EUROPEAN CHEMICALS AGENCY

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on

Terphenyl, hydrogenated

ECHA/RAC/RES-O-0000007224-79-01/F

ECHA/SEAC/RES-O-0000007305-77-01/F

IUPAC NAME(S): Terphenyl, hydrogenated

EC NUMBER(S): 262-967-7

CAS NUMBER(S): 61788-32-7

10/03/2023

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LIST OF ACRONYMS AND ABBREVIATIONS

CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CSP	Concentrated Solar Power
CSR	Chemical Safety Report
C/E	Cost-effectiveness
C&L	Classification and Labelling
DP	Dechlorane Plus
EAC	Equivalent Annual Cost
ECHA	European Chemicals Agency
EEA	European Economic Area
EEE	Electrical and electronic equipment
EiF	Entry into Force
EPA	Environmental Protection Agency
ERC	Environmental Release Category
EU	European Union
GDP	Gross domestic product
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 (according to REACH Article 8)
ORC	Organic Rankine Cycle
PBT	Persistent, Bioaccumulative and Toxic
PC	Product Category

PEC	Predicted Environmental Concentration
PET	Polyethylene terephthalate
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)
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
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

About this Report

The preparation of this restriction dossier on Terphenyl, hydrogenated was initiated on the basis of Article 69(4) of the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1]. The proposal has been prepared using the most recent version of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of **Annexes** with more detailed information and analysis as well as details of the references used.

The Istituto Superiore di Sanità (ISS - on behalf of the Ministry of Health), hereafter referred to as the Dossier Submitter, would like to thank the many stakeholders that made contributions to the stakeholder consultations and provided information during interviews and meetings.

RAC and SEAC box

RAC and SEAC noted several inconsistencies between different sections and between the Background Document and its annexes. These inconsistencies relate to the conditions of the restriction proposal concerning derogations.

The justification for this consideration is explained in the RAC and SEAC opinion.

Summary

The substance was identified as potentially having Persistent, Bioaccumulative and Toxic (PBT) properties. Accordingly, in 2008 Terphenyl, hydrogenated was included in Commission Regulation 465/2008/EC[2] for further assessment as part of the Existing Substances programme. As a substance characterised as an Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), Finland assessed Terphenyl, hydrogenated using a weight-of-evidence approach considering the properties of its constituents and published its evaluation report in 2017, concluding that Terphenyl, hydrogenated is very persistent and very bioaccumulative (vPvB). In November 2017 the inclusion of Terphenyl, hydrogenated as a Substance of Very High Concern (SVHC) was recommended and in 2018 it was duly added to the Candidate List.

Terphenyl, hydrogenated is not manufacturered in the European Union (EU) and the imported volume for 2020 is estimated with 7 500 tonnes. The main use with approximately 90% annual tonnage is as a high-temperature Heat Transfer Fluid (HTF). Other uses include applications as processing solvent and as plasticiser. Only two potentially viable alternatives exist for the HTF-use, which also have similar persistent and bioaccumulative properties. Both alternatives have been included in the Commission's Roadmap on Restriction[3] as part of a functional grouping approach for HTF use.

The Dossier Submitter concluded that although the HTF use is via closed loop manufacturing systems, environmental emissions are still possible. Furthermore, as vPvB and PBT chemicals

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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://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R0465

[3] Microsoft Word - Draft-Restrictions-Roadmap.docx (chemicalwatch.com)

are treated as non-threshold substances, even low levels of environmental emissions could be sufficient to demonstrate a risk and therefore a REACH Restriction was identified as the most relevant and proportionate Regulatory Management Option (RMO).

Moreover, for all non-HTF uses an unacceptable risk for the environment has been identified. When Terphenyl, hydrogenated 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 potential exposure and emission sources of Terphenyl, hydrogenated 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 Terphenyl, hydrogenated is used as a **plasticiser** it may be released into the environment during the various life cycle steps. The Lead Registrant (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 Terphenyl, hydrogenated 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 (see **Annex B.9.**: Exposure Assessment). Moreover, under the plasticiser use Terphenyl, hydrogenated will be incorporated into/onto an article. At the end of the service life, the article has to be disposed. During the disposal at a waste treatment plant Terphenyl, hydrogenated 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 24 000 entries in the SCIP database containing Terphenyl, hydrogenated have been notified to the Substances of Concern In articles as such or in complex objects (Products) (SCIP) database. Most entries are related to the use as plasticiser in polymers. 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 Terphenyl, hydrogenated.

The worst-case cumulative releases of Terphenyl, hydrogenated from 2025 to 2044 have been estimated with a total volume of 19 584 tonnes within the 20 years considered, which corresponds to an average annual release of 979 tonnes.

Terphenyl, hydrogenated 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. 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 Terphenyl, hydrogenated. 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.

PBT/vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse even when releases cease. Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of risk characterisation ratios. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk. Therefore, the Dossier Submitter concluded that the risk associated to the use of Terphenyl, hydrogenated is not adequately controlled and action is required on a Union-wide level and that the proposed restriction is the most appropriate measure.

In line with the Committee for Socio-Economic Analysis (SEAC) recommendation (ECHA, 2014), proportionality of the proposed restriction is assessed through a cost-effectiveness (C/E) analysis.

The proposed restriction is targeted to the exposure situations that are of most concern, e.g. the use of Terphenyl, hydrogenated as a plasticiser and during the life-cycle stage of articles. The proposed restriction is effective and reduces potential risks to an acceptable level within a reasonable period of time.

The proposed restriction 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.

Furthermore, the proposed Restriction has a high C/E (€ 90/kg Terphenyl, hydrogenated emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. The total costs have been estimated with approximately € 1.5 billion, assuming a 5-year transitional period for plasticiser use for the production of aircrafts and their spare parts.

RAC and SEAC box

RAC and SEAC proposed changes to the conditions of the restriction for derogations.

The details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.

Based on analysis of the effectiveness, practicality and monitorability of the assessed options, the below Restriction is proposed by the Dossier Submitter. The final legal wording will be ultimately decided by the European Commission after receiving the Risk Assessment Committee (RAC) and SEAC opinions.

Proposed Restriction:

Brief title: Restriction on the use of Terphenyl, hydrogenated and derogations.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Terphenyl, hydrogenated CAS No: 61788-32-7 EC No: 262-967-7	1. Shall not be placed on the market from [18 months after entry into force]: a) As a substance on its own. b) As a constituent of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w.

	c) In articles or any parts thereof containing Terphenyl, hydrogenated in concentrations equal or greater than 0.1% w/w. 2. By way of derogation, Paragraph 1 shall not apply to the use and placing on the market as a heat transfer fluid, provided that such sites implement strictly controlled closed systems (SCCS) with technical containment and organisational measures to prevent environmental emissions. 3. By way of derogation, Paragraph 1 shall not apply to the use and placing on the market in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats, as long as these applications are covered by the WEEE Directive (2012/19/EU). 4. By way of derogation, Paragraph 1 shall apply after entry into force +5 years, for the use and placing on the market in aerospace and defence applications and their spare parts, maintenance and repairs.

