller tonnage band than the one registered for PHT. Therefore, it is believed that cyclohexylbenzene is not or will not be available in sufficient volumes, even considering that the potential uses as alternative to PHT (solvent or process medium, and laboratory chemical) represent less than 10% of the volume of PHT used in the EU.

E.2.3.4.2. Human health risks related to Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

There is no harmonised classification for cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0). The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Skin Irrit. 2; H315	50 notifications
- Eye Irrit. 2; H319	47 notifications
- Acute Tox. 4; H302	41 notifications
- Not classified	13 notifications
- Asp. Tox. 1; H304	7 notifications
- STOT RE 2; H373	3 notifications

The industry self-classification included in the REACH registration dossier for health effects is Asp. Tox. 1 (H304).

Based on the self-classification in the registration dossier and on the additional notified classifications to the C&L Inventory, cyclohexylbenzene is assumed to present a generally low hazard to human health.

E.2.3.4.3. Environment risks related to Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

There is no harmonised classification for cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0). The notified classifications in the ECHA C&L Inventory for environmental effects are summarised below (assessed October 2021):

- Aquatic Acute 1; H400	55 notifications

- Aquatic Chronic 1; H410	55 notifications

The industry self-classification included in the REACH registration dossier for environmental effects is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB, because it does not meet the screening criteria for persistency and toxicity, although bioaccumulation criteria could be met.

E.2.3.4.4. Technical and economic feasibility of Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

According to the published data (GMI, 2020), the use of cyclohexylbenzene as solvent plays an important role in different industries, where the substance is highly used as a solvent in plastics, painting, and adhesives.

No information about technical and economic feasibility of this alternative has been reported in the responses to the SEA questionnaires.

One of the main characteristics for an organic substance to be considered a good solvent is its degree of unsaturation. The unsaturated compounds (mostly C=C double bonds) can crosslink (react) with oxygen to form epoxides, which are highly reactive. This crosslinking causes the formation of long chain molecules which are no longer liquid but solid (termed gums or varnishes), decreasing the solvent function of the material. For this reason, the best solvents are organic compounds that show a low unsaturated degree.

The bromine index is a parameter used to estimate the unsaturation degree. It is defined as the fraction of reactive unsaturated compounds in the organic substance, and it is expressed as grams of bromine (Br2) reacted with 100 g of the sample of the material. The lower this index, the better the solvent behaviour of the substance.

According to the technical information published by the producers of solvents (Eastman, 2022), the bromine index for cyclohexylbenzene[54] (393) is higher than the same parameter for PHT (290). Therefore, its solvent behaviour will be worse compared to PHT

E.2.3.4.5. Other information on Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

No other information available.

E.2.3.4.6. Conclusions on Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

Cyclohexylbenzene has been assessed as a potential alternative to PHT for the use as solvent or process medium. Although this substance is not suspected of having PBT properties, it cannot be considered an adequate substitute for PHT due to technical reasons (high unsaturated degree), and the registered volumes are not sufficient to fully replace PHT for this function. For this reason, cyclohexylbenzene cannot be considered a suitable alternative for PHT as a solvent or process medium.

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[54] According to its SDS (https://ws.eastman.com/ProductCatalogApps/PageControllers/MSDSShow_PC.aspx) cyclohexylbenzene is the main component (90%) of the MCS-2805 product

E.2.3.5. Assessment of Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

E.2.3.5.1. Availability of Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

The REACH registration tonnage band for Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues is 10,000 – 100,000 tonnes per year. This tonnage band is identical to the volume registered for PHT, so it is expected that the substance may cover all the uses as alternative to PHT: plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical.

E.2.3.5.2. Human health risks related to Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

There is no harmonised classification for Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7). The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Not classified:	94 notifications
- Asp. Tox. 1; H304:	89 notifications

The industry self-classification included in the REACH registration dossier for health effects is Asp. Tox. 1 (H304) if the substance shows a kinematic viscosity ≤ 20.5 mm^2/s at 40°C. If this viscosity is higher, then the substance is not classified.

On the basis of self-classification in the registration dossier and the majority of the notified classifications, Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues is assumed to present a generally low hazard to human health.

E.2.3.5.3. Environment risks related to Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

There is no harmonised classification for Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7). The notified classifications in the ECHA C&L Inventory does not show any entry related to the environmental risks, as neither does the registration dossier.

Therefore, based on this information, the substance seems to present a low hazard to environment.

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB because it does not meet the criteria for toxicity and bioaccumulation, although persistency criteria could be met. The Italian CA launched a PBT assessment for this substance in 2012, that was finally developed under a SEv after the inclusion of the substance in the CoRAP in 2014. The final decision of this SEv was published in June 2016 and it required registrants to perform additional environmental studies (soil simulation and effects on terrestrial organisms), in order to provide ECHA with further information to clarify the PBT concern. The deadline for the submission of the tests results was December 2019. The SEv is still ongoing.

E.2.3.5.4. Technical and economic feasibility of Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues can be used as a secondary plasticizer in vinyl formulations, dielectric fluid, concrete and asphalt release agent, wire rope lubricant and other specialty lubricant applications (Sasol, 2019). These applications are quite different to the functions of PHT as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical.

According to the responses to the SEA questionaries, PHT is used as plasticiser in coatings, adhesives, two-component products that are used for sealants, as well as castings for the protection of joints of buried high voltage cables. Furthermore, it is used in the production process of electro-insulating varnishes and resins, and in many formulations of polyurethane systems. But the main application as plasticiser is in adhesives and sealants for the aerospace industry. Due to the particularities of this industrial sector, the substitution of PHT by alternatives becomes a very long and expensive process. The customer qualification and approval of the alternatives can take several years and involve a significant testing demand. In some cases, this process could require investments of more than 100 000 € as R&D costs.

E.2.3.5.5. Other information on Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

No other information available.

E.2.3.5.6. Conclusions on Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues has been assessed as a potential alternative to PHT for the uses as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical. Available volumes of the substance are sufficient to cover these uses. The substance shows low hazards for both human health and environment. However, the PBT status of this substance is still under assessment. Therefore, if this status is confirmed in the near future, the substitution of PHT by Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues could become a regrettable substitution. Furthermore, the feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

E.2.4. Summary and conclusion from the assessment of alternatives

The assessment of alternatives indicates that there is not a universal alternative to PHT that covers all the IU of this substance. No alternative has been found for PHT when used as a HTF, plasticiser, adhesive and sealants, paints and coatings, and ink and toners.

Only one potential alternative has been found for the use as solvent or process medium (biphenyl).Nevertheless, there is some uncertainty as to whether this alternative would be technically and economically suitable for this application. On one side, there could be some further technical criteria not fulfilled that cannot be found by looking at the substance properties alone. On the other side, there could also be other costs (e.g., R&D and investments) that might make the potential alternatives not viable. The fact that the responses to the SEA questionnaires have not provided specific information on alternatives for this use suggests that these alternatives are likely not viable.

It is worth noting that most of the alternatives initially considered in this Section would lead to a regrettable substitution if they were selected as final alternatives to PHT. Regrettable substitution leads to a non-level playing field in the European chemicals market. When a substance is replaced by another chemical which ultimately leads to equal or higher levels of hazard or risk, the Regulation is introducing a discriminatory factor on the M/Is of the replaced substance, because this leads to a loss of market share in favour of a substitute substance that does not show any advantage in terms of protection to human health or the environment. This in addition undermines the credibility of the regulatory process.

Finally, it should be noted that, in general terms, the responses to the SEA questionnaires on potential alternatives have been very scarce and poor. Since no specific technical and economic data related to the potential alternatives has been provided by the impacted actors, it is assumed that this assessment of alternatives for the functions of PHT and its conclusions are valid. If impacted actors do not agree with the conclusions, it is strongly recommended that they provide information during the public consultation allowing the Dossier Submitter to revise this analysis and its conclusions.

E.3. Restriction scenario(s)

The restriction scenarios are defined by the anticipated behaviour of affected actors (current downstream users of PHT) in response to the ROs. All actors will not necessarily react the same way when faced with a restriction, but they will choose amongst the options that are available to them. These so-called behavioural responses must be defined so that they can be included in the SEA in a meaningful way.

The behavioural options deemed most plausible are:

1. **Switch to alternative substances:** This option is only available for the uses for which alternatives are available from the EiF + allowed transition period, where the transition period may vary between uses. Those that can switch to an alternative sooner may gain a greater EU market share (e.g., first mover advantage). If there are no alternatives available at EiF + allowed transition period, production of products depending on PHT will have to cease. During the downtime, loss of sales, market share and possibly loss of jobs will occur.
2. **Business reallocation outside EEA:** For the users that have customers outside the EU, relocations of their operations is a possible response to a restriction.
3. **Company would abandon business related to PHT globally:** For users that cannot find an alternative or the cost of transitioning is too high, the remaining option is to cease all production.

The behavioural responses are based on information received from stakeholders through the SEA questionnaires.

E.3.1. Use of PHT as HTF

The three ROs have the following requirements set out for the use of PHT as HTF:

RO1 and RO2 include a derogation for the use and placing on the market for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

RO3 means a practical ban on the manufacture, use, and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.

Since under RO1 and RO2 this use of the substance is allowed at the industrial level, and all the respondents are industrial companies, the behavioural responses of the users have only been analysed considering the application of RO3 (total ban).

Close to two-thirds of the respondents (64.7%) that are using PHT as HTF answered that they would switch to alternative substances in case of a restriction of PHT. This result contrasts with the conclusions obtained in the assessment of alternatives (**Annex E.2**), in which, according to the responses of the same companies, an alternative to PHT as HTF is not currently available. There are three plausible explanations for this:

- The respondents assume that they will be forced to switch to an alternative with the same (or similar) regulatory pressure, that will face the same issues in the close future but that solves the current problem. This is considered to be the most likely explanation.
- The respondents trust that an alternative will appear during EiF + 18 months. Specifically, references to trusting the know-how of the supplier are made, which implies that the respondents may not have a full picture of the possibility to provide a valid alternative to the use of PHT as a HTF.
- Non-informed alternatives are currently available, that have not been disclosed due to being part of the know-how of the companies. However, while one reply suggests this possibility, no specific details on this option have been provided to verify the validity of potential alternatives.

In fact, 44.8% of the respondents have declared that they are actively looking for alternatives, through the investment in R&D activities. This value is lower than the result obtained to the general question (64.7%) because some PHT users lack the necessary expertise to perform these activities and they are confident/dependent on the know-how of their suppliers.

The number of respondents that answered that they would relocate the business outside EEA and those that answered that they would abandon the business globally is the same (17.6% in each case).

Considering the behavioural responses received in relation to the different industrial sectors that are using PHT as HTF in their production process, the proportion is the following:

Table 97. Responses from HTF users related to different industry sectors

Industrial sector	**Switch to alternative substances**	**Business reallocation outside EEA**	**Company would abandon business**
Chemicals	66.7%	20.0%	13.3%
Fuels and petrochemicals	61.5%	15.4%	23.1%
Plastics	100.0%	0	0
Cement	0	0	100%
Steel	100%	0	0
Paints	50%	50%	0
Total	**64.7%**	**17.6%**	**17.6%**

It is interesting to note that all the respondents from the industrial sectors of plastics and steel production would opt for switching to alternative substances, while all the respondents from the industrial sector of cement production would abandon the business related to PHT globally.

Results obtained from companies dedicated to the chemicals and petrochemicals production sectors, which are the main proportion of respondents, are very similar, with a vast majority of companies opting for switching to alternative substances. Again, it is worth highlighting that it is likely that those that replied that they would switch to an alternative are probably considering other commercially available products based on substances that may have the same properties as PHT, and which would therefore follow the same regulatory path in the future. This assumption is based on the consideration that, for a substance to be used as a non-pressurised, high temperature HTF, some properties that may be related to PBT consideration are required.

E.3.2. Use of PHT as Plasticiser in Production of Aircrafts

The three ROs have the following requirements set out for the use of PHT as plasticiser in the production of aircrafts:

RO1 includes a derogation for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts from EiF + 5 years.

RO2 and RO3 result in the practical ban on the manufacture, use, and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.

In this case, the analysis of the behavioural responses has considered all the proposed ROs, because the only difference between RO1 and the total ban (RO2 and RO3) is the implementation timing, which is longer in the first case.

The only respondent that has declared that is producing PHT for the use as plasticiser answered that the company would switch to alternative substances in case of a restriction of PHT for this use. In fact, this firm is actively looking for alternatives through their own investment and resources in R&D activities.

Considering the responses to the call for information by the COM on the possible socio-economic consequences of the inclusion of PHT in the Authorisation List of the most important sectorial associations of the aerospace industry in the EU and USA (public consultation performed on the summer of 2020), the development and qualification of potential alternatives that can meet the strict safety and performance demands required for use in aerospace applications will take many years due to the stringent testing and thorough validation that must take place for every individual application where PHT is used across an aircraft product.

This position would be interpreted as an implicit acceptance of this industrial sector for the switch to alternatives provided that there is enough time to implement them, and it matches with the answer of the only respondent to the SEA questionnaire for this use of PHT.

Therefore, the assumed behavioural responses for the use of PHT as plasticiser in the production of aircrafts are to switch to an alternative by 100%.

E.3.3. Other uses of PHT

The three ROs have the following requirements set out for all of the other uses of PHT:

RO1, RO2 and RO3 mean the restriction (total ban) on the manufacture, use, and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.

No respondents of the SEA questionnaire have indicated that a REACH restriction would pose a problem for all of the other uses of PHT, outside the uses as HTF in industrial premises and as plasticiser in the production of aircrafts. For this reason, no derogations were considered for these uses in the definition of the ROs.

It is therefore also assumed that all of the other uses would be able to transition to alternatives by EiF + 18 months, and the assumed behavioural responses for these uses are to switch to an alternative by 100%.

E.3.4. Definition of the strictly controlled closed systems

RO1 and RO2 include a derogation that shall apply for the use and placing on the market of PHT for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

The conditions and requirements that a HTF installation shall comply with to be considered as a strictly controlled closed system are defined below.