Report

1. The problem identified

Terphenyl, hydrogenated has been identified as a vPvB substance and was included in the Candidate List on 27 June 2018. This UVCB substance was assessed by evaluating the different relevant constituents present in the substance. At least one of these constituents (ortho-terphenyl) fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1%), Terphenyl, hydrogenated is considered to fulfil vPvB criteria. Detailed information is provided in Section 8 to the CSR of the LR (Solutia, 2019) and the SVHC Support Document (ECHA, 2018a). Also, further information is available in **Annex B.1.2.** on Composition of the substance, **Annex B.4.1.** on Degradation, **Annex B.4.3.** on Bioaccumulation, and **Annex B.8.1.** on the assessment of PBT/vPvB properties.

In 2020/2021 the Dossier Submitter conducted a Regulatory Management Option Analysis (RMOA) which concluded that a restriction is the most appropriate regulatory instrument to address the substance (and potentially further substances used as HTF having a similar hazard profile in the future). The analysis clearly demonstrates that Restriction is the most proportionate regulatory management option. Conversely, Authorisation is considered to be a disproportionate, less practical and less effective provision, also on the base of the lack of suitable alternatives and that the investment cycles for heat transfer fluids on industrial sites are extending beyond the typical authorisation review periods granted under REACH.Chapter E.1.3. in the Annexes further outlines the proportionality of restriction versus authorisation.

Due to the fact that only two viable alternatives exist for Terphenyl, hydrogenated in industrial heat transfer applications, Finland conducted in 2020 an RMOA on the two existing alternatives[4]. This RMOA was part of a functional grouping approach for high temperature, non-pressurised heat transfer fluids (HTF), which might be used as substitutes for Terphenyl, hydrogenated. As a result of the Finnish RMOA, 1,2,3,4,-tetrahydro-(1-phenylethyl)-naphthalene (EC 400-370-7) was included in CoRAP for substance evaluation[5] and Dibenzylbenzene, ar-methyl derivative (EC 258-649-2) has been scrutinised under the Dossier Evaluation process[6]. This (technical) functional grouping approach can be understood as a tool to ensure that chemicals with different chemistry but similar hazard properties and same use pattern, resulting from their technical function, are regulated together in the same timeframe in order to help avoid regrettable substitution by implementing potential risk management measures jointly. Because functionality of chemicals results in specific, intrinsic properties, it is expected that the physical-chemical properties and environmental behaviours will also be similar among substances with a similar function. However, since these two alternatives have not yet been subject to the same level of scrutiny applied at EU level under REACH as Terphenyl, hydrogenated, the Dossier Submitter decided to submit a Restriction Proposal on Terphenyl, hydrogenated and not on the “functional group”. Though, it can be assumed that the restriction of Terphenyl, hydrogenated can serve as an example for the restriction of the other two substances.

On the 21 April 2021, the Dossier Submitter registered its intention to submit a Restriction Proposal on Terphenyl, hydrogenated.

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[4] Assessment of regulatory needs list - ECHA (europa.eu)
[5] https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e183ed8910
[6] https://echa.europa.eu/de/information-on-chemicals/dossier-evaluation-status/-/dislist/details/0b0236e1814c1de4

Although o-terphenyl is the component that categorises Terphenyl, hydrogenated as a vPvB substance, the restriction proposal applies to the UVCB substance as a whole for regulatory and compositional reasons.

Regarding the regulatory process, it is worth noting that both the Annex XV Dossier for identification of the substance as SVHC on the basis of the criteria set out in REACH Article 57 (Tukes, 2018), and the support document for identification of the substance as an SVHC because of its vPvB properties (ECHA, 2018a), concluded on the assessment of Terphenyl, hydrogenated as a UVCB substance and not on the assessment of their individual components. Literally, both documents state: "As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1% w/w), terphenyl, hydrogenated is considered to fulfil the vPvB criteria. In conclusion, terphenyl, hydrogenated meets the criteria for a vPvB substance according to Article 57 (e) REACH".

Regarding the composition of Terphenyl, hydrogenated, o-terphenyl is part of the UVCB substance (as the other individual components) and cannot be considered in a separate way. O-terphenyl (CAS 84-15-1) is not a chemical product itself and it is not marketed as an individual substance in the EU. Furthermore, it has not been registered under REACH and, therefore, its individual restriction would not make sense.

When Terphenyl, hydrogenated is used as a plasticiser it may be released into the environment during the various life cycle steps. The exposure calculation clearly showed that the plasticiser use is far more critical for risk management than the HTF use. For all non-HTF uses an unacceptable risk for the environment has been identified. When Terphenyl, hydrogenated 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.

Just before the dossier sumission in March 2021 the SCIP Database had a total number of more than 12 000 database entries of articles containing Terphenyl, hydrogenated. This is demonstrating that articles and their service life pose a risk to environmental releases too and need to be restricted as well. The current implemented risk management measures are not sufficiently effective to control the risks at the waste stage of articles. In December 2022, the SCIP Database had a total number of almost 25 000 database entries (or factsheets).

The article categories notified were reported as follows:

- Measuring instruments and apparatuses
- Electrical machinery and equipment and components thereof
- Machinery and mechanical appliances and components thereof
- Base metals and articles thereof
- Vehicles, aircraft, vessels and associated transport equipment and parts thereof
- Articles of stone, plaster, cements…
- Plastics and articles thereof
- Products of the chemical or allied industries
- Pulp of wood or of other fibrous cellulosic material
- Miscellaneous manufactured articles
- Textiles and textile articles, knitted or crocheted fabrics

Uses of terphenyl hydrogenated in mixtures are reported in the SCIP database in cases where the mixture become part of the article (e.g. coated articles) with an integral mixture.

Suppliers of articles notified that Terphenyl, hydrogenated was for example included in adhesives and sealants but also in printing inks and toners. The use of Terphenyl, hydrogenated as HTF in domestic appliances and electrical machinery was reported as well. The use of Terphenyl, hydrogenated in these cases is as HTF in the electromechanical temperature controls of ovens and stoves[7] or of electrical capillary thermostats.

Terphenyl, hydrogenated is used in sealants and as an additive in polymers. Relevant materials include silicones, rubbers, epoxies, polyurethanes, and phenolic resins. In addition, Terphenyl, hydrogenated is used in metals applications.

The information provided in the SCIP database was used to confirm and identify uses. The SCIP database confirms that Terphenyl, hydrogenated is used in articles, which are used in complex objects, such as vehicles (cars, trains, planes), Electrical and Electronic Equipment (EEE), construction and building components, or furnishings.

Separation and properly management of Terphenyl, hydrogenated containing parts in the waste phase seems difficult. Therefore, it seems very complex that Terphenyl, hydrogenated containing waste from articles will be removed from waste streams in an economically feasible way. In addition, high recycling rates required for different waste streams (e.g., end-of-life vehicles, waste EEE recycling) in the EU and as well the Circular Economy prohibit large-scale incineration. In addition, the capacity of high-temperature incineration could be an issue due to the large volumes of wastes from EEE and the automotive sector.

There are examples that for some chemicals the human and environmental exposures occur through product use and disposal, rather than in the manufacturing stage. For example, in the case of DEHP, used as a plasticizer in polymer products, about 95% of the emissions occur from end-product uses and waste handling. Referring to the Dechlorane Plus (DP) Restriction Report (ECHA, 2021a), DP was released to the environment significantly during use phase and from waste disposal and recycling activities. On a global scale, the highest DP concentrations were detected close to known production sites or electronic waste (e-waste) treatment facilities. The use of DP in articles was as well recommended to be banned.

The DS submitter therefore assumes, that current OC's and RMMs are not sufficient to address the concern at the waste-stage because the uses in articles are widespread, complex and partly unknown.Therefore a complete restriction of Terphenyl, hydrogenated use in articles (> 0.1% w/w) is the most appropriate risk management measure, except the use as HTF in thermostat due to lack of risk. An estimation of costs related to these measures is therefore not possible.

1.1. Manufacture and Uses

This section draws on **Annex A** which provides further details on the manufacture, import and use of Terphenyl, hydrogenated.

According to the information from the REACH Registration on the ECHA public dissemination website (ECHA, 2021b), there are currently 6 active registrants of Terphenyl, hydrogenated. The amount of Terphenyl, hydrogenated manufactured and or imported into the EU is, according to registration data on the ECHA public dissemination website in the range of 10 000-100 000 tonnes per year. This is diverging from the volumes reported by industry and the information collected during stakeholder consultations. Based on information received

[7] REACH - Information on critical substances (miele.co.uk)

from stakeholders, the global volume of Terphenyl, hydrogenated manufactured 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 per year includes as well estimates of imports in articles and formulations in the order of 100 tonnes per year. A significant number of SCIP database entries (> 24 000) are reported in the SCIP Database (ECHA, 2021c), and it is proven that mixtures containing Terphenyl, hydrogenated 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. The trend in the EU and globally shows a significant increase of volume during the last years, the Danish Environmental Protection Agency (EPA) referenced in its report[8] a steady growth in the HTF market. This was confirmed by feedback during the public consultation.**Table 1** provides an overview of estimated EU volumes of Terphenyl, hydrogenated.

Table 1. Estimated volumes in the EU, based on stakeholder information.

	Terphenyl, hydrogenated Volume in EU (tonnes per year) - incl. in Articles imported		
	2020	2019	2018
Non-EU Manufacturers (via their ORs or EU affiliates)	7 000	5 100	4 200
EU Importers	500	400	200
Total Volume in EU (tonnes per year)	7 500	5 500	4 400

The main use of Terphenyl, hydrogenated (approximately 90% of the tonnage according to the stakeholder feedback) is as HTF in industrial installations. 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 Terphenyl, hydrogenated 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. Terphenyl, hydrogenated is used as a plasticiser mainly for the production of coatings, sealants, and adhesives and in polymer applications. The final coatings, 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

[8] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net).

application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, Terphenyl, hydrogenated is also used as plasticiser in coatings and inks.

Very little information regarding the use of Terphenyl, hydrogenated, mainly as plasticiser, for the production of coatings, paints and inks, and as additive in plastic applications, was provided in the different public consultations (official and unofficial) issued for this substance: the LR SEA questionnaire from 2018, the socio-economic impact questionnaire from COM on 2020, the responses to the 10th Recommendation received by ECHA in 2020, and the DS SEA questionnaire from 2021. Also, no information regarding these uses can be found via internet search.

As commented in **Annex D.2.**, the decreasing participation in the SEA questionnaires from 2018 to 2021 suggests that the industry involved in these uses has already started the reformulation/substitution process of the substance. But no information is available regarding the alternative substances used in substitution.

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 2** was prepared showing the EU volumes used for the main applications of Terphenyl, hydrogenated 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).

As shown in the below **Table 2**, the main use of Terphenyl, hydrogenated with approximately 90% annual tonnage is as a high-temperature non-pressurised HTF. When used as an HTF, Terphenyl, hydrogenated 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 2. 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/Aids	35	0.47
Corroson Inhibitor Oils	4	0.05
Analytical Standards	1	0.01
Microscope Immersion Oils	0.5	0.01
Total non-HTF	**771**	**10.32**

Table 3 outlines the use as HTF and it shows the estimated EU installed base in existing plants handling Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated into the environment.

Approximately 35% of that volume (2 275 tonnes) was used for replacements of the whole Terphenyl, hydrogenated 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. 60% (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 3. 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 Terphenyl, hydrogenated 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.

According to feedback of the lead registrant, all uses as HTF should be considered as industrial and no uses are considered professional. **Table 4** 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 4** since the United Kingdom (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 Terphenyl, hydrogenated 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 4. 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**

Table 5 provides an overview on the number of systems installed and installed volume per EU Member State. Italy, Germany, and France cover 70% of the volume and 75% of the systems.

Table 5. 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**	**25 000**			

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

1.2. Hazard, exposure/emissions and risk

1.2.1. Identity of the substance(s), and physical and chemical properties

This section draws on **Annex B** which provides further details on the identity, physical and chemical properties for Terphenyl, hydrogenated.

1.2.1.1. Name and other identifiers of the substance(s)

An overview of the name of the substance and other identifiers is given in **Table 6**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021b), the SVHC Support Document (ECHA, 2018a) or the Chemical Safety Report (CSR) from the LR (Solutia, 2019).

Table 6. 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

<u>Type of substance:</u>

UVCB.

<u>Description of the UVCB substance:</u>

Terphenyl, hydrogenated is produced by hydrogenation of a mixture of o-, m- and p-terphenyl and various quaterphenyls. The degree of hydrogenation is typically below 75%.

Terphenyl, hydrogenated is a complex substance containing isomers of terphenyl and quaterphenyls as well as their hydrogenated versions.

<u>Methods of manufacture of the UVCB substance Terphenyl, hydrogenated:</u>

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)[9].