General regulatory conditions

The installation shall comply with all of the legislation in force, at the European, national, regional, and local levels, related to the design, construction, and operation of HTF systems, and to the protection of human health and the environment.

Specifically, the main European legislation that should be considered is the Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (Pressure Equipment Directive – PED)[55].

PED is applicable to PHT because for most of the systems the maximum allowable temperature of the HTF installations (325-350°C) exceeds the flashpoint of the substance (170°C)[56], according to Point 1(a) of Article 13 to PED.

The installations shall be designed and constructed (new installations), adapted (existing installations), and operated according to technical requirements as outlined in the following guidelines, although any other guidelines or standards that ensure the same or higher level of safety than the ones listed below may be utilized:

- DIN 4754-1: Heat transfer installations working with organic HTFs - Part 1: Safety requirements, test.

  This standard applies to heat transfer appliances in which organic HTFs are being heated with atmospheric pressure to reach a temperature above or below their initial boiling point. The document applies to heating appliances only in so far as the pipes of the heater contain the HTFs. The document has the purpose of satisfying protection targets for the production and supply, in particular those specified in the PED.

- NFPA 87: Standard for Fluid Heaters.

  This standard provides safety guidance for fluid heaters and related equipment to minimize fire and explosion hazards that can endanger the fluid heater, the building, or personnel.

These guidelines and standards should be used as a basic requirement when designing, building, and operating new systems. In addition, existing systems must be assessed on a regular basis using the most up-to-date standards.

Technical protection measures (system and process safety)

Technical protection methods must be taken in order to guarantee the closed behaviour of the installation and to avoid improper emissions to the environment. Examples of this kind of measures are compiled in the following non-exhaustive list:

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[55] PED. Current consolidated text: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0068-20140717&qid=1639053469715

[56] PHT flash point value listed in the disseminated registration dossier in ECHA webpage: https://echa.europa.eu/registration-dossier/-/registered-dossier/15941/4/12

- Existence of general leakage collection systems
- Use of containment devices installed beneath flanges and pumps
- Use of retention systems in pumps and valves to ensure that any leakage of PHT through the seals is safely drained off and collected in a contained space
- PHT level monitoring

The interactions of the closed system with the atmosphere require special care, particularly draining points, sampling devices, joints, valves, and pumps. Containment devices should be installed beneath such system locations to avoid emissions to the environment.

Low-boiling fractions, formed as breakdown products of PHT at high temperatures, must be evacuated from the system. Different procedures (condensation, venting, etc.) can be used to complete this process, and the residuals are disposed of either internally or through an authorized external company.

Also, special containment measures should be taken for processes out of the usual OCs of the system, as shutdown and start-up of the process, or drain, fill, top-up, and disposal operations of degraded PHT.

General protection measures (structural and organisational)

Structural and organisational measures are essential for maintaining the safety of a closed HTF system, such as through proper maintenance and inspection. Examples of this kind of measures are compiled in the following non-exhaustive list:

- Performance of tests to prove the suitability of joints
- Periodical evaluation of the PHT quality (minimum once a year)
- Recurring inspections performed by competent technical bodies (internal or external)
- Control programs for potential leakages
- Training for operators and for maintenance and inspection teams

All operation, maintenance, and inspection operations, as well as all processes carried out outside of normal operating conditions, such as drain, fill, top-up, etc., should have written procedures and instructions in place. This documentation should be integrated into any management system implemented in the company (e.g., the Health, Safety, and Environment Management System - HSE).

E.4. Economic impacts

Economic impacts are concerned with costs or cost savings comparing the “proposed restriction” scenario with the “baseline” scenario. Economic impacts comprise the net costs to manufacturers, importers, downstream users, distributors, consumers, and society as a whole. “Net costs” should take into account both costs to actors due to a restriction and possible cost savings caused by the transfer to alternatives.

In considering the “costs” in a restriction scenario the question that needs to be evaluated is, what is the amount that society has to pay in terms of the other resources such as labour and capital in order to secure a cleaner environment or improved human health. Therefore, at the most fundamental level, the economic cost of a “restriction” scenario is the value to society of these other resources that are used up in order to implement it. This is counted as a cost because the resources that are used up are then not available for other purposes. Economic impacts include for example:

- Cost of new equipment or production process necessary to comply with the proposed restriction or ceasing use of equipment and facilities before the end of their intended life;
- Operation and maintenance costs (labour costs, energy costs, etc.);

- Cost differences between different substances due to different production costs and purchase prices of the substances as well as R&D costs (substitution costs);
- Cost differences due to differences under the scenarios (due to reduced or improved efficiency for example)
- Changes in transport costs;
- Design, monitoring, training, and regulatory costs.

As the ultimate focus of a socio-economic impact assessment is to determine the costs (and benefits) to society of a "restriction" scenario, an important aspect of the cost calculation process is the distinction between private and social costs. Therefore, the starting point for assessing the costs to society of a "restriction" scenario is usually to look at the impact on those particular groups or sectors affected. The costs incurred by a particular sector or group as a result of a "restriction" scenario are called the private costs. By contrast, the social costs are the costs of a policy to society as a whole – from an EU perspective this includes all 27 Member States, although costs to non-EU members need to be reflected, as relevant. These subjects are discussed in **Annex E.6**.

The costs of the three ROs (RO1, RO2 and RO3) are estimated based on the behavioural assumptions set out in E.3. and the responses received from the different stakeholder consultations, plus information obtained via literature searches.

Due to the assumptions made and the uncertainty related to them, the investment costs have not been presented as equivalent annual costs (EAC), using a discount rate. EAC is a process whereby non-recurrent (e.g., capital, plant down-time) costs of a measure are equalised over its lifetime using the relevant discount rate.

Because of the expected increase in economic impacts from RO1 to RO3, the impact analysis will start with most severe option, which is RO3.

E.4.1. Economic Impacts of RO3

E.4.1.1. Substitution and Investment Costs

Substitution costs are defined as including both - any one-off or recurring costs directly associated with the substitution process, including R&D costs, investments, cost of raw materials (e.g., chemicals, water, and other input materials) and energy costs. Information on substitution costs, required investments and alternatives were obtained during the stakeholder consultations.

As outlined in **Annex E.3.** for the **Plasticiser Uses,** a switch to alternative substances is most likely. However, no information on potential alternative substances could be obtained since substitution investigations have not started by industry and PHT was identified as important to extremely important substance by all respondents. It was mentioned that phthalates could be used but are not an option due to similar intrinsic environmental issues. Checking on Online-Sales platforms[57] for chemicals prices, chemical costs ranging from 5€ – 8€ per kg PHT could be revealed. Since those sellers are mostly located in China it can be assumed, that the costs in the EU will be ranging between 6-10 € per kg, with an average value of 8€ per kg. Surveying the costs for benzoate or phthalate-based plasticiser, the Dossier Submitter assumes that the price range will be very similar. It is therefore supposed that there are **no additional cost for the chemical substitutes** and that due to lack of information load levels and performance for alternatives are comparable.

However, stakeholders from the aviation industry commented, that replacement of PHT in such sealant and adhesive formulations and the wide range of applications and parts that they

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[57] Alibaba.com, Lookchem.com

are used on within the aerospace and defence industry is not trivial and would be costly and prolonged. In order to meet the extreme demands of the conditions in which these sealants and adhesives operate, these products must be resistant to water, salt, fog, fuels, oils, hydraulic fluids, and other chemicals. They must also maintain flexibility over a wide range of temperatures and be able to adhere to a wide range of substrates. There are also requirements that these products need to meet in terms of processability such as the density, cure time, pot life and miscibility.

The replacement is an iterative process and the time to develop alternative formulations, test them against performance requirements, qualify and validate their use can take many years depending on the specific use of a material and component.

If the performance of the article made with the alternative is equivalent, the OEM needs to work with the airworthiness authority to certify that the changes do not impact vehicle performance. Failure to meet or exceed the technical requirements will likely not be approved by the authority. For structural applications, validation may require additional full-scale demonstration article testing. Given the complex natures of these products, supply chains can be very long and involve several levels of different companies, some large and some small, who are all responsible for supplying each other.

One stakeholder provided a cost estimate of **R&D costs** of **100 000 €.** From the consultation process it can be assumed, that about 20 companies are preparing the formulations for the plasticiser use. Only one actor mentioned that if the use of PHT is restricted, he would cease its business. The Dossier Submitter therefore assumes that at least 10 companies are supplying the aviation industry would substitute PHT in their formulations, resulting in an estimated **R&D cost of 1 000 000 €** (10 x 100 000 €) in total.

Beside R&D costs, transitioning to alternatives is usually associated with **investment costs** (e.g., changes in the production process) unless the alternative is a known drop-in alternative. In the case of PHT on information received from stakeholders it is clear that there are no drop-in alternatives available. It is therefore reasonable to assume that investment costs will be incurred, such as costs for purchasing equipment and installation costs for this equipment. However, because the plasticiser applications are reformulations only, the investment costs will be limited. The Dossier Submitter therefore assumes a total **investment cost** of **1 Million €** for the formulators (10 x 100 000 €).

Additional operational costs may also contribute to the overall costs. Nonetheless, since no information has been found related to other operational costs and lack of information provided by the stakeholders, it was not possible to quantify these other potential costs.

The aviation sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. New materials or design changes can only be introduced on the aircraft if testing and compliance demonstrations have been approved. The re-approval will result in the issuance of a **Supplemental Type Certificate** (STC)[58], change approval or repair approval[59,60]. Related costs and fees depend on the STC type, the airplane and as well the workload for the ECHA and the COM. Some costs can be seen in the COM Implementing Regulation (EU) 2019/2153 of 16 December 2019 on the fees and charges levied by the EU Aviation Safety Agency[61].

However, since the type of needed STC is not clear for the Dossier Submitter, an amount of **1 Million €** is assumed for **aviation re-approval** of introducing new materials.

For the **non-aviation plasticiser uses and the other uses** (e.g., solvents, corrosion inhibitors) no information was provided at all by the stakeholders. Therefore, the same cost

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[58] Supplemental Type Certificates | EASA (europa.eu)

[59] 2c27ddcc-dd0c-49e3-85ba-fa64b0813775 (europa.eu)

[60] Registry of restriction intentions until outcome - ECHA (europa.eu)

[61] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R2153&from=EN

range is assumed with the exception of the STC re-approval costs.

Regarding the **HTF Use**, about 2/3 of the stakeholders replied that they would switch to alternatives and the remaining respondents said, they are abandoning the business (17%) or reallocate outside of the EU (17%). However, it is worth highlighting that it is likely that those that replied switching to an alternative are probably considering the other two commercially available products that may have the same or similar properties as PHT (vPvB or PBT), and which would therefore follow the same regulatory path in the future. This assumption is based on the consideration that, for a substance to be used as a non-pressurised, high temperature HTF, some properties which are related to PBT consideration are unavoidable (see **Annex E.2.** – Alternatives). The Dossier Submitter therefore assumes, that 25% would cease business in the EU (in particular SMEs), 25% would reallocate their business outside of the EU and 50% of the users would switch to alternative substances or to alternative technologies. It is assumed that in total 25% would substitute PHT with substances, which do not have the required thermal stability and therefore need replacement every 2-4 years due to the high degradation rate (instead of 20 years for PHT). 25% would switch to alternative heating system - like steam - which would carry very high investment costs. As shown in **Annex A** (Manufacture & Use) there are about1 500 plants using PHT as HTF. It is assumed that 25% (375 sites) of the total sites would:

- Case 1: relocate to non-EU
- Case 2: abandon business in the EU
- Case 3: switch to alternative HTFs with lower thermostability
- Case 4: switch to alternative technologies, such as steam heating systems.

Related to Case 1, business relocation will likely happen by the larger companies with flexibility in their production location. Regarding the costs associated with the set-up of new plants in non-EU, no information was provided via the stakeholder consultations. According to Lemmens (2016)[62] a medium-size ORC plant will cost about 400 000 – 500 000 €. A large size PET manufacturing plant with manufacturing capacity of several hundred-thousand tonnes will likely cost several hundred million €.[63] If only 10 million € as an average value will be allocated for the 375 plants assumed to relocate outside of the EU, an investment amount of 3.75 Billion would be the result. The dismantling and disposal costs of the old plants[64] will be considered under Case 2.

Most of the ORC plants would need to close their business according to Case 2, since their temperature window is very tight and only high temperature HTFs will work. Moreover, ORC plants are mostly run by SMEs and connected to the region. This would have a negative impact on renewable energy targets under the EU Green Deal activities related to clean energy production to address climate change, as the energy generated from ORC plants is considered renewable.

Dismantling and disposal costs for abandoned plants are considered to be 250 000 € per site based on different case studies[65,66,67], amounting for Cases 1 and 2 in a cost position of 750 plants x 250 000 € = **187.5 million €**.

Regarding Case 3, mineral oils would be used because the two other high-temperature alternatives[68] are not available as substitutes due to their PBT properties. The costs of a mineral oil is estimated to be about 50% less (= 4 € per kg) but the replacement frequency

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[62] Energies | Free Full-Text | Cost Engineering Techniques and Their Applicability for Cost Estimation of Organic Rankine Cycle Systems (mdpi.com)

[63] Indorama to Build New PET Resin Manufacturing Plant (powderbulksolids.com)

[64] Plant Decommissioning- How to decontaminate, dismantle and decommission process plants | Abhisam

[65] 1857c756-b264-49a6-bca7-9283b59fc0cf (sc.gov)

[66] Case Studies – Technical Demolition Services (tdsinternational.co)

[67] Demolition & Decommissioning Case Studies - EWMI

[68] 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene and dibenzylbenzene, ar-methyl derivative

in the plant would be at least 5-times higher. In the considered 20 years' timeline from 2025-2049, the complete filling needs to be replaced at least 4-times, resulting in a 2-times higher costs for HTF fluids based on mineral oil. Presuming, that the expected 375 plants would as well represent 25% (= 6 250 t) of the total installed volume, the following chemical costs would occur:

- Complete refill costs = 6 250 € x 4 000 € = **25 Million €**
- 2-times exchange of degraded HTF = 6 250 € x 4 000 € x 2 = **50 Million €**

The refill and exchange costs do not include **cleaning and rinsing procedure** at the sites. An additional cost of 10 000 € was reported per site summing up to an additional amount of **750 000 €.**

In addition, existing material in plants would need to be disposed of as waste, disposal costs of all installed volume would be resulting after the ban of PHT in 2025, adding-up in a total cost of 25 000 t x 250 € = for thermal **disposal** of **6.25 Million €.** Disposal costs were obtained from the literature[69] and via personal communication with hazardous waste handlers.