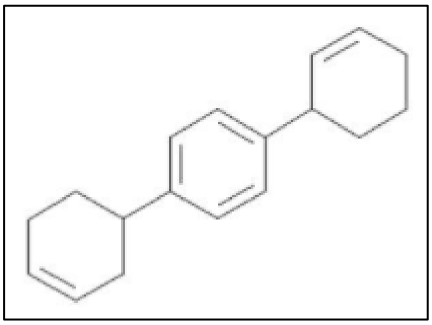
According to a patent (CN103804114A, 2014), Terphenyl, hydrogenated is manufactured within the production process of biphenyl (C12H10, CAS 92-52-4). Basically, terphenyls are manufactured merely as an accompanying product in the manufacture of biphenyl and vice-versa. Consequently, the economical manufacturing of both substances separately is not possible on commercial scale. The Danish EPA published in its report on Biphenyl (40 - FINAL REPORT, 2014)[10], that Monsanto (now Solutia) manufactures 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:

Figure 1. Structural formula of Terphenyl, hydrogenated**.**



1.2.1.2. 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.

The composition of the substance (boundary) according to the SDS[11] is the following:

[9] 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

[10] 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

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

Table 7. 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

1.2.1.3. Physicochemical properties

An overview of the physiochemical properties is given in**Table 8**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021b), the SVHC Support Document (ECHA, 2018a) and the CSR of the LR (Solutia, 2019).

Table 8. Physicochemical properties

Property	Substance	Value	Reference
Physical state	Terphenyl, hydrogenated (CAS 61788-32-7)	Clear pale-yellow liquid	Lead Dossier
Melting point / Freezing point	Terphenyl, hydrogenated (CAS 61788-32-7)	below -24°C (pour point)	ECHA, 2018a
Boiling point	Terphenyl, hydrogenated (CAS 61788-32-7)	342-400°C (1 013 hPa)	ECHA, 2018a
Density	Terphenyl, hydrogenated (CAS 61788-32-7)	1 013 (20°C)	ECHA, 2018a
Vapour pressure	Terphenyl, hydrogenated (CAS 61788-32-7)	0.002 hPa (20°C)	ECHA, 2018a
Partition coefficient	Terphenyl, hydrogenated (CAS 61788-32-7)	5.3 - 6.5 (20°C)	ECHA, 2018a
Water solubility	Terphenyl, hydrogenated (CAS 61788-32-7)	0.061 mg/L (20°C)	ECHA, 2018a
Flashpoint	Terphenyl, hydrogenated (CAS 61788-32-7)	170 °C (1013 hPa)	ECHA, 2018a

Auto flammability	Terphenyl, hydrogenated (CAS 61788-32-7)	374°C (1013 hPa)	Lead Dossier
	Terphenyl, hydrogenated (CAS 61788-32-7)	399°C (1013 hPa)	Lead Dossier
Viscosity	Terphenyl, hydrogenated (CAS 61788-32-7)	133 mm^2/s (static, 20°C)	Lead Dossier
	Terphenyl, hydrogenated (CAS 61788-32-7)	79.56 mm^2/s (25°C)	Lead Dossier,

1.2.2. Justification for grouping

Not relevant for this substance.

1.2.3. Classification and labelling

No harmonised classification is reported for Terphenyl, hydrogenated in Annex VI of Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

There are no proposals for new or amended harmonised classification of Terphenyl, hydrogenated on the Registry of Intention.

The range of classifications that have been notified to the Classification and Labelling (C&L) Inventory (ECHA, 2021d), 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, 2021d) checked on 12th October 2021 is the following:

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

Detailed notifications are given in **Table 9**:

Table 9. 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/Form	27	X

2	Aquatic Chronic 4	H413	H413			State/Form	596	
3	Aquatic Chronic 2	H411	H411	GHS09			18	
4	Not classified						15	
5	Aquatic Chronic 4	H413	H413		M(Chronic) = 0	State/Form	7	
6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H410	GHS09 Wng		State/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	

The co-registrants of Terphenyl, hydrogenated provided the following self-classification in the registration dossier (ECHA, 2021b):

- 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

1.2.4. Hazard assessment

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

This restriction report is based on the established PBT/vPvB properties of Terphenyl, hydrogenated. Therefore, the human health endpoints and a toxicity assessment are not relevant for this dossier.

1.2.5. Exposure assessment

1.2.5.1. Life cycle of Terphenyl, hydrogenated

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

According to registration information, Terphenyl, hydrogenated is not manufactured within the EU after Brexit. 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. Terphenyl, hydrogenated is used as a plasticiser mainly to produce 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, Terphenyl, hydrogenated is also used as plasticiser in coatings and inks. In addition, professional service life scenarios are also relevant for Terphenyl, hydrogenated since the substance is incorporated into or onto articles when used in adhesives and sealants as well as in coatings and inks.

Furthermore, Terphenyl, hydrogenated 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 Terphenyl, hydrogenated. 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.

Currently, Terphenyl, hydrogenated is used in the following applications:

- Use in adhesives and sealants.
- Use in coatings and inks.
- Use as additive in plastic applications.
- Use as Heat Transfer Fluid inindustrial installations.
- Use as HTF in thermostats in electromechanical temperature controls
- Use as solvent/process medium.
- Use as laboratory chemical.

According to the information provided by the respondents to the SEA questionnaire, the disposed Terphenyl, hydrogenated comes from different sources:

- Periodical collection of degradation/decomposition products
- Complete drain of the heat transfer system
- Sampling of Terphenyl, hydrogenated for periodic quality control
- Dismantling of the heat transfer system
- Spills and leakages

Terphenyl, hydrogenated partially degrade at high temperature and, for this reason, a periodical collection of the decomposition products and a consequent refill with pure Terphenyl, hydrogenated is needed. The degradation products of Terphenyl, hydrogenated (mainly low boiling fractions) are collected into a vent line, condensed, and sent to a dedicated collection vessel. This equipment is part of the closed system, so there is no environmental exposure to these by-products. These degraded products are water fraction/emulsion with Terphenyl, hydrogenated.

The renewal of the Terphenyl, hydrogenated (overall annual volume of 2 275 tonnes) in the heat transfer system is required because the substance begins after many years in service to age (in some cases until 20 years), resulting in degradation products, an increase in viscosity, and solids begin to form. The overall heat transfer performance of the system can become less efficient. In addition, the elevated viscosity and solids content will result in accelerated fluid degradation[12]. Once the fluid quality has been analysed and found to be compromised, the system will need to be drained.

After the fluid has been cooled, it can safely be drained via pumps through the use of appropriate procedures and Personal Protective Equipment (PPE) from the system into storage tanks for disposal. According to the feedback during the stakeholder consultations, the removal of the fluid from the system as well as the refill takes place in sealed and contained areas. Furthermore, the storage tanks are part of the closed system, so there is no environmental exposure to the drained Terphenyl, hydrogenated.

Periodic sampling of Terphenyl, hydrogenated is necessary to control and evaluate the quality of the Terphenyl, hydrogenated installed in the heat transfer system. The Terphenyl, hydrogenated generated during the sampling process is collected in little containers.

According to the responses to the SEA questionnaires, spills of Terphenyl, hydrogenated in the heat transfer systems are occurring very rarely or are unlikely, and they are therefore considered to be incidents. All the main equipment in the closed system, like pumps, valves, tanks, etc., are equipped with containment devices in order to avoid any spills of Terphenyl, hydrogenated, so no exposure to the environment is expected. However, if they eventuate residual Terphenyl, hydrogenated on sealed/contained area is being removed by using absorbent material, such as mats or loose media. Once any remaining fluid has been absorbed, this material is removed for appropriate disposal.

The disposed products are transported to certified and qualified waste operators, directly inside the collection tanks, after drumming into barrels, or by truck. Piping and hoses of the trucks, collection tanks, and barrels are cleaned in the same disposal companies and the solvent-water mixture is disposed together with the received product.

The disposal of degraded, drained, or sampled Terphenyl, hydrogenated is similar to the disposal of e.g., lubricating oils. The waste code used is 14 06 03 "Other solvents and solvent mixtures", according to the table of equivalence of Annex III to Regulation 2150/2002[13].

Afterward, the disposal product is incinerated in plants that are known as Waste-To-Energy (WTE) sites, for recovering its calorific value. In this process, the heat from the combustion generates superheated steam in boilers, and the steam drives turbogenerators to produce electricity. Modern European Waste-to-Energy plants are clean and safe, meeting the strictest emission limit values placed on any industry set out in the EU Industrial Emissions Directive[14]. It should be noted that Terphenyl, hydrogenated has a calorific value of approximately 44 MJ/kg, which is in the same range as currently used fuels (e.g., diesel, petrol, crude oil, LPG)[15]. It means that the energy recovery of these disposal products is an efficient process.

In case a plant has to be dismantled, the whole heat-transfer system needs to be emptied, flushed, rinsed, and cleaned prior to dismantling. The cleaning and rinsing procedure has been described and monetized as well in the Annex E.4.1.1. "Substitution and Investment Costs" for the Economic Impacts of RO3.

Please note that the long-range transport (LRT) potential has not been assessed in detail because low-volatility compounds are typically not meeting the key preconditions for LRT

[12] Article-CHEmarch13-Heat-Transfer_0.pdf (therminol.com)

[13] Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics (Consolidated version: 18.10.2010).

[14] The Industrial Emissions Directive - Environment - European Commission (europa.eu)

[15] Heat values of various fuels - World Nuclear Association (world-nuclear.org)

chemicals. More volatile substances would be transported more rapidly and over larger distances than less volatile compounds.

The boiling point of Terphenyl, hydrogenated is ranging between 335°C (initial boiling point) and >400 °C (final boiling point). The value used in the CSR is the 10% point (101 325 Pa: 342 °C). Substances with a boiling point of 240-260 to 380-400 are considered as semi- to non-volatile.

In addition, the German Environment Agency (UBA) described PMT (Persistent, Mobile, and Toxic) criteria in 2019[16]. In the case of mobility it has been defined a logKoc value of 4 or less for mobile substances and a logKoc value of 3 or less for very mobile ones. The criteria on mobility have been refined by the draft Commission Delegated Regulation amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (CLP) in order to include PMT and vPvM substances into CLP[17].

"A substance shall be considered to fulfil the mobility criterion (M) when the log Koc is less than 3. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log Koc value for pH between 4 and 9 is less than 3."

As the logKoc value for Terphenyl, hydrogenated is 5.5 (see Annex B.4.2.) the substance can be considered as not mobile. Therefore, long-range transport is not expected. The substance is likely to adsorb to soil and sediment and will not be available for LRT, even not via particles or biota.

1.2.5.2. Data collection

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.

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

Up until now only a few international measurements of Terphenyl, hydrogenated in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with Terphenyl, hydrogenated, while Sturaro et al. (1995)

[16] The final PMT/vPvM criteria after public consultation | Umweltbundesamt

[17] Annexes to the Delegated Regulation.pdf (europa.eu)

detected Terphenyl, hydrogenated as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

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

Moreover, the SCIP database (ECHA, 2021c) was screened for Terphenyl, hydrogenated. At the date of access (2 March 2022) more than 12 000 articles containing Terphenyl, hydrogenated 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 close to 85% of Terphenyl, hydrogenated use in articles is related to plasticiser uses. Therefore, there is also significant potential for release of Terphenyl, hydrogenated to the environment from waste disposal activities (see **Annex B.9.**: Exposure assessment). The information obtained through analysis of the SCIP database will be addressed in the exposure assessment (please refer to **Annex B.9.**).

The DS does not know what exactly the additional uses (15%) are and would therefore ask that this is being clarified during the Public Consultation. Besides consulting the SCIP Database, a comprehensive internet search was conducted to identify additional applications in articles. Moreover, it cannot be excluded that the remaining 15% are as well plasticizer uses but were not notified accordingly in the SCIP database.

According to our understanding, the unclear uses are not of importance, otherwise responses should have been received during the different stakeholder consultations. It is not expected that a full ban will have a severe impact.

Furthermore, migration modelling was conducted by FABES Forschungs-GmbH (FABES, 2021). 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.

The leaching/migration of Terphenyl, hydrogenated from a special epoxy topcoat, used in the aerospace & defence industry, into the surrounding air/atmosphere as well as the migration of Terphenyl, hydrogenated from a sample plate made of polysulfide sealant into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach. For further information please refer to **Annex B.9.9.3** and **Annex B.9.13.3**, respectively.

In addition, exposure measurements at industrial sites using Terphenyl, hydrogenated as HTF were conducted. A monitoring program was designed and developed at a number of industrial sites that use Terphenyl, hydrogenated in order to obtain updated information on potential environmental emissions of Terphenyl, hydrogenated from industrial uses as HTF. Companies that participated in this program were requested to collect both air and soil samples, from locations at which releases of Terphenyl, hydrogenated could be regarded to be more likely. For further information please refer to **Annex B.9.3.3**.

1.2.5.3. Exposure assessment

1.1.5.3.1. Human health assessment

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

1.1.5.3.2. Environmental assessment

Two assessments were conduction: a quantitative estimation of releases into the environment as well as a qualitative assessment. For multiple identified uses information was lacking hence the qualitative assessment is based on the quantitatively estimated emissions.