Due to the fact, that these "alternative" substances are not drop-in alternatives and would require re-design and modifications of the plants, investment costs would be necessary. During the stakeholder consultations investment costs between 0.1-10 Million € were reported per installation. Assuming an average value of 1 Million € per site, **retrofitting costs** of 375 x 1 Million. € = **375 Million €** would occur.

It needs to be noted, that due to the retrofitting of the concerned plants, **downtime** during shutdown of the plants will be needed. Respondents reported between 1 month and 12 months and loss of revenue between **2 Million € - 100 Million €**. Assuming an average value of 5 Million € loss in revenue per site (not considering potential market share loss), a cost of 375 x 5 Million € = **1 875 Million €** would result.

In addition, R&D costs in a range of 10 000 – 20 000 € were reported by industry, HTF users would mostly rely on the suppliers to provide an adequate alternative since R&D on utility substances is not really in the scope of their R&D work. Assuming 10 000 € of **R&D Costs** for 375 plant result in an additional cost of **3.75 Million €**.

Moreover, several respondents reported that alternative substances not meeting the high temperature range will result in a reduced performance, lower efficiency, and loss of yield. Since no numbers were provided, only an assumed **loss in efficiency** of 25 000 € per installation (which is a relatively low number) would result in a total additional cost of **€ 9.37 Million.**

Case 4 represents the complete switch from classical organic fluids to high pressure vapour phase (e.g., steam) systems. This complete exchange of equipment would require significant capital investment to modify process furnace systems and other process equipment. Steam pressures of 130 bar or more might be required, which would need serious operational and safety measures. Costs for rebuilding the plant excluding downtime were reported in ranges of 10 – 50 Million €. Assuming only a value of 10 Million € will result in an amount of **3 750 Million €** if 375 plants will switch to **alternative technologies**.

Any changes in operational and maintenance costs for all cases were not considered because no information was available to the Dossier Submitter.

There are likely additional costs, which were not considered but could have a significant impact, in particular on the HTF sector. PHT and Biphenyl (CAS 90-43-7) are co-produced in the same chemical reaction. The yield or conversion rate per substance is described in the

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[69] Baar-Ebenhausen: Preiserhöhung bei der GSB - 42 Millionen Euro Investitionen in die Technik - 206000 Tonnen Sonderabfall im Jahr 2019 angeliefert (donaukurier.de)

literature with generally 50/50[70,71]. Biphenyl is used as a component in HTFs in Solar Systems. In case of a ban of PHT it is likely, that manufacturing of biphenyl is not competitive anymore. However, since PHT is not manufactured in the EU and no details are available, no cost estimations could be included.

Table 98 summarises the Substitution Costs for RO3. In total about10 Billion € could result from the substitution. More than 99% of the costs are associated to the HTF use, mostly allocated to investment costs.

Table 98. Substitution and Investment Costs for RO3

Type of Substitution Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Chemical Costs	0	0	50
R&D Costs	1	1	3.75
Re-Approval Costs	1	0	0
Disposal Costs Installed Volume	0	0	6.25
Cleaning & Rinsing	0	0	0.75
Downtime during Retrofitting	0	0	1 875
Refill	0	0	25
Investment and Retrofitting	1	1	375
Investment: Installation of new Technologies	0	0	3 750
Investment: Installation of new Plants in non-EU	0	0	3 750
Investment: Decommissioning & Disposal	0	0	187.50
Loss in efficiency and yield	0	0	9.37
Subtotal	**3**	**2**	**10 032.62**
Total Sum (Million €)	**10 037.62**		

E.4.1.2. Cost of loss in profits and reduced EU production

If companies have to reduce their EU production and sales of products temporarily or permanently on PHT, there will be associated profit losses, which are considered as costs to society. The “sales at risks” are represented by substances and products for which a reduction in sales as a result of a restriction on PHT are most likely.

The total PHT volume sold in the EU by importers and manufacturers of the substance in the HTF use is according to **Annex A** (Manufacture and Use) 6 700 tonnes per year. Allocating a

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[70] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net)

[71] CN103804114A - Method for preparing hydrogenated terphenyl - Google Patents

PHT cost of 8 000 € per tonnes would result in a loss of revenue of 53.6 Million € per year. Considering the 20 years period under review (2025 – 2049) would result in a loss of 1 072 Million € in revenue for the HTF market. Considering a common gross margin of 25%, the **profit loss amounts to 268 Million €.** The profit loss for the plasticiser uses in the **aviation industry** accounts for **17.2 Million €** (430 tonnes per year x 8 000 € x 20 x 0.25) assuming as well a margin of 25%. The profit loss for the non-aviation plasticiser uses and the remaining other uses is assumed to be **13.62 Million €** (340.5 tonnes per year x 8 000 € x 20 x 0.25). In summary, a **total profit loss** for the prohibited sales of PHT in the amount **298.82 Million €** can be noted.

Estimating the profit losses for the downstream industry is more difficult. Due to a very similar scenario in the Restriction Proposal by Norway for the substance Dechlorane Plus[72], where the flame retardant is used in the aviation industry, the same approach was taken. The substance is used in the aviation Industry as a flame retardant in electrical & electronic equipment, such as wire & cable plastic coatings, coil bobbins, cable straps, switches, small electronic appliances, and computers (motherboards, chargers, and hard-plastic connectors).

For Dechlorane Plus a "profit at risk" for the aviation industry of 41 Million € per year was estimated (see **Annex E.4.3.**) in the Restriction Proposal for a total ban. Basis for the calculations were the revenues for the PRODCOM Codes 22299180 (Plastic parts for aircraft and spacecraft) and 29311000 (Insulated ignition wiring sets and other wiring sets of a kind used in vehicles, aircraft, or ships). Since the latter is cross-sectoral, only 10% of this Code was allocated to aircraft. PRODCOM (PRODucts of the European COMmunity) is a EU wide survey of production mainly for the manufacturing industries collected under Council Regulation (EEC) No 3924/91 and provides statistics on the production of manufactured goods carried out by enterprises on the national territory of the reporting countries. PRODCOM is available via the Eurostat Webpage[73]. Since PRODCOM does not provide information on profit margins, Norway used older data (2003 – 2007) from Eurostat used for this purpose (a profit margin of 10.1% was used). Since the scenario for PHT in the use as plasticiser in the Aviation industry is alike, a total **profit loss of 820 Million €** was taken into account (41 Million € per year x 20 years).

Regarding the profit losses of the downstream users of HTF applications, in particular the PET industry was very concerned. The PET business is already exposed to imports from Asia and Middle East as it is a commodity polymer resin. Already about 1 Million tonnes per year are imported into EU and the EU PET industry needs to produce against import parity pricing, which sets the upper limit on sales price and the EU cost structure is already above the Asian one. This puts an additional margin squeeze on industry. Global PET players have already many locations outside EEA. Furthermore, a reduction in plant capacities of PET commodity resins would also impact upstream industry for the monomers production, like terephthalic acid and ethylene glycol in the EU. A gradual disappearance of PET industry in the EEA would also deteriorate capability in (chemically) recycling plastics, in particular as PET is one of the best recyclable plastics available the EU.

The EU PET market is 3.5 Million tonnes per year (2019), of which 1 Million tonnes is imported from third countries. The PET costs per tonne are ranging between 850 and 950 USD (see **Figure 33**), which corresponds to 750 – 850 € per tonnes. Assuming a profit margin of 10% and a loss of 25% sold EU volume (625 000 tonnes per year) due to site closures, relocation outside EU and competitiveness reasons, a loss in profit from EU-based material of about 531 Million € could occur for 20 years (625 000 t x 850 € x 10% = 53.12 Million € x 20 years = 1 062.4 Million €).

It is reasonable to assume that for all other HTF uses, a similar loss in profits will result, therefore a **revenue loss of 2 125 Million €** for all DU HTF applications is estimated.

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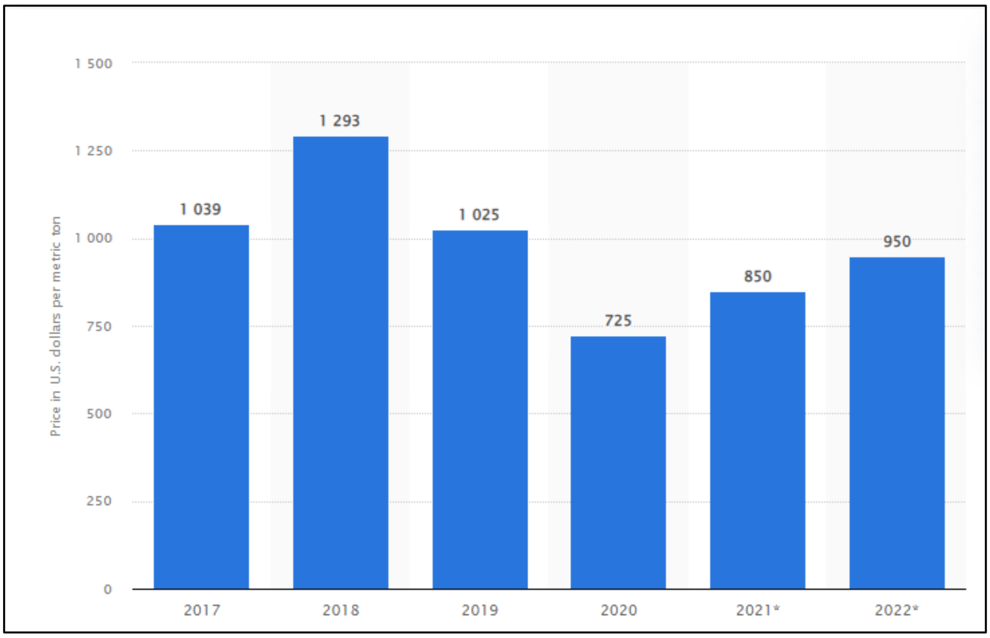
[72] Registry of restriction intentions until outcome - ECHA (europa.eu)

[73] Overview - Prodcom - statistics by product - Eurostat (europa.eu)

Figure 33. Price of PET worldwide from 2017 to 2020 with estimated figures for 2021 and 2022, in US $ per metric ton (Source: Statista 2022)



Downstream User sales outside the aviation and HTF sectors are not considered to be at risk, as it is assumed that the lack of input from stakeholders during the public consultation indicates that the restriction is not likely to pose an issue for other potential uses of PHT, and it is therefore expected that all other uses can be substituted before the end of the transition period by 2025 (EiF + 18 months). As shown in **Table 99**, the total "**profit at risk**" is estimated with **3 244 Million €.**

Table 99. Summary of loss in profits and reduced EU production of RO3

Type of Lost Profits	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Sales of PHT by Importers and Manufacturers	17.2	13.62	268
Downstream User Sales	820	0	2 125
Subtotal	837.2	13.62	2 393.00
Total	**3 243.82**		

E.4.1.3. Enforcement Costs (compliance costs)

Enforcement costs are administrative costs incurred by Member States National Enforcement Authorities (NEAs) to ensure that actors on the EU27 and EEA30 market comply with the EU regulations. By evaluating data reported from European studies on inspection and enforcement costs of REACH restrictions (Milieu, 2012[74]; RPA, 2012[75]), ECHA assessed the administrative burden of enforcement for new restriction proposals. ECHA concluded that based on data reported by Member States, the average administrative cost of enforcing a restriction is approximately 55,000 € per year and EEA Member State. Assuming constant administrative costs of enforcement over the time horizon under consideration (2025 – 2045), the value of **compliance costs** over 20 years is **33 Million €** for EEA30 (55 000 € x 30 EEA MS x 20 years). This estimate is assumed to be relevant for all ROs in the same way. The 33 Million. € have been distributed equally over the 3 different uses.

It is worth noting that the Netherlands used the same value in their Restriction Proposal on PAH in granules and mulches used in infill materials[76]. For the purpose of the current assessment, the value of 55 000 € per year should be seen as only illustrative in terms of the potential order of magnitude of the cost.

E.4.1.4. Summary of Costs for RO3

The estimated **total costs for RO3 are in the range of 13.3 Billion €.** Around 93% are allocated to the use as HTF, followed by about 6.4% by the plasticiser use in aviation. The costs on the non-aviation plasticiser uses and the remaining uses (e.g., solvents) are contributing insignificantly with below 0.5%. **Table 100** provides the summary of the costs.

Table 100. Total costs for RO3

Type of Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Substitution and Investment	3	2	10 032.62
Profit Losses	837.2	13.62	2 393.00
Enforcement costs	11	11	11
Subtotals	851.2	26.62	12 436.62
% of Total costs	6.39	0.20	93.41
Total Sum	**13 314.44**		

E.4.2. Economic Impacts of RO2

The difference between RO3 and RO2 is, that there is a derogation in place for all HTF uses. Consequently, the costs for all non-HTF uses remain the same, since these applications will be prohibited as of 2025.

Most of the costs of the HTF use will be taken out, except for enforcement costs and costs related to structural and organisational (e.g., training) improvements of the plants, as needed. The derogation will apply, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

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[74] report_study8.pdf (europa.eu)

[75] report_study11a.pdf (europa.eu)

[76] Registry of restriction intentions until outcome - ECHA (europa.eu)

During the stakeholder consultations costs for those improvements were communicated with 10 000 – 30 000 €. For the Dossier Submitter it is reasonable to assume, that for the 1 500 plants using PHT an average cost of 20 000 € would apply, resulting in a total cost of **30 Million €**. The on-site measurements conducted in several HTF plants (see **Annex B.9.**) demonstrated, that most had these strictly controlled closed systems in place and potentially only training is needed. In addition, the enforcement costs will be applicable to the HTF uses, since the implementation of e.g., containment and training measures should be inspected as well. In comparison to RO3, the total costs of RO2 have been significantly reduced to an amount of about **919 Million €**. The cost contribution of HTF uses is now at about 4.5% and the majority of the costs is carried by the Aviation plasticiser use (>90%). The remaining uses carry about 3%. **Table 101** is summarizing the costs for RO2.

Table 101. Total costs for RO2

Type of Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Substitution and Investment	3	2	30.00
Profit Losses	837.2	13.62	0
Enforcement costs	11	11	11
Subtotals	851.2	26.62	41.00
% of Total costs	92.64	2.90	4.46
Total Sum	**918.82**		

E.4.3. Economic Impacts of RO1

Regarding RO1, the costs for the HTF use and the "Non-Aviation Plasticiser" and "Other Uses" remain the same as compared to RO2. Because the aviation plasticiser use will receive a derogation for 5 years (2025 – 2029), the loss in sales of PHT from PHT manufacturers and importers to formulators of sealants and adhesives will be reduced to 15 years. The profit loss by the importers and manufacturers of PHT in the aviation industry accounts for **12.9 Million €** (430 tonnes per year x 8 000 € x 15 x 0.25). Same reduction due to a shortened restriction timeline applies for the profits at risk in the aviation industry. As a **profit loss 615 Million €** was taken into account (41 Million € per year x 15 years) for the aviation supply chain. The Dossier Submitter believes that this is a worst-case consideration and potentially an overestimation, because the 5 years derogation (after EIF) should have provided most actors in this industry sufficient time to substitute the use of PHT as plasticiser in the aviation sector. PHT was included in the Candidate List in June 2018[77], thus providing more than 10 years of time for reformulation and re-certification (Supplemental Type Certificates).

Table 102 summarises the costs for RO1.

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[77] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

Table 102. Total costs for RO1

Type of Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Substitution and Investment	3	2	30.00
Profit Losses	615	13.62	0
Enforcement costs	11	11	11
Subtotals	629	26.62	41.00
% of Total costs	90.29	3.82	5.89
Total Sum	**696.62**		

E.4.4. Cost Comparison of ROs

The table below (**Table 103**) compares the costs for the different ROs to the Baseline Scenario. It is not surprising that RO3 shows the highest cost, since it is the most severe RO. The amount of RO3 is 19-times higher than RO1 and 14-times higher than RO2. Substitution and investment costs in RO3 account for >75%. In RO2 and RO1 there is a shift towards profit losses, with share of >90% for both ROs.

Table 103. Comparison of total costs for RO1 – RO3 relating to the Baseline

Type of Costs	**RO1**	**RO2**	**RO3**
	in Million €		
Substitution & Investment	35.00	35.00	10 037.62
Profit Losses	628.62	850.82	3 243.82
Enforcement costs	33.00	33.00	33.00
Total Costs (in Million €)	**696.62**	**918.82**	**13 314.44**

Eastman Chemical has announced[78] to invest up to 1 billion US$ in a material-to-material molecular recycling facility in France to recycle up to 160 000 tonnes annually of hard-to-recycle plastic waste that is currently being incinerated. The plant and an innovation centre would be expected to be operational by 2025, creating employment for approximately 350 people and leading to an additional 1 500 indirect jobs in infrastructure and energy. The most suitable and efficient technology would be based on PHT as HTF. The economic impacts of this project have not been evaluated and included in the calculation but could add additional costs to RO3 if technology based on PHT would not be available.

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[78] Our Announcement in France | Molecular Recycling | Eastman

E.5. Risk reduction capacity

E.5.1. Benefits to the environment and human health

In 2018 PHT was identified as a substance meeting the criteria of Article 57 (e) as a substance which is vPvB, in accordance with the criteria and provisions set out in Annex XIII of REACH. PHT is chemically stable in various environmental compartments with minimal or no abiotic degradation (see **Annex B.4.1**) and is very bioaccumulative, which means that the concentrations in the environment may increase over time (see **Annex B.4.3**).

The ECHA Guidance for PBT/vPvB assessment (Chapter R.11) (ECHA, 2017) states: "Experience with PBT/vPvB substances has shown that they can give rise to specific concerns that may arise due to their potential to accumulate in parts of the environment and

- that the effects of such accumulation are unpredictable in the long-term;
- such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in substance concentration".

Another aspect of the vPvB concern important to consider is the political objective to phase out the use of vPvB substances, see for example the recent COM Chemicals Strategy for Sustainability towards a Toxic-Free environment[79]. Furthermore, Recital 70 of the REACH Regulation states that exposure of the environment and humans from substances of very high concern should be reduced as much as possible.

In the case of PHT, it has been demonstrated via monitoring of environmental emissions from HTF systems that air emissions are very unlikely to occur, however spills and leakages may result in accumulation of (low) amounts of PHT in soil. It is estimated that other uses have a greater impact to the release of PHT to the environment, such as the use in coatings, adhesives, or sealants (See **Annex D**).

E.5.2. Emission reductions as a proxy for potential benefits

Quantification of risks is currently not possible for PBT or vPvB substances, which makes quantification of benefits challenging.

Moreover, for these substances a full cost-benefit assessment is usually not feasible due to their specific properties. Decisions on PBT measures appear to be rarely motivated explicitly by arguments of C/E. IVM (2015)[80] reported there is a wide "grey zone" between EUR 1 000 and EUR 50 000 per kg PBT emission avoided.

However, the potential benefits will be linked to the environmental stock and therefore also reduction in emissions. SEAC[81] is advising the use of emission reductions, in combination with factors of concern, including the level of persistence and bioaccumulation, long-range transport potential and uncertainty, as a proxy for potential future benefits (ECHA, 2008).

For PHT, factors which may indicate additional concern beyond the vPvB properties include professional uses and service life of articles manufactured with PHT (see **Annex A.2**). These uses may result in exposure of PHT to parts of the population as well as to the environment. Combined with the vPvB properties, this can lead to significant impacts not likely for uses related to localised emissions and exposure only.

As recommended by SEAC (ECHA, 2014), a cost-effectiveness (C/E) analysis approach was followed, using emission reductions as a proxy for benefits. The advantage of this approach

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[79] https://ec.europa.eu/environment/strategy/chemicals-strategy_es

[80] Institute for Environmental Studies (2015): Benchmark development for the proportionality assessment of PBT and vPvB substance. Report R-15/11.

[81] Committee for Socio Economic Analysis. Committee for Socio-Economic Analysis - ECHA (europa.eu)

is the total emission reduction associated with the implementation of a restriction is independent from the timing of the reduction, as long as they fall within the analytical period considered.

E.5.3. Changes in emissions

Contrary to the economic impacts, the expected emission reduction that can be achieved under each restriction scenario will not be affected by the behavioural responses to the restrictions. The reason for this is that the restriction sets out when manufacture and use must cease, and the emissions of PHT will cease accordingly (however, effects of emissions from articles in which PHT has been used need to be taken into account). There is a possibility that some actors using PHT as plasticiser will switch voluntarily to alternatives before entry into force. However, this was not considered in the emission estimations.

As described in the baseline scenario of PHT in **Annex D.3**, the continued use of PHT was estimated as illustrated in **Figure 30**. It should be noted that emissions prior to 2025 were not considered. Furthermore, the model assumes that emissions ceases when the use of PHT is banded for a certain use. In reality, parts of the emissions particularly for the use as plasticiser will occur during the service life of the articles including PHT and thus, after the ban is in force. A significant share of the emissions occur at the end-of-life stage. Furthermore, if the use as HTF is banned, it has to be taken into account that due to required emptying and disposal of the currently installed base (ca. 25 000 tonnes in approximately 1 500 plants in the EU), there is a significant potential for additional releases that have not been taken into account in this analysis. Therefore, the reduction in emissions compared to the baseline will in reality be spread over the entire analysis period (2025- 2044), which is not shown in the following figures.

Figure 34 illustrates the trend of expected emissions for RO 1 where a derogation exists for plasticiser uses in the aviation industry (5 years after entry into force) and a general derogation for HTF uses, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

Since the HTF emissions are likely to be an overestimate as mentioned before, the introduction of controlled closed systems with engineered containment measures to minimise environmental emissions was considered with an emission reduction of 75% compared to the baseline scenario.

Figure 34. Expected releases of PHT for RO1

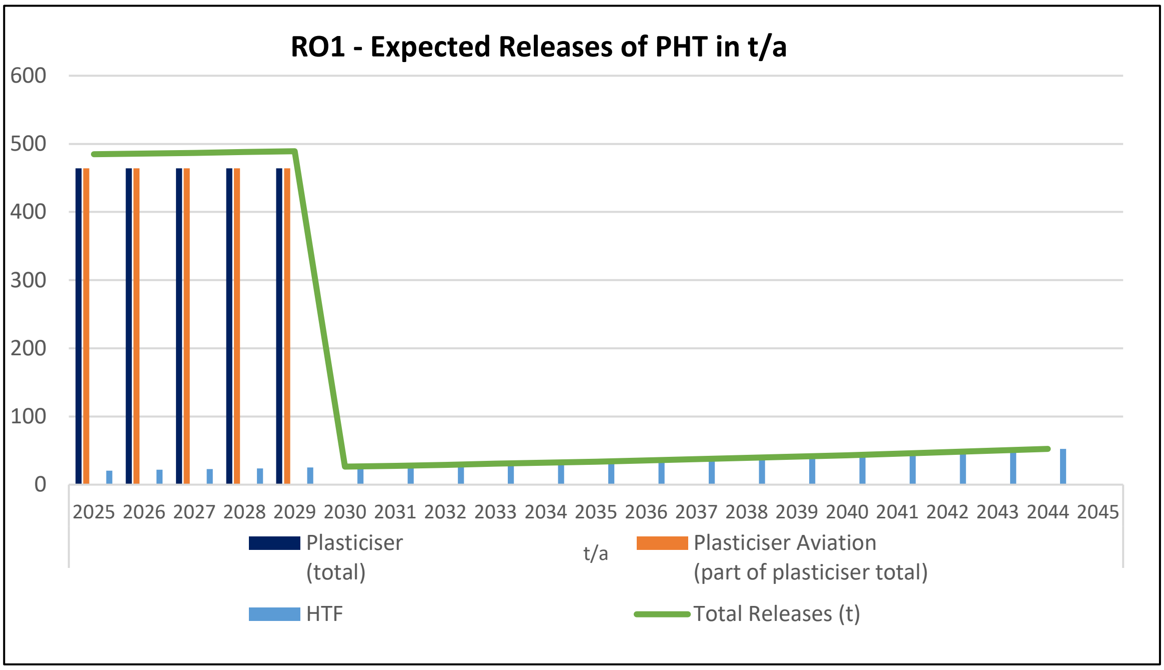
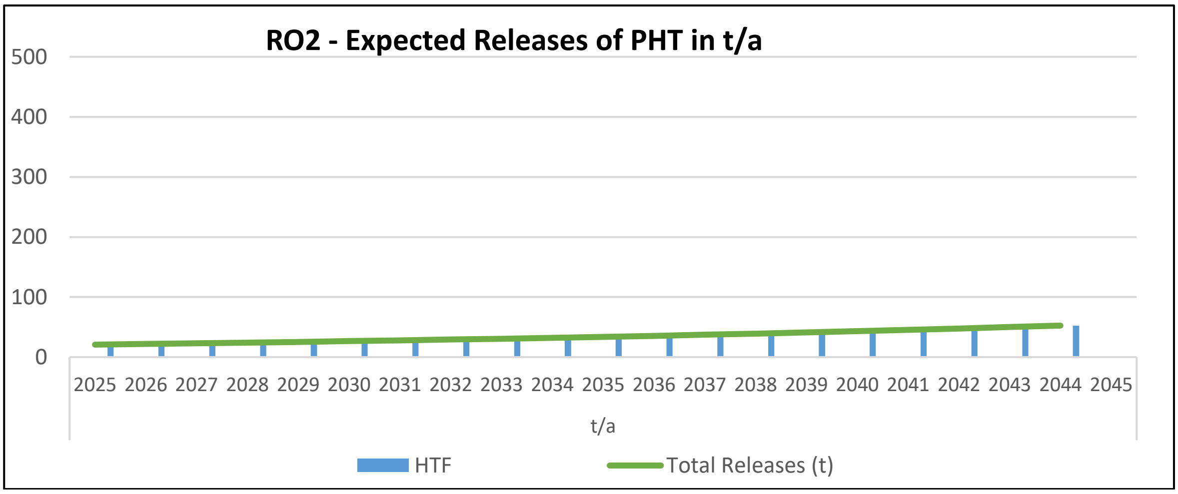