However, the "Consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves" was only assessed qualitatively.

Quantitative assessment

For each exposure scenario an overview table with the input parameters is given in **Annex B.9.** Thereby 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.

Additionally, a table displaying the initial releases to air, water and soil based on the release rates is included in **Annex B.9** for each scenario. The releases are calculated using generic exposure methods.

The environmental exposure assessment is based on the default release factors in accordance with ECHA Guidance R.16 (ECHA, 2016). Using the default release factors has to be regarded as worst-case approach overestimating the actual emissions.

In case other information on the releases are available and applicable for Terphenyl, hydrogenated, e.g., Specific Environmental Release Categories (SpERCs) or Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents this information is used in preference to the default release factors as indicated in ECHA Guidance R.16 (ECHA, 2016). Additionally, specific information was made available through the Exposure & Release Questionnaire (2018) by the LR.

Moreover, information was received via the public consultation. Thereby, information received via the public consultation was in line with the information received via the Exposure & Release Questionnaire (2018).

For further information on the used release factors please refer to the respective scenario in **Annex B.9**.

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 risk management measure 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.

The properties of Terphenyl, hydrogenated that have been assumed in the exposure assessment were taken from ECHA's dissemination page.

Qualitative assessment

A qualitative assessment was performed collectively for various uses. Thereby, the uses were arranged based on the market section. Hence, a collective qualitative assessment was performed for:

- the HTF uses,
- the adhesive/sealant uses,
- the coating/ink uses,
- the miscellaneous uses, and
- the consumer use as HTF in thermostats.

As indicated before, the results of the quantitative assessment was used as basis for the qualitative assessment if specific information was lacking.

Moreover, information received via the public consultation was taken into account as well.

Based on the outcome of the qualitative assessment, all uses were prioritised based on their contribution to the identified risk.

RAC box

RAC concludes that the methodologies used to assess environmental releases of Terphenyl, hydrogenated are not robust enough to draw quantitative conclusions on emissions and emission reduction.

Based on a qualitative evaluation of the available information, RAC concludes that releases to the environment from all uses within the scope of the proposed restriction are expected (i.e. current information specifying operational conditions and risk management measures cannot guarantee that releases are controlled under the conditions of use).

A further elaboration on this can be found in the RAC opinion.

1.2.5.4. Summary of environmental exposure assessment

Quantitative assessment

The share of the total emissions was evaluated based on the market sector. The analysis showed that the HTF use has by far the largest share of the total emission in the high emission scenario. All other uses have a share of a few percent, each. However, the result of the high emission scenario is not regarded as reliable since the actual emission associated with the industrial use of Terphenyl, hydrogenated is unrealistic and overestimates the actual emission. For further information please refer to Section B.9.3.1.

Consequently, the high share of the total of the high emission scenario and the share of the individual use needs to be interpreted with caution.

Looking at the low emission scenario the “Service life of articles produced from use as plasticiser” has a share of approximately approx. 32 % of the total emissions followed by the “Direct use for industrial coatings/inks applications” (approx. 24 %) and “Service life of articles produced from use of coatings and inks” (approx. 17 %).

Table 10. Emission sources of Terphenyl, hydrogenated.

Scenario	Share of total (%) Low emission scenario	Share of total (%) High emission scenario
Manufacture*	0	0

Scenario	Share of total (%) Low emission scenario	Share of total (%) High emission scenario
Formulation of coatings/inks	2.67	0.07
Direct use for industrial coatings/inks applications	**24.27**	1.65
Direct use for professional coatings/inks applications	6.72	0.13
Service life of articles produced from use of coatings and inks	**16.95**	0.09
Use as HTF at industrial sites	0	**94.91**
Laboratory analysis	<0.001	<0.001
Formulation of adhesives and sealants	1.49	0.19
Use of adhesives and sealants at industrial sites	6.75	2.17
Use of adhesives and sealants by professionals	5.46	0.23
Service life of articles produced from use as plasticiser	**32.02**	0.16
Formulation, transfer and repackaging of substances in preparations and mixtures	1.70	0.01
Use as solvent/process medium	1.81	0.39
Use as laboratory chemical by professionals	0.16	<0.001

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

As stated in Table 26 of **Annex B.9.3.3.**, 13 sites have contributed to the measured data, although no specific information about the heat transfer systems has been received from Site S-09 (basic chemicals producer). Regarding the other 12 sites, they have 17 heat transfer systems installed with a Terphenyl, hydrogenated volume of 2 356 tonnes (2 336 m3). This represents 1% of the sites and 9.8% of the volume of Terphenyl, hydrogenated installed (according to the data included in Table 6 of **Annex A.2.**).

Among these sites, 8 have systems with a volume of Terphenyl, hydrogenated installed over 50 tonnes, and the other 4 have systems with a volume of Terphenyl, hydrogenated installed between 10 and 50 tonnes. None of the measured sites have systems with a volume of Terphenyl, hydrogenated installed below 10 tonnes.

However, the final calculations for the low emission scenario are estimated through the responses from the SEA questionnaires and the on-site exposure measurements. Both represent a selection of different industries and different company sizes (large and SME). Therefore, the DS believes that the result is representative enough to draw conclusions. In addition, the DS considers that the large range of the different emission scenarios has been taken to have a safety net.

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

- 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 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 11. Emission sources of Terphenyl, hydrogenated based on market sector.

Scenario	**Share of total (%) Low emission scenario**	**Share of total (%) High emission scenario**
Coatings/inks	**50.6**	1.94
HTF	0	**94.91**
Adhesives/sealants	**45.73**	2.75
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.67	0.40

Table 12 the estimated emissions for each compartment (air, water, and soil) are displayed. These include the sum of estimated releases to the air, water, and soil. The redistribution in the Sewage Treatment Plant (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 43 and 39%, respectively) whereas the release to air is lower (approximately 18 %).

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 12. Estimated total EU releases for Terphenyl, hydrogenated**.**

Environmental compartment	**Estimated EU emissions based on data on volume for 2021**		
	Low (kg per year)	**High (kg per year)**	**Share of total (%)**
Air	11 400	710 000	18.18 – 39.82
Water	26 800	706 000	42.74 – 39.6
Soil	24 500	367 000	39.07 – 20.58
All / Total	62 700	1 783 000	100

The estimated regional Predicted Environmental Concentrations (PECs) for Terphenyl, hydrogenated in the EU are summarised in the following table.

Table 13. Estimated regional PECs for Terphenyl, hydrogenated in the EU.