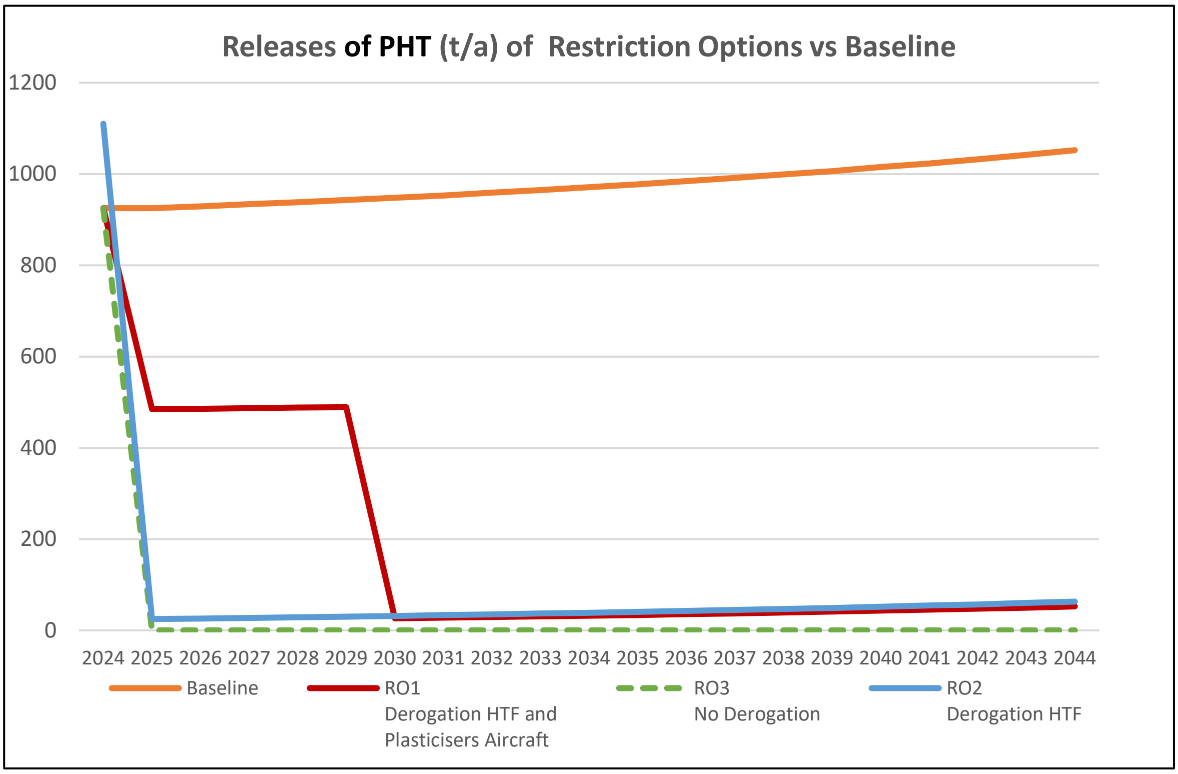
Figure 35 shows the expected releases for RO2, where the derogation exists only for the use of PHT as HTF. Consequently, emissions will only arise from the use of HTF.

Figure 35. Expected releases of PHT for RO2



In case of RO3 where no derogations exist, all emissions will cease in 2025. **Figure 36** does exhibit the expected emissions of each RO in comparison to the baseline scenario.

Figure 36. Expected emissions of each RO in comparison to the baseline scenario



The overall emission reduction capacity of each RO was estimated by calculating the total emission (incl. all uses) under each scenario with reference to the total emissions under the baseline scenario (= 100%). Consequently, the abovementioned inaccuracies in the timing of the emission reductions have less impact on the emission reduction capacities of the ROs. The longer the time period used for the analysis, the more accurate the total emission reductions.

As the average annual emission reductions are estimated by dividing the total emissions by the number of years in the analysis period (20 years), the same uncertainties as for the total emission reductions also apply to the annual estimates. The expected achievable emission reductions for each RO are presented in **Table 104**, based on the total release quantities of all uses.

Table 104. Emission reduction capacity of all ROs

	Total Emissions (tonnes)	**Total Emissions (%)**	**Emission Reduction Capacity (%)**
Baseline	19 584	100	0
RO1	3 006	15	85
RO2	686	3,5	96.5
RO3	0	0	100

As expected, the most stringent RO (RO3) with a complete ban of PHT as of 2025 has the highest emission reduction capacity. However, RO1 and RO2 are both very effective and lead to high emission reductions between 85% - 96.5% of the baseline emissions. It is important to note that both ROs include a continuation of HTF use.

Due to the high number of entries of articles containing PHT in the SCIP database (> 12,000, see **Annex A**), the question was raised if a restriction of imported articles with PHT content of greater than 0.1% w/w is considered sufficient to adequately address the concerns or if the restriction should cover concentrations as well < 0.1%, since REACH Article 7(2) on "Notification Requirements", Article 33 on "Supply Chain Communication" and the "SCIP Notifications" do not apply. This is an uncertainty since it is not clear, how many articles with concentration levels < 0.1% of PHT are being imported and if those imported articles would pose a risk of environmental exposure.

E.6. Other impacts

E.6.1. Social impacts

Societal impacts are impacts that may affect workers, consumers, and the general public that are not covered under health, environmental or economic impacts (ECHA, 2008), including employment, working conditions, job satisfaction, and education of workers and social security. Depending on the RO selected for PHT, societal impacts may vary significantly. A complete restriction leading to a practical ban of all uses of PHT (RO3) would have a significant impact down the supply chain, particularly related to potential job losses in many industries that rely on PHT as an HTF. In contrast, RO1 would allow the continued use of PHT in this application (provided operations are undertaken under certain containment measures) and therefore the impact would be limited.

E.6.1.1. Employment

In many cases, it will be difficult to obtain quantitative information on employment impacts, especially on specific issues such as different occupational groups (in particular without direct consultation with industry representatives and trade associations).

Impacts on EU employment are closely linked to what extent there might be any potential production stops or any permanent closure of production and relocation of production outside the EU under each restriction scenario.

Via the stakeholder consultation process, some numbers were provided by the HTF industry, which allows at least a qualitative/semi-quantitative assessment to calculate lost jobs. In total, 4 147 potential jobs at risk were reported. As described under **Annex E.4.1.1.** (Substitution and Investment Costs under RO3) it is assumed, that 25% of the HTF users (375 sites) would relocate to non-EU and another 25% (375 sites) would abandon business in the EU. Assuming, that 50% of the 4 147 jobs at risk would be lost, the **lost jobs** in the EU's **HTF industry** using PHT would be **2 074**.

Regarding employment in the Aviation plasticisers use, the Dossier submitter wants to refer again to the work done under the Restriction Proposal of Dechlorane Plus by Norway (see **Annex E.6.1.1**., Table 112 of Dechlorane Plus Restriction Proposal)[82]. The share of the relevant jobs at risk under the restriction scenarios was assumed proportional to the share of profits at risk. Since the same profits at risk numbers were taken for PHT, it is reasonable to reference as well to the lost jobs. The relevant jobs associated with the use of Dechlorane Plus has been assessed with ca. 10 000. Under a full ban of the substance, Norway assumes

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[82] Submitted restrictions under consideration - ECHA (europa.eu)

that approximately 15% jobs are at risk for the use in aviation. The Dossier Submitter assumes, that for the PHT use as plasticiser in the **aviation industry** due to its complex value chain, ca. **1 500 jobs could be lost** for a total PHT ban.

Putting the lost revenues of the "**non-aviation plasticiser and other uses**" into perspective with the aviation plasticiser use, the percentage is ca. 1.6%. This would result in ca**. 24 lost jobs**.

For RO1 it is assume, that 50% of the formulators in the aviation plasticiser industry will be able to reformulate until the restrictions enter into force, so that the lost jobs will be reduced to half, which means 750 lost jobs would occur.

According to the SEA guidance (ECHA, 2008)[83], the total societal value of a job loss is "around 2.7 times the annual pre-displacement wages". Since the number of jobs at risk in the various Member States is not known, the average annual gross salary in the EU is reported at € 24 700[84] for 2018. Therefore, an average annual gross salary of 25 000 € was used. The resulting average annual jobs at risk and their net present value over the analytical period (2025 – 2044) are shown in **Table 105**. The Societal Loss was calculated by the number of lost jobs, multiplied by 2.7 and 20 years, respectively 15 years for aviation plasticiser use under RO1.

Table 105. Number of jobs at risk and their value in Million €

Sector	RO1		RO2		RO3	
	Lost Jobs	Societal Value Million €	Lost Jobs	Societal Value Million €	Lost Jobs	Societal Value Million €
HTF	0	0	0	0	2 074	2 800
Plasticiser Aviation	750	760	1 500	2 025	1 500	2 025
Plasticiser non-Aviation and Other Uses	24	32.4	24	32.4	24	32.4
Total per RO	**774**	**792.4**	**1 524**	**2 057.4**	**3 598**	**4 857.4**

Eastman Chemical has announced to invest up to 1 billion US$ in a material-to-material molecular recycling facility in France to recycle up to 160 000 tonnes annually of hard-to-recycle plastic waste that is currently being incinerated. The plant and an innovation centre would be expected to be operational by 2025, creating employment for approximately 350 people and leading to an additional 1 500 indirect jobs in infrastructure and energy. The most suitable and efficient technology would be based on PHT as HTF. The economic impacts of this project have not been evaluated and included in the calculation but could add additional costs to RO3 if technology based on PHT would not be available.

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[83] https://echa.europa.eu/documents/10162/2324906/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

[84] The average gross salary was estimated based on an average EU gross earning of € 13.7/h uplifted to 2020 (Eurostat), 40.3 hours work weeks (Eurostat, 2018b) and 33 holidays per year (European Data Portal, 2016).

E.6.2. Wider economic impacts

The proposed restriction (RO1) is not expected to affect competition between EU and non-EU actors placing products on the market in the EU significantly, due to the derogation for the use of PHT in HTF applications and the time-limited derogation for plasticiser uses in the aviation industry. It is expected that after 5 years of derogation, the aviation plasticiser industry will have successfully substituted PHT in this application.

In contrast, implementation of RO3 would create distortion and unfair competition, since many products (e.g., PET) could be produced outside the EU using the more competitive heat transfer systems based on the use of PHT. Moreover, in case of a complete PHT ban, some chemicals could not be produced in the EU anymore, which would play against the objective of a sustainable and self-sufficient EU chemical industry. In addition, PHT is used in certain key renewable energy technologies, therefore any ban would undermine the EU Green Deal activities related to clean energy production to address climate change. Due to the lack of information, those potential economic impacts have not been quantified.

E.6.3. Distributional impacts

The distributional impacts are not societal costs as such, as a negative impact on one actor can be counterbalanced by an equal but positive impact on another actor. However, distributional impacts may still be important, in particular, if “losing” actors are part of a vulnerable group.

Information received in the stakeholder consultations indicates that the main sectors adversely affected by a restriction on PHT are the general manufacture of chemicals (including PET production), energy generation (via ORC systems), and the aviation industry. These cover large sectors with a strong presence in the EU, as well as SMEs. Under a full ban of PHT for all uses (RO3), the potential higher resilience of larger companies to adapt to changes compared to smaller businesses would not play a role; since it is not expected that feasible alternatives to PHT in its use as HTF (that would not lead to regrettable substitution in the future) will be available to downstream users in the short term, all industries (large or small) would be expected to be impacted in a similar way. Distribution of profits to industries that would transition early to different substances in the HTF sector does not play a role in the evaluation and therefore incentives for a proactive transitioning away from an SVHC cannot be considered.

E.7. Practicality and monitorability

E.7.1. Implementability and manageability

Implementability is related to the degree in which the actors involved are capable to comply with the restriction proposal. On the assumption that no feasible alternatives for PHT are available for the use as HTF, without generating a situation of regrettable substitution, it is evident that RO3, leading to a full ban of PHT, would be complex to implement and manage for many users of PHT. Companies would be forced to change their production processes to either using other products that would likely result in similar regulatory action in the future, or a complete redesign of the heat transfer systems, which would lead to significant costs; relocation or closure of activity would be the other alternative options. In contrast, RO1 would allow continued use of PHT in the main application, provided that the relevant actors would adapt their installations to specific technical requirements. RO1 would also allow for sufficient time for the aviation industry to switch to alternative products in the use of PHT as a plasticiser in this sector. To be implementable within a reasonable timeframe, a restriction should be designed that a supervision mechanism exists and is practically implementable for enforcement authorities. The proposed restriction (RO1) is easily understandable for effected parties and therefore implementable and manageable. Furthermore, it is implementable as companies can test for concentration limits in concerned articles or make it a condition of sourcing contracts. In addition, the proposed restriction provides sufficient time to the impacted supply chains to transition.

E.7.2. Enforcement and monitorability

To be enforceable, a restriction needs to have a clear scope so that it is obvious to enforcement authorities which products are within the scope of the restriction and which are not. Moreover, the restriction needs a concentration limit value that can be subject to supervision mechanism. The proposed RO1 provides these prerequisites. The monitoring of the proposed restriction is expected to be done through enforcement.

Enforcement activities under RO1 should focus on two actions; firstly, authorities should verify that downstream users of PHT as a HTF adapt their installations - if needed - to introduce appropriate means of containment to minimise releases and ensure adequate collection of any potential release of the substance. This could be developed via identification of the relevant actors using PHT in this sector and implementation of inspections by the relevant Member States.

The second action would be related to the import of PHT into the EU, as such, in mixtures or in articles, and the production of articles in the EU. For articles placed on the market, authorities could check the documentation from the supply chain confirming that articles do not contain PHT. The SCIP Database could be useful to identify, if new articles have been notified after the restriction, that do contain PHT. In addition, it is expected that the verifications will be carried out via testing. A concentration of 0.1% w/w is the limit that is applicable to PHT in articles, as this is the limit that triggers notification requirement under article 7(2) of REACH, and the information requirement under REACH Article 33.

The concentration limit of 0.1% w/w would therefore provide an option to establish enforceability criteria.

Analytical methods for quantitative determination of PHT are available via NIOSH 5021 "o-Terphenyl" NIOSH Manual of Analytical Methods (NMAM), Fourth Edition. This method could be used for the purpose of establishing concentrations of PHT in articles, however its implementation may require certain adaptations by specialised laboratories. The method is available in the public domain[85].

Due to the classification of PHT as vPvB, notification of any violation of the restriction in the RAPEX System[86] is not relevant, since it only applies to dangerous products, not vPvBs.