Environmental compartment	Lower estimate	Upper estimate	Unit
Fresh water	3.52E-6	6.74E-4	mg/L
Sediment (freshwater)	0.222	42.52	mg/kg dw
Marine water	4.39E-7	7.49E-5	mg/L
Sediment (marine water)	0.028	4.703	mg/kg dw
Air	9.53E-6	3.29E-4	mg/m³
Agricultural soil	6.49E-4	0.022	mg/kg dw
Man via environment - inhalation (systemic effects)*	9.53E-6	3.29E-4	mg/m³
Man via environment (oral)**	3.74E-4	0.063	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 (ECHA, 2016) 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 (FABES, 2021) as well as the monitoring data.

Qualitative assessment

Consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves

It is concluded that only a marginal amount of Terphenyl, hydrogenated is used in thermostats used in ovens, stoves, and similar electric and electronic equipment (EEE).

According to information provided by the lead registrant, the quantity sold on this market is assumed to be <1 t/a, i.e. very small compared to its use as industrial HTF. The lead registrant presumes that the volume of HTF used in ovens is max. 10 ml. This means that a use of 1 t/a is equivalent to 100 000 thermostats or 100 000 ovens. Furthermore, the lifetime of a stove is likely to be more than 20 years and they are usually collected through take-back schemes at their end-use location. During the use of the article by consumers, the Dossier Submitter supposes that there is no relevant release of Terphenyl, hydrogenated since it is contained in a closed vessel which is installed in the complex article. There are no emissions identified during the consumer use of Terphenyl, hydrogenated as HTF in thermostats in electro-mechanical temperature controls of ovens and stoves.

Furthermore, the disposal of EEE is regulated by the WEEE Directive (2012/19/EU)[18] and the Waste Framework Directive 2008/98/EC[19]. Large household appliances like electric stoves, other large appliances used for cooking and other processing of food, cockers and thermostats are explicitly covered according to Annexes 1 and 2 of this Directive.

According to Article 8 of the WEEE Directive removal of all fluids from WEEE is required. Fluids must be safely removed prior to crushing or shredding operations.

"Proper treatment, other than preparing for re-use, and recovery or recycling operations shall, as a minimum, include the removal of all fluids and a selective treatment in accordance with Annex VII".

The selective treatment of hydrocarbons is specifically mentioned in Annex VII of the WEEE Directive. indicated. Although it cannot be completely ruled out that Terphenyl, hydrogenated could be released during treatment of the e-waste it is assumed that there are usually no emissions of Terphenyl, hydrogenated due to the regulations that are in place. The consumer will not be getting into contact with Terphenyl, hydrogenated, unless in cases of misuse. Further, with regard to the lifetime of ovens etc. and the very little amount of Terphenyl, hydrogenated used in thermostats as HTF this use is regarded as of very little concern regarding emissions of Terphenyl, hydrogenated into the environment. No inevitable emissions are expected which need to be minimised.

Hence, this use is not considered to contribute significantly to the overall risk that is associated with the use of Terphenyl, hydrogenated and any risk are covered by existing EU legislation (WEEE Directive).

Conclusion: This use is not considered to contribute significantly to the overall risk that is associated with the use of Terphenyl, hydrogenated.

Heat transfer fluid (Except the "Use as heat transfer fluid in thermostats in electromechanical temperature controls of ovens and stoves")

The releases associated with the laboratory use are regarded as very small (if any). Hence it is concluded that the laboratory use to determine the lifetime of the Terphenyl, hydrogenated used as HTF does not lead to inevitable emissions which need to be minimised.

Taking all information from the Exposure & Release Questionnaire (2018) and the public consultations into account it is safe to say that Terphenyl, hydrogenated is contained in a strictly controlled, closed system when used as HTF.

All respondents are well aware that it is crucial to not release any Terphenyl, hydrogenated into the environment.

Consequently, emissions to the environment are regarded as highly unlikely during normal operations. There are no systematic releases when Terphenyl, hydrogenated is used as HTF. Only accidental releases which occur rarely are anticipated. But it was highlighted by multiple respondents in the public consultations that there are systems in place to remove and deal with leakage appropriately, before Terphenyl, hydrogenated can escape into the environment.

[18] EUR-Lex - 02012L0019-20180704 - EN - EUR-Lex (europa.eu)

[19] EUR-Lex - 32008L0098 - EN - EUR-Lex (europa.eu)

It is hence concluded that the industrial use of Terphenyl hydrogenated as HTF does not lead to inevitable emissions. Further, it became clear that industry goes to great length to ensure that there is no emission during the running of the HTF system.

The findings are also supported by the exposure measurements which were conducted (for further information please refer to Section B.9.3.3.)

Nevertheless, a Guidance Document on Strictly Controlled Closed Systems (SCCS) is written to ensure that all HTF system which are run with Terphenyl, hydrogenated fulfil the same standard of "zero emission".

According to feedback of the lead registrant, all uses as HTF should be considered as industrial and no uses are considered professional.

Conclusion: The analysis of the HTF by the supplier are not considered to contribute significantly to the overall risk that is associated with the use of Terphenyl, hydrogenated. The use of Terphenyl, hydrogenated as HTF at industrial sites is already managed appropriately with no emissions to the environment. Regarding both uses the use as HTF at industrial site is not expected to contribute at all to the identified risk, whereas the analysis of the HTF at a lab is regarded as of minor concern regarding the identified risk. Further information is available in the Annex (Chapter B.9.19.3.).

Adhesives/sealants

Regarding the formulation it is concluded that < 1 – 7.51 % of the used volume will possibly be released into the environment. However, it us assumed that it can be expected that that solvent waste is handled appropriately by certified waste handlers which would result in an even lower release.

Regarding the end-uses a release, especially when used by professional cannot be denied. Especially when used outdoors a release to water and soil is highly likely. Even if all waste would be handled and recycled accordingly emissions into the environment are expected. Due to the lack of information, it is uncertain whether further RMMs are in place which reduce emissions. Hence, it is concluded that for the two end-uses emission are inevitable, whereas the professional end-use is more critical than the industrial end-use.

Regarding the service life of article no specific information are available to the DS. A constant release is expected although the amount that will possibly be release is unclear. Further, the treatment of disposed articles is uncertain. Hence, it is concluded that the service life scenario is associated with a high uncertainty, but emissions are regarded as inevitable.

Conclusion: The formulation as well as the industrial use of adhesives and sealants are regarded as of minor concern and are not expected to contribute significantly to the identified risk. However, the professional use is identified as critical, especially when the sealants/adhesives containing Terphenyl, hydrogenated are used outdoors. Furthermore, the service life of articles containing Terphenyl, hydrogenated is regarded as critical and actual emissions are uncertain due to the lack of specific information. Concluding that the service life as well as the professional use will contribute significantly to the identified risk.