E.8. Proportionality (comparison of ROs)

Proportionality is a general principle of EU law. It restricts authorities in the exercise of their powers by requiring them to strike a balance between the means used and the intended aim. More specifically, proportionality requires that advantages due to limiting the right are not outweighed by the disadvantages to exercise the right. In other words, the limitation on the right must be justified. A pre-condition is that the measure is adequate to achieve the envisaged objective. As highlighted in Section E.5, the risks and thereby the benefits of PBT and vPvB substances cannot be quantified, and in the case of vPvBs, there are no known impacts. This prohibits the use of a traditional cost-benefit analysis to assess proportionality.

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[85] 5021.new (cdc.gov)

[86] Safety Gate for dangerous non-food products (europa.eu)

To evaluate the acceptability of regulatory options despite the lack of quantitative information on benefits, SEAC recommends using C/E values and "a comparator or a "benchmark" on the level of costs that are deemed to be worthwhile taking when reducing emissions" (ECHA, 2014). The total cost of introducing a restriction on PHT is higher for the more stringent ROs (RO2 and RO3) and the largest cost component by far is the potentially loss of profits due to not having a feasible alternative to switch to in case of a full ban (RO3), mainly related to the use of the substance as HTF. Equally, the more stringent restriction scenario, would lead to the higher emission reductions and, by proxy, higher potential environmental benefits. The main trade-off on a societal level is the potential environmental benefits associated with reducing emissions of PHT vs. the cost to industry and society from potential investment costs and profit and job losses, as well as to supply disruption for products that may be difficult to produce without access to PHT as a HTF (e.g., PET). Based on the lack of feasible alternatives, it is difficult to evaluate substitution costs and R&D activities in detail.

Table 106 provides a comparison of environmental emissions versus expected costs, jobs at risk and the social impacts for the different ROs evaluated.

Table 106. Total economic impacts vs Emission values and Emission Reduction Capacity

	Total Cost (in Million €)	**Social Impacts** (in Million €)	**Total Economic Impact** (in Million €)	**Total Emissions** (tonnes)	**Emissions Reduction Capacity** (%)
Baseline				19 584	0
RO1	696.62	792.40	1 489.02	3 006	85
RO2	918.82	2 057.40	2 976.22	686	96.5
RO3	13 314.44	4 857.40	18 171.84	0	100

To determine whether the estimated costs of kg/PBT substance emissions reduced are likely acceptable for EU society, SEAC recommends using a benchmark to compare the cost against. There are currently no agreed benchmarks for PBT and vPvB substances, but a comparison could be drawn based on previous studies and estimated costs of regulations implemented in the past, e.g., Oosterhuis and Brouwer (IVM, 2015). The conclusion drawn in the paper is that costs below 1,000 € per kg reduced emission is generally deemed acceptable.

Table 107 shows the C/E estimates for each RO. The proposed RO1 has a high cost-efficiency (90 €/kg PHT emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1.

Table 107. C/E of all ROs

	Total Economic Impact (€)	Total Emissions (tonnes)	Total Emissions (kg)	PHT Reduced against Baseline (kg)	C/E (€/kg PHT)
Baseline		19 584	19 584 000	-	-
RO1	1 489 000 000	3 006	3 006 000	16 578 000	**90**
RO2	2 976 000 000	686	686 000	18 898 000	**157**
RO3	18 172 000 000	0	0	19 584 000	**928**

The cost-efficiency falls within the benchmark zone for being acceptable.

RO2 has with 96.5% a higher emission reduction capacity but a lower C/E with a factor of 1.7 (157 €/kg PHT emissions avoided) compared to RO1. RO3 as most stringent RO has the highest emission reduction potential but at much higher costs (928 €/kg PHT emissions avoided), which are a factor of 10 compared to RO1.

Comparing with other PBT/vPvB substances under restriction, C/E values of 464 €/kg for DecaBDE[87] and 20 000 €/kg for Dechlorane Plus were developed. In the Microplastics Restriction Report[88], ECHA developed for leave-on cosmetic products a cost-efficiency of 430 €/kg of reduced emissions. **Table 108** shows C/E ratios of other recent REACH restriction.

Table 108. C/E-Ratios of recent (incl. ongoing) REACH Restrictions

REACH Restriction	**€/kg**
Lead Gunshot in Wetlands	9
PAHs in Clay Targets	130
Lead in PVC	308
D4/D5 in Wash-off Cosmetics	415
DecaBDE	464
Phenylmercury Compounds	649
PFOA Substances	734

E.9. Conclusion

To identify the most appropriate measure to address the risks of the PHT use, an analysis of risk management options (RMOA) was conducted, including regulatory measures under REACH, other existing EU legislation and other possible Union-wide RMOs, and it was concluded that a Restriction under REACH is the most appropriate risk management option.

A number of ROs were assessed on the basis of effectiveness, practicality, and proportionality. The conclusion of the Dossier Submitter’s assessment is to **propose Restriction Option 1**.

The proposed restriction is targeted to the exposure that are of most concern, e.g., the use of PHT as a plasticiser. The proposed restriction is effective and reduces potential risks to an acceptable level within a reasonable period of time. It is assumed to impose low costs to reduce a potential risk and that the measures are proportionate to the risk. The restriction is practical because it is implementable, enforceable, and manageable, as the proposed restriction is easy to understand and communicate down the supply chain. Testing and sampling methods exist for enforcement activities.

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[87] Registry of restriction intentions until outcome - ECHA (europa.eu)

[88] Registry of restriction intentions until outcome - ECHA (europa.eu)

Annex F: Assumptions, uncertainties, and sensitivities

This Annex sets out the key variables and assumptions used in the analysis (Section F.1. Input parameters and assumptions) and identifies uncertainties induced by uncertainty in the input parameters used (Section F.2. Uncertainty).

F.1. Input parameters and assumptions

A large number of input parameters and assumptions have been used to derive the quantitative results in the restriction proposal. All input parameters and assumptions are reported throughout the report. Therefore, the Dossier Submitter does not see the necessity to repeat in particular the input factors in this section.

The input parameters on **Volumes & Uses** (**Annex A**) as well as number of sites using PHT are considered to be quite accurate, since consistent data was provided from industry during the stakeholder consultations and direct interviews with concerned parties.

Related to the input parameters on the **Exposure Assessment** (**Annex B.9.**), all assumptions have been referenced in the respective tables. Exposure values have been derived by applying defaults according to ECHA Guidance R.16. For the plasticiser uses a FEICA SpERC (FEICA SPERC 5.1a.v3) was applied for the refinement of the default assumptions. The estimates of the refined assessment are referred to as "lower estimate". They are assumed to represent the reasonable worst-case emissions. The high emission scenario represents a worst-case assumption whereby e.g., the default release factors as indicated in ECHA Guidance R.16 are used. Hence, the high emission scenario has to be regarded as a very conservative approach overestimating real exposure levels. Regarding the migration modelling, it needs to be noted that this is an abstract process aiming at calculating the maximum number of substances which might be transferred to the medium in contact, with various simplifications and assumptions. It is important to understand that the migration modelling used for the purpose of this proposal does not seek to reproduce all the details of the real mechanisms; instead, the objective is to provide an estimate of potential migration for getting an indication of potential emissions into the environment via the migration path of plasticizers used in coatings, sealants, and articles. The Dossier Submitter assumes that some additional PHT volume will be entering the EU via articles, due to the high number of notifications in SCIP. It is to be noticed that the number of articles containing PHT imported into the EU and exported from the EU is not known with any certainty. Hence, the exposure assessment for the service life scenarios is based on the volume of PHT itself supplied to the EU market.

Concerning the **Baseline** scenario (**Annex D**), the Dossier Submitter assumes an average growth trend for the HTF use of 5% annually and a stagnant trend for the plasticiser applications from 2025-2035. Beyond 2035, the uncertainty in any projection increases and makes it difficult to identify the driving factors for the plasticiser use. Due the SVHC listing the reformulation will kick in, resulting in a drop of the plasticiser use in the EU. It is expected that the decrease in volume as of 2036 will be 5% per annum. On the other hand, it is very likely that the production of articles including PHT as a plasticiser will be relocated outside the EU and that the volume of imported articles containing PHT into EU will increase.

The **Impact Assessment** (**Annex E**) of this dossier is surrounded by various assumptions and uncertainties. The behavioural responses are based on comments made by industry via the stakeholder consultations. The same applies for the Economic Impacts as outlined in **Annex E.4.** and **Annex E.6**. Most of the input data was derived from responses of industry. It should be noted, that due to the similarity of the application of PHT in the aviation industry compared with the use of Dechlorane Plus in Aviation, the same approach and figures developed in the Dechlorane Plus restriction was used. Regarding loss in efficiency when using an alternative substance for the HTF use, an amount of 25 000 € per installation was used. There is a lot of uncertainty if this number is matching reality.

Related to the Risk Reduction Capacity (E.5.) the model assumes that emissions cease when the use of PHT is banned for a certain use. In reality, parts of the emissions particularly for the use as plasticiser will occur during the service life of the articles including PHT and thus, after the ban is in force. A significant share of the emissions occurs at the end-of-life stage. Furthermore, if the use as HTF is banned, it has to be taken into account that due to required emptying and disposal of the currently installed base (about 25 000 tonnes in about 1 500 plants in the EU), there is a significant potential for additional releases that have not been taken into account in this analysis.

Assumptions made, in particular in the cost assessment, should be tested and verified in the stakeholder consultation on this Annex XV dossier.

F.2 Uncertainty

Exposure assessment

Owing to a lack of site-specific exposure information for the EU, a generic approach closely aligned with ECHA Guidance R.16 has been used for the exposure assessment. The approach involves a number of assumptions and, where appropriate, a realistic worst-case approach has been chosen in line with ECHA Guidance R.16.

The lack of information on fractions released to air, water, and soil from the various processes during PHT's lifecycle creates significant uncertainties in the exposure assessment.

The approach used is based on a combination of relevant release factors from OECD Emission Scenario Documents (ESD), industry Specific Environmental Release Categories (SpERCs) and default release factors from ECHA Guidance R.16. In 2018 an Exposure & Release Questionnaire was sent out to users of PHT. Information obtained from this questionnaire is also used in the exposure assessment. It is uncertain though whether the used information is applicable to all sites where PHT is used in the same way.

For certain input factors assumptions had to be made based on best knowledge. This is also associated with a higher uncertainty. Moreover, for the fraction released to solid waste for some of the uses no information is available. Hence the emissions are possibly underestimated for those uses.

Details of the specific factors used are given for each individual use in Section B.9.

The Predicted Environmental Concentrations (PECs) have been estimated using EUSES v2.1.2 as implemented in CHESAR v3.7. This model uses basic information on the properties of PHT and, combined with estimates of the amounts of PHT released, calculates the resulting concentrations in the environment using standard models.

The approach used is generic and uncertainties arise in modelled outputs from a number of sources as well. It is to be noticed that the number of articles containing PHT imported into the EU and exported from the EU is not known with any certainty. In addition, it is an uncertainty if a restriction of imported articles with PHT content of greater than 0.1% w/w is considered sufficient to adequately address the concerns or if the restriction should cover concentrations as well < 0.1%, since REACH Article 7(2) on "Notification Requirements", Article 33 on "Supply Chain Communication" and the "SCIP Notifications" do not apply. This is an uncertainty since it is not clear, how many articles with concentration levels < 0.1% of PHT are being imported and if those imported articles would pose a risk of environmental exposure.

Exposure measurements

Related to the exposure measurements, attempts were made to capture releases of PHT from industrial sites operating high temperature, non-pressurized heat transfer systems using the substance as a HTF. Air samples were collected from locations from which it was assumed that PHT was more likely to be released. However, no significant concentrations of PHT were detected from the samples that were generated. This can be due to many factors, since the set-up largely depended on capturing situations from which PHT would be released in a state that could be captured by a nearby air sample collector. This proved to be difficult for many reasons, one of them being the limited time duration of the sampling (approximately four hours per sample). Furthermore, the low volatility of PHT makes it difficult for the substance to be released a measurable way in a non-continuous sampling system. In contrast, additional information obtained during the monitoring exercise has shown to be valuable in terms of identifying potential releases of PHT. While limited in number, the soil samples that were collected at one site resulted in detection of PHT (or its compounds identifiable via analytical techniques). In addition, an event occurred in which releases of PHT from a HTF were visually observed during the sampling. These events suggest that while limited, PHT releases at industrial establishments are possible and may accumulate over years of operation, particularly if systems are not operated under strictly controlled containment systems.

Cost and C/E

The estimated costs for the ROs are associated with some degree of uncertainty. Information received from individual actors during the stakeholder consultation were extrapolated to entire industries. This poses uncertainty, as the exact data for non-responding companies are unknown. Moreover, the accuracy of the collected data and the robustness of the adopted methodology introduce uncertainty. In particular, estimations of market growth rates, estimation of total market size (in the plasticiser value chain) as well as not declared margins, turnovers, and costs for closing and dismantling sites, may be subject to uncertainty. Assumptions made on behavioural responses are intrinsically uncertain.

The C/E calculations incorporate both, emissions, and costs, thus, the same uncertainties described before will apply to the C/E-estimates as well. It is hardly possible to reduce these uncertainties any further without more information from stakeholders. Therefore, the conclusions of this dossier should be verified in the stakeholder consultation of this Annex XV dossier.

F.3. Sensitivity analysis

Adopting only the most likely value (estimated or average) of each impact within an Impact Analysis provides no indication of the level of uncertainty surrounding the analysis and hence has implications for any decisions based on the conclusions. Instead, it is recommended that information be developed on the range of plausible outcomes associated with a given option. This type of information is developed through the use of sensitivity analysis, which is a generic term for the techniques that involve identifying key assumptions (or variables) for which uncertainty as to their values could significantly affect the conclusions drawn on costs or benefits. Sensitivity analysis is therefore used to identify the variables that contribute most to uncertainty in predictions.

As highlighted in Section F.2., there are uncertainties associated with some of the input factors and consequently results of the analysis. However, since the use volumes have been identified as reliable and the exposure assessment was conducted according to ECHA Guidance, the dossier is considered to be robust.

The key uncertainties are considered to be profit losses, estimations of market growth rates, estimation of total market size (in the plasticiser value chain) as well as not declared margins, turnovers, and costs for closing and dismantling of sites.

Table 109 shows in a simple manner the sensitivity of key outcomes of the Impact Analysis. The arrows indicate the impact of the uncertainty of some key parameters on the outcomes of the SEA. "↓" means, that the assumption lowers the estimate and"↑" means that the assumption increases the estimate.

Table 109. Sensitivity of key uncertainties

Parameter tested	**Impact on Emissions**	**Impact on Costs**	**Impact on C-/E-Ratio**
Market growth rate underestimated	↑	None	↑
Market growth rate overestimated	↓	None	↓
Cost overestimation	None	↓	↓
Cost underestimation	None	↑	↑

Annex G: Stakeholder information

Extensive information is available on PHT related to its use patterns. The REACH Registration Dossier (ECHA, 2021a), the CSR document (Solutia, 2019), the Annex XV Dossier (Tukes, 2018) and the information available from the ECHA Website on PHT (ECHA, 2021e) were used as important sources for information. In order to complement these sources, detailed stakeholder interactions took place during the Public Consultations in the SVHC identification process and the ECHA Prioritization Process, which did include the call for information on Socio Economic Impacts by the COM.

On 5 March 2020 until the 5 of June 2020, the ECHA, on behalf of the COM, launched a call for information in order to obtain data on the uses and conditions of use of substances considered in the Draft 10th recommendation for prioritisation of substances for inclusion into Annex XIV. In the framework of this call, the COM asked for submission of information on the possible economic, social, health and environmental impacts (costs and benefits) of possible inclusion into Annex XIV. The questionnaire template is included in the Restriction Proposal (see template in Appendix 3). A summary of the inputs to the call for information on socio-economic elements related to ECHA's 10th draft Recommendation for prioritisation was presented by the COM on the 40th Meeting of Competent Authorities for REACH and CLP (CARACAL)[89] on the 29th of June 2021. The Annex to the COM Summary[90] included 26 non-confidential documents submitted by industry as shown in **Table 110** below.

50% of the comments received by the COM were related to PHT, the remaining 50% were allocated to the other 6 substances that were included in ECHA'S recommendation. This is reflected by the feedback to ECHA, where the responses on ECHA's Draft 10th Recommendation for PHT[91] include 57 pages, and > 50% of all responses related to the recommended 7 substances where related to PHT.

Table 110. Stakeholders responding to the call for Socio-Economic information by the COM

PHT	Chemical, Pharmaceutical, PET, Metal and Aerospace	IPI Global
		Framatome
		Indorama (NL)
		Adven
		JSC Neo GROUP
		Sipol
		Uniconfort
		Palsgaard
		660 Individual France
		STEAG new energies
		ADM SIO
		Grupa Azoty
		Leroux
		677 Individual Germany
		678 Individual Germany
		DSM
		Hydro Aluminium
		Indorama Spain
		ASD
		GIFAS
		Germany MS
		AR Metallizing
		WKO
		BASF
		AIA
		Rodun

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[89] Circabc (europa.eu)

[90] Circabc (europa.eu)

[91] Submitted recommendations - ECHA (europa.eu)

Furthermore, the Dossier Submitter had several telephone interviews with the Lead- and Member Registrants as well as individual users of the substance via its consultant.

In early 2018, the LR of PHT conducted a simplified socio-economic impact analysis for PHT, in the context of the process to identify Terphenyl, hydrogenated as SVHC. It was based on responses to a questionnaire (see template in Appendix 2) addressed to their downstream users. 24 completed questionnaires were received from SMEs and large companies, including HTF uses in different industrial sectors (aluminium, polymers, chemicals, ORC) and plasticiser users (sealants, coatings, adhesives). This information was used for the preparation of the Risk Management Option Analysis of the Dossier Submitter in 2020 (ISS, 2021).

In the course of the restriction proposal preparation, the Dossier Submitter launched, between the 21 of June and the 30 of September 2021, a SEA Questionnaire (see template in Appendix 4) to the PHT value chain, including manufacturers, importers, downstream users, article manufacturers and equipment manufacturers (e.g., boiler makers) via its technical consultant. In addition, some relevant industry associations were contacted. In total about 250 questionnaires were sent and 29 replies were received from different industry sectors. Further information is available under "**Annex E.4.** Economic Impact".

In conclusion, there were several opportunities for stakeholders to contribute and many responses and contributions were received and evaluated.

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APPENDICES

Appendix 1:

Exposure/Emissions Questionnaire (Source: LR, 2018)

Extended questionnaire regarding Identified Uses of the substance (Human Health and Environment)

Substance	Terphenyl, hydrogenated

Downstream User XY is using Substanze "Z" as a heat transfer fluid (HTF, PC 16) for Biofuel Manufacturing. This can be considered as one Identified Use. By doing this, the HTF containing 50% of Substanze "Z" is filled into the HT system from drums (PROC 8b). Prior to the transfer, the HTF is stored in a closed system (e.g. PROC 1). Industrial workers, who are responsible for performing these processes are wearing a respirator (estimated efficiency: 90 %) and gloves conforming to EN 374 (estimated efficiency 95 %) as hygiene standard. While storage is a continuous process, the HTF transfer is happening within 45 min. The processes are performed at a temperature of 20-25°C. All processes are performed indoors where basic general ventilation (1 - 3 Air changes per hour) and Local exhaust ventilation take place.
Measured data at these workplaces are not available. This example could be also extended by integrating further information on the system in which the HTF is used. This could compromise information on sampling, re-filling procedures, equipment cleaning as well as waste management (end of service-life). Please inetegrate all relevant activities from the initial use of the substance/product until its waste life.

Example 2
The Substance "Z" is used as heat transfer fluid (HTF, PC 16) for Biofuel Manufacturing. In this case, ERC 7 (Use of functional fluid at industrial site) represents the most suitable release category for the Identified Use "Heat transfer fluids" which defines specific (conservative) environmental releases. However, estimated releases to the different compartments can be provided as well. These release estimations are based on the technical measures and/or Operational Conditions (OCs) which are further specified in the example table below. In case you can estimate how much of the substance used in one year is released into air/water/soil, please fill out the respective cells (column E-G). If you cannot estimate releases of the substance into the environment, please leave this fields empty.

In case different life-cycle stages are relevant for your company (e.g. use as HTF with its respective service-life) and environmental emissions differ, please indicate this in the questionnaire.

				Estimated release to environmental compartment			**AIR - Type of RMM**		**WATER - Type of RMM**		**SOIL - Type of RMM**			
Identified Use Name	**Complete tonnage**	**Number of sites**	**ERC**	**Air [%]**	**Water [%]**	**Soil [%]**	**Technical and operational measures**	**Typical efficacy [%]**	**Technical and operational measures**	**Typical efficacy [%]**	**Technical and operational measures**	**Typical efficacy [%]**	**Remark on environmental releases (incl. wastelife)**	**General remarks / Monitoring data**
Example: ES2 (IS): Heat transfer fluids	50 tonnes/year	1	ERC 7 (Use of functional fluid at industrial site.)	2	0	0	Collecting and condensing of vented products	Default value: 98 % (max. achievable: 99 %)	no wastewater produced; wastewater during equipment cleaning is incinerated	not applicable	Substance is only handled indoors and direct release to soil can be exclused. Installation outside (e.g. pump groups) are on sealed surfaces.	not applicable	only negligible amounts of the substance may be released into air; environmental released to wastewater and soil can be excluded; used HTF are always incinerated according to local legislation	-

Please enter relevant information here

				Estimated release to environmental compartment			AIR - Type of RMM		WATER - Type of RMM		SOIL - Type of RMM		Additional remarks	
Identified Use Name / Exposure Scenario	Complete tonnage	Number of sites	ERC	Air [%]	Water [%]	Soil [%]	Technical and operational measures	Typical efficacy [%]	Technical and operational measures	Typical efficacy [%]	Technical and operational measures	Typical efficacy [%]	Remark on environmental releases (incl. wastelife)	General remarks

Appendix 2:

Questionnaire on Socio-Economic Impacts (Source: LR, 2018)

February 28, 2018

Glossary:

ALARA:

An acronym for „As Low As Reasonably Achievable‟ ALARA is an approach that aims to maintain the level of exposure to hazardous chemicals as far below regulatory limits as possible. It aims to achieve the lowest possible dose to the workers, the population or the environment.

Alternative Substance:

Alternative substances are defined as safer chemicals which are replacing more hazardous substances. This kind of substitution can bring substantial benefits for the company itself, the environment and the health of workers and consumers.

Authorisation:

Authorisation is a process within the REACH regulation that aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. It is a complex procedure which includes public consultations and time-limited authorisations for substances included in the process. Authorisation are applied for by industry.

https://echa.europa.eu/substances-of-very-high-concern-identification-explained

Exposure:

Chemical exposure can be defined as the measurement of both the amount of, and the frequency with which, a substance comes into contact with a person or the environment.

Restriction:

Restrictions are an instrument within the REACH regulation for risk reduction in order to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures for exposure minimization, specific labelling or restrictions in uses. Restrictions are carried out by the regulatory bodies.

https://echa.europa.eu/regulations/reach/restriction

SME:

Small and medium-sized enterprises (SMEs) are defined in the EU recommendation 2003/361. The main factors determining whether an enterprise is an SME are:

- **staff headcount**
- either **turnover** or **balance sheet total**

Company category	**Staff headcount**	**Turnover**	or	**Balance sheet total**
Medium-sized	< 250	≤ € 50 m		≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m
Micro	< 10	≤ € 2 m		≤ € 2 m

These ceilings apply to the figures for individual firms only. A firm that is part of a larger group may need to include staff headcount/turnover/balance sheet data from that group too. For more details: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

I. Company description

1. Please indicate the industry sector that you are representing. Use NACE nomenclature from below:
http://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Business_economy_by_sector_-_NACE_Rev._1.1

II. Type of company

2. Please indicate whether your company is considered a SME (*small and medium enterprise)* in the EEA. (See Glossary above for definitions.)

Yes	**No**

III. Use of Substance

3. Please explain how you use the substance and in what application. Tick box in case application is mentioned below.

Heat Transfer Fluid Biomass	Heat Transfer Fluid Aluminum	Heat Transfer Fluid Chemical Industry/PET	Heat Transfer Fluid Bakery/Food	Heat Transfer Fluid Others	Coatings	Others

Please describe Use in case application was not mentioned above and add further details.

In case of "Others", please specify with short description (e.g. Use as a plasticizer in paints; use as a HTF in pharma industry): In case of use as Heat Transfer Fluid (HTF), please add relevant temperature range: °C =

4. Please explain the benefits of the substance for your business.

(e.g. mention the reason you are using this Eastman product):

5. Please indicate the number of your employees exposed to or handling the substance in 2017 in the EEA (European Economic Area = EU + Iceland, Liechtenstein and Norway).

0	**1 – 5**	**5 - 10**	**10 - 50**	**50 – 100**	**>100**

6. Please indicate your turnover generated on products produced in the EEA (European Economic Area) using the substance in 2017 and your estimate of the total market size (in €) for products produced in the EEA using the substance in 2017

Your turnover concerned by the substance **in the EEA in 2017**	**Total market concerned by the substance** **in the EEA in 2017**

IV. Most plausible reaction and criticality

7. How important is the substance for your operations?

Extremely Important	**Important**	**Less Important**	**Do not know**

8. Suppose that the substance was to be phased out or its continued use subject to REACH Authorisation, what would be the most likely impact to your company? Please estimate the split of the turnover of products manufactured with the use of Terphenyl, hydrogenated generated in the EEA between options indicated below.

	Use of an alternative substance	**Business termination in the EEA**	**Business reallocation outside the EEA**
Phase Out: **% of the turnover generated using the substance in the EEA**			
REACH Authorisation: **% of the turnover generated using the substance in the EEA**			

9. If the substance is phased out or authorisation of the substance would force your company to terminate and reallocate your business, please explain why.

(e.g., why could you not further operate your business?):

10. If in question 8 you did not attribute any share of your turnover of products manufactured with the use of Terphenyl, hydrogenated generated in the EEA to the REACH Authorisation application, please explain why.

11. Suppose that the continued use of the substance would require complying with a REACH Restriction imposing release limit **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA), determined in the REACH registration dossier of Terphenyl, hydrogenated. Please estimate the split of your turnover of products manufactured with the use of Terphenyl, hydrogenated generated in the EEA between options indicated below.

	Continued use of the substance	**Use of an alternative substance**	**Business termination in the EEA**	**Business reallocation outside the EEA**
% of the turnover generated using the substance in the EEA				

12. If the REACH restriction imposing the aforementioned release limit (ALARA) would force you to terminate and reallocate your business, please explain why.

V. Use of an alternative substance

13. Please indicate how you evaluate potential alternatives to the substance for your industry. Please evaluate their technical and economic feasibility and their fitness for use in your application.

Substance	**General assessment of the alternative**
Alternative 1 (please specify)	
Alternative 2 (please specify)	
Alternative 3 (please specify)	

14. Please provide a rough estimate of additional costs that you would encounter when switching to the alternative.

Substance	**Additional operating costs/annum (e.g. refills, top-ups)**	**Additional R&D and investment costs**	**Costs for structural alteration/ replacement measures**	**Cost resulting from yield losses**	**End-of-life costs**
Alternative 1 (please specify)					
Alternative 2 (please specify)					
Alternative 3 (please specify)					

15. Please explain your answer above - How would potential alternatives affect your product or operations performance, including costs?