Coatings/inks

Regarding the formulation it is concluded that about 1 – 5.5 % of the used volume will possibly be released into the environment. However, it us assumed that it can be expected that process waste may be recycled or incinerated by waste disposal company which would result in an even lower release.

Regarding the end-uses a release, especially when used by professional can not be denied. Especially when used outdoors a release to water and soil is highly likely. Even if all the process waste would be recycled or incinerated the assumed emissions into the environment can still be expected. Due to the lack of information, it is uncertain whether further RMMs are in place which reduce emissions. Hence, it is concluded that for the two end-uses emission are inevitable.

Regarding the service life of article no specific information are available to the DS. However, a constant release is expected although the amount that will possibly be release is unclear. Further, the treatment of disposed articles coated with a coating containing Terphenyl, hydrogenated is uncertain. Hence, it is concluded that the service life scenario is associated with a high uncertainty, but emissions are regarded as inevitable.

Conclusion: The formulation of coatings and inks is regarded as of minor and the industrial use of coatings and inks is regarded as of moderate concern regarding the identified risk. However, the professional use is identified as critical, especially when the coatings/inks containing Terphenyl, hydrogenated are used outdoors. Furthermore, the service life of articles containing Terphenyl, hydrogenated is regarded as critical and actual emissions are uncertain due to the lack of specific information. Concluding that the service life as well as the professional use will contribute significantly to the identified risk.

Miscellaneous uses

Regarding the formulation it is concluded that about 4.5 % of the used volume will possibly be released into the environment, not taking into account solid waste containing Terphenyl, hydrogenated which is produced during the process. Furthermore, information regarding the treatment of the generated waste is not available to the DS.

The releases for industrial use as solvent/process medium derived based on the default release factors of the assigned ERC are not representative since they significantly overestimate the actual emissions. It is concluded that the results of the refined, low emission scenario are more reasonable. Further, it is assumed that the solid waste for disposal which is generated during the industrial use as solvent/process medium is treated by certified waste handlers. Taking the solid waste for disposal out of the equation the total release associated with this use are marginal (4 kg per year). The releases associated with this use would hence be only approx. 0.25 % of the used volume.

For the use as laboratory chemical by professionals no specific information is available to the DS, e.g., it is not known how much will be released via waste. Nevertheless, it appears to be reasonable that the waste generated will be treated by certified waste handlers. The percentage of the used volume which is released (10 %) is high.

Especially the use as laboratory chemical by professionals is of concern. Although only a very small amount (1.5 t/y) of Terphenyl, hydrogenated is used for this application the releases are expected to be high. Further, the treatment of potential solid waste cannot be answered.

Moreover, the evaluation of the formulation scenario is associated with a higher uncertainty, e.g., regarding the amount of waste that is generated and how it is treated.

Conclusion: Of the three herein assessed uses the formulation and the use as laboratory chemical by professional are regarded as potentially problematic. Due to the lack of information the question of how waste is treated cannot be answered sufficiently. Hence, the two indicated uses are regarded as of moderate concern regarding the identified risk.

Summary of prioritization & conclusion

Table 14. Prioritization of uses based on their contribution to the identified risk.

Identified Use	**Market Sector**
Uses assumed to contribute significantly to the identified risk	
Articles produced from use as plasticiser	Adhesives/sealants
Use of adhesives and sealants by professionals	Adhesives/sealants
Articles produced from use of coatings and inks	Coatings/inks
Direct use for professional coatings/inks applications	Coatings/inks
Uses assumed to be of moderate concern regarding the identified risk	
Direct use for industrial coatings and inks applications	Coatings/inks
Uses assumed to be of minor concern regarding the identified risk	
Formulation of adhesives and sealants	Adhesives/sealants
Use of adhesives and sealants at industrial sites	Adhesives/sealants
Formulation of coatings or inks	Coatings/inks
Use in laboratory analysis	HTF
Formulation, transfer, and packing of substances in preparations and mixtures	Misc.
Use as solvent or process medium	Misc.
Use as laboratory chemical by professionals	Misc.
Uses assumed to be of negligible concern regarding the identified risk	
Use as HTF at industrial sites	HTF
Consumer service life as HTF in thermostats in electromechanical temperature controls of ovens and stoves	Stand-alone HTF use

1.2.6. 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 Terphenyl, hydrogenated, to the environment or to humans cannot be adequately addressed in a quantitative way.

Due to the vPvB properties of Terphenyl, hydrogenated, emissions will lead to an increased exposure of humans and the environment since the substance will build up over time.

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). Measures to reduce the ongoing emissions are therefore regarded as mandatory.

1.3. Justification for an EU wide restriction measure

Terphenyl, hydrogenated 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[20] 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, Terphenyl, hydrogenated 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, risk management measures 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated is used as a **plasticiser** it may be 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated will be incorporated into or onto an article. At the end of the service life, the article has to be disposed. During the disposal at a waste treatment plant the Terphenyl, hydrogenated 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 Terphenyl, hydrogenated have been notified to this database. Most entries

[20] Submitted recommendations - ECHA (europa.eu)

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 close to 85% of Terphenyl, hydrogenated use in articles is related to plasticiser uses. Therefore, there is also significant potential for release of Terphenyl, hydrogenated to the environment from waste disposal activities (see **Annex B.9.**: Exposure assessment). The Dossier Submitter assumes that at the waste life-cycle stage the uccrently implemented risk management measures are not sufficiently effective to control the risks.

Terphenyl, hydrogenated 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 Terphenyl, hydrogenated in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with Terphenyl, hydrogenated resulting potentially from accidental pinhole leaks or faulty joints in the heating coils, while Sturaro et al. (1995) detected Terphenyl, hydrogenated as contaminant in food cardboard packages made from recycled material containing carbonless copy paper. Terphenyl, hydrogenated and diarylethanes, alkyl-naphthalenes, cyclohexane, and dibutyl-phthalate had replaced PCBs as solvent. The use of Terphenyl, hydrogenated in carbonless copy paper has discontinued many years ago.

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

1.4. Baseline

This section draws on **Annex D** which provides further details on the baseline scenario in terms of current and future use and emission volumes and the methodology used to estimate them. The "baseline" is the scenario in the absence of any restriction or other RMO or intervention being implemented to reduce the environmental risks from manufacture, import and use of Terphenyl, hydrogenated.

The baseline is a projection of future Terphenyl, hydrogenated volumes used in the EU and the corresponding projected releases of Terphenyl, hydrogenated 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 Terphenyl, hydrogenated. The baseline scenario describes the "business as usual" situation. The baseline was developed based on the data gathered on manufacture, import and use of Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated. The baseline scenario is compared to the proposed restriction scenario in the Impact Assessment (**Annex E**) in terms of both costs and benefits.

1.4.1. Volumes