Substance	**Expected impacts on product and operational performance**
Alternative 1 (please specify)	
Alternative 2 (please specify)	
Alternative 3 (please specify)	

VI. REACH compliance costs Restriction

16. Please indicate a rough estimate of compliance costs of the REACH restriction considered in this questionnaire.

REACH Restriction	**Additional operating costs / annum**	**Additional R&D and investment costs**
ALARA release limit		

17. Please explain why (if at all) your cost would increase under the considered restriction.

REACH Restriction with ALARA release limit	

VII. Lost jobs

18. How many jobs would you be forced to terminate in the EEA in each considered scenario?

Number of lost jobs	**REACH Authorisation route**	**REACH Restriction with ALARA Release Limit**
0-10		
10-50		
50-100		
Other (include precise answer if available)		

19. Please explain what types of jobs would be lost in the EEA, in which regions and for what reasons.

REACH authorisation route		
REACH restriction with ALARA release limit		

VIII. Other effects

20. Please indicate any other information concerning that you consider relevant for the socio-economic analysis of the substance.

Appendix 3:

EU Commission Questionnaire on Socio-Economic Impacts (Source: ECHA, 2020, during SVHC Prioritisation Process)

PRIORITISATION

PUBLIC CONSULTATION ON SOCIO-ECONOMIC IMPACTS

The objective of this consultation is to inform policy makers about the economic and social consequences of the authorisation requirement. You are invited to provide specific information about the use of the substance and available alternatives, impacts on the environment, public health and society, and impacts on the supply chain and competitiveness.

This questionnaire contains 32 questions and is aimed at individuals, organisations, companies, as well as Member States. Due to the variation of the questions, it is possible that you are not able to answer to all of them.

Thank you for your contribution!

SUBSTANCE

1. What is the name of the substance on which you comment? Please specify if your replies concern more than one substance, e.g. a group of substances with similar uses.

USES

2. What is the use of the substance (sectors, types of uses, categories of products, etc.)?
    a. In general?
    b. By your company? *(only for companies)*

3. Can you specify the use in terms of volume/value?
    a. Overall in the EU?
    b. By your company? *(only for companies)*

4. Is the substance essential for certain uses (e.g. in terms of being indispensable for the product or process, for ensuring safety of the production process)? Which ones? Be specific on which property/function of the substance makes it essential.
5. Is the substance present in a finished article? If yes, at what concentration? Environment and Health?

6. Does the use of the substance imply any risks/exposure/releases for workers, consumers or environment?

7. What measures have been put in place to prevent these risks/exposure/releases?

8. How can exposure to workers or consumers be further reduced? How can releases into the environment be further minimised?

9. Are you aware of any relevant information (e.g. study or article) quantifying the cost of environmental or human health impacts related to the use of the substance?

AVAILABILITY OF ALTERNATIVES

10. Are you aware about any alternative substances, processes or technologies currently available for the use(s) of the substance?
    a. If yes, what are these alternatives and where are they used?
    b. What are the main differences between using these alternatives compared to the substance in question?
    c. What are the hazard properties of the alternatives compared to the substance in question?
    d. Are the alternatives already available, i.e. drop-in alternatives? Or do their implementation require changes in the production process and investments?
    e. What is the expected price of alternatives, per unit (e.g. per kilo, tonne)?
    f. Would an alternative require the same, more or less volume (e.g. in kilos, tonnes) compared to the substance in question?

11. Would the use of these alternative substances, processes or technologies have a positive or negative impact, or no effect, on sustainability (considering the whole life cycle: manufacture of the substance/production/consumption/waste/recycling)?

12. Are you planning to substitute the substance? If so, by when? *(only for companies)*

13. Are there uses for which there are no alternatives (substances, processes or technologies)? If yes, could you explain why?

14. If there are no alternatives, are you aware of any research, development and innovation efforts attempting to develop them? If so, how long do you expect that the development / testing can take?
    a. In the EU or in non-EU countries?
    b. By your company? *(only for companies)*

MARKET AND SUPPLY CHAIN

15. Specifying the use of the substance, both overall in the EU and by your company, what is the annual volume/value of the substance:
    a. Placed on the EU market?
    b. Manufactured in the EU?
    c. Imported into the EU?
    d. Exported from the EU?

16. Could you specify the sector in which the substance is used and describe the supply chain, including your role in the supply chain?

17. Can you provide data on the turnover of the concerned sectors and the number of people employed? What is the turnover of the substance/substance-related products vs. the total turnover of the sector?

18. Can you estimate the relative weight of SMEs in the concerned sectors (in terms of number of companies and employment) in your country /in the EU?

19. Are the manufacturers of the substance or downstream users concentrated in a single/limited number of Member States or in a limited number of regions?

COMPETITIVENESS

20. What would be, or has been, the overall cost and time of substitution for the particular use you are providing information on? This includes (if relevant) the need of changes in the production process, need for new product testing, qualification and certification, etc.

21. What is the expected impact of substitution costs on the costs of your inputs or final products? What is expected impact on your sales in the EU/outside the EU countries? *(only for companies)*

22. Please describe the typical length of the order cycle / investment cycle.
    a. To the concerned sectors?
    b. To your company? *(only for companies)*

23. Please describe what the impacts of including the substance in Annex XIV of REACH would be? This includes changes in the competitive position with respect to non-EU competitors in the EU market and in third markets.
    a. To the concerned sectors?
    b. To your company? *(only for companies)*

OTHER IMPACTS OF INCLUSION IN ANNEX XIV (innovation and business opportunities)

24. If the substance is included in Annex XIV to be eventually phased out, would it create business opportunities (e.g. gaining new markets or higher market share, development of alternative substances / products / production techniques)?
    a. In your sector?
    b. For your company? *(only for companies)*

25. What effects do you expect on enterprises' capacity to innovate? (The capacity to produce more efficiently and higher quality and a larger scale of products and services and the capacity to bring R&D to the market)

26. Are you aware of any likely effects on recycling or sustainability?
27. In your opinion, if the substance is included in Annex XIV to be eventually phased out, would the economy, society or the environment be better or worse off (all factors considered)? Why?

APPLICATION FOR AUTHORISATION *(only for industry actors)*

28. If the substance is included in Annex XIV, would you consider applying for an authorisation? Are you aware if your suppliers/downstream users would consider to apply?

29. How would you envisage that the submission of an application for authorisation could be organised, considering your specific uses and the structure of the supply chain: would you envisage an application by manufactures/importers of the substance or formulators (upstream the supply chain)/ or applications by downstream users or a combination of all)?

30. What main challenges in preparing an application do you expect for your specific case? Would you envisage applying for your own uses or would you apply to cover uses of your downstream users? Would you apply jointly with other downstream users covering the same use?

REGULATORY OPTIONS

31. Do you consider that other regulatory options could better address the concerns for human health or the environment for which the substance is recommended for inclusion in Annex XIV? What are these regulatory options and why would they better address the concerns?

OTHER REMARKS

32. Would you like to provide additional comments/information on the possible socio-economic impacts?

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Appendix 4:

Questionnaire on Socio-Economic Impacts by Dossier Submitter (June 2021)

Questionnaire for Terphenyl, hydrogenated

I. Company description

1. Please provide identification information of your company in the EEA[92] and the relevant contact person.

Company Name	
Country	
Contact person name	
Role	
Telephone number	
e-mail address	

2. Please indicate the industry sector that you are representing. Use NACE nomenclature from:
   [Archive: Business economy by sector - NACE Rev. 1.1 - Statistics Explained (europa.eu)]

Industry sector	
NACE code	
Additional information	

3. Please provide information on your company at the EEA level (use aggregated figures)

Total Turnover	
Total number of workers	
Is your company an SME[93]?	
Number of sites in the EEA in which PHT is handled (please specify country per site)	

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[92] EEA: European Economic Area = EU + Iceland, Liechtenstein, and Norway. It is expected that all the replies to the following questions refer to this economic area.

[93] Small and Medium-sized Enterprise, according to the recommendation from the European Commission of 6 May 2003. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32003H0361

II. Uses and volume

4. Please indicate volume of PHT used[94] in the past three years (expressed as tonnes per annum)

2018	2019	2020
Comments:		

5. Please indicate in which applications / sectors of use your company is using PHT, including estimated% of volume[95] used in each sector.

Sector of use	Estimated% of volume used		
	2018	2019	2020
Heat Transfer Fluid			
Plasticiser			
Coatings and sealants: industrial applications			
Coatings and sealants: aerospace applications			
Processing solvents / processing aids			
Laboratory chemicals			
Microscope immersion oils			
Articles (connectors)			
Articles (temperature controls and thermostats)			
Other (please specify):			

6. Is PHT present in finished articles? If 'Yes', at what concentration?

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[94] It is assumed that your role in the supply chain is as DU of PHT; if you imported any volume of the substance in the past years, please provide information on imports in the "Comments" box.

[95] To be calculated as volume used in each sector, divided by total volume used (summation of values provided in question 4, per year).

III. Economic information and alternatives

7. Please indicate relevant business indicators (please specify units in which data is provided, e.g., tonnes, k€, m€).

Business indicator	**2018**	**2019**	**2020**
Revenue linked to products manufactured involving the use of PHT			
Net profit (after taxes) linked to products manufactured involving the use of PHT (please specify parameter used)			
% of your company's business linked to products manufactured involving the use of PHT (e.g., ratio between revenue obtained from PHT and total company revenue)			
EEA market share (%) of your company for products manufactured involving the use of PHT			

8. In addition to the economic information provided above:
    a. How would you describe the importance of the use of PHT for your business?

Extremely Important	**Important**	**Not very important**

    b. If you have answered "extremely important" or "important", could you please provide further details, if possible, in terms of why PHT is critical for your business?

In order for an alternative to be considered viable, it must be technically and economically feasible, provide an equivalent level of performance, be available in sufficient quantity when needed by industry, and it has to result in overall reduced risk compared to the chemical of concern. Alternatives may involve replacement of a chemical by another chemical, or by a combination of chemicals, or by switching to different technologies. If an alternative is not considered viable at present time, it needs to be evaluated if it is expected that it will become viable in the future.

9. Please provide information related to activities developed by your company, aimed

at finding or introducing alternatives to the use of PHT, including investment and duration

10. Please indicate how you evaluate potential alternatives[96] to the use of PHT for your specific use(s) in the table below, according to the following parameters.

   a) Technical viability: describe if the alternative can be used for the required technical function at your site. Indicate if differences in performance are expected that would render the alternative unacceptable for your use, also if any tolerances for performance deviation are established in order to justify the answer.
   b) Economic feasibility: describe if the implementation of the alternative would be justified from a business perspective, and if this can be done without business disruption. Provide details on costs that the company would need to face if the alternative were to be implemented (e.g., raw material costs, plant modifications, training of staff, investment cycle, etc.).
   c) Risk/Regulatory comparative: Evaluate potential risks for human health and the environment for the alternatives; are they regulated equally to PHT, or can it be expected that they will be in the future?
   d) Time to implementation: if it is not possible to implement an alternative now, but it could be possible in the future, provide a justified timeline for the implementation.

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[96] Even if an alternative is not considered to be viable based on the description provided at the beginning of this section, its characteristics should be described, to provide evidence that a proper assessment of alternatives has been made.

Alternatives[97]	**General assessment of the alternative**
Alternative 1 (describe alternative and technical function)	Technical viability:
	Economic feasibility:
	Risk/Regulatory comparative:
	Timeline to implementation (if feasible):
Alternative 2 (describe alternative and technical function)	Technical viability:
	Economic feasibility:
	Risk/Regulatory comparative:
	Timeline to implementation of alternative (if feasible):

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[97] If more alternatives have to be assessed, please add rows, or provide more copies of the current page as needed.

11. If you were forced to substitute PHT from use in your processes, what do you think would be the consequence for your company? Please mark with "X" the option that you believe is more likely. If possible, specify in the box below how many jobs would be lost in the EEA in case of termination of business in the region, or what would be the expected cost and time for implementation of an alternative.

Switch to alternative substances	**Business reallocation outside EEA**	**Company would abandon business related to PHT globally**

12. If the use of PHT was to be allowed under conditions that would imply the adoption of additional technical measures[98], would it be possible to establish a limit of investment that would be acceptable to your company to continue the business?

13. Please indicate any other information of concern, or that you consider relevant for the socio-economic evaluation of PHT, keeping in mind indirect impacts for the EU economy, environment, and society (e.g., impact on capacity for innovation, impacts on environment due to more/less efficient processes, increased/decreased costs of products, etc.).

IV. Emissions and exposure

14. Are environmental emissions from PHT adequately controlled from your use of the substance? Please provide information, detailing what containment systems are in place to ensure that releases of PHT are minimised. For example, for Heat Transfer

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[98] For Heat Transfer Systems, a valid reference on technical standards that could be required for operating HTS is the German Industry Standard DIN 4574 – more information on Section VI

Systems the following should be considered.

a. Existence of collection vessel.
b. Performance of tests to prove the suitability of joints.
c. Use of containment devices installed beneath flanges and pumps
d. Use of an inert gas as protection of the fluid against oxidation.
e. Periodical evaluation of the fluid quality (please, specify frequency).
f. Use of pumps with mechanical seals.
g. Use of valves with mechanical seals.
h. Repetitive inspections performed by competent technical bodies.
i. Control programs for potential leakages.
j. Fluid level monitoring.
k. Specific detail on containment measures would be useful for:
    - Drain of PHT
    - Fill and top-up of PHT
    - Disposal of degraded PHT

15. For Heat Transfer Systems, have any of the following Standards and Regulations been considered during design, construction, and operation of the HTF system?

	Considered?
General Product Safety Directive 2001/95/EC	
Pressure Equipment Directive 2014/68/EU	
German Industry Standard DIN 4754	
Other National Standards and Regulations (please, specify)	

16. For Heat Transfer Systems, please provide information on the following parameters:

	HTS 1	HTS 2	HTS 3
Operating temperature			
Pressure			
Volume of PHT used			
Time of service of HTF system			

17. Please provide information on disposal of PHT, indicating volumes disposed of and how frequently disposal occurs, as well as destination of disposed product.

18. Do you have any information or approximate indication about yearly emissions of PHT to different environmental compartments (e.g. soil, air, water)?

19. Please provide any further information that you consider relevant for the purpose of controlling emission of PHT to the environment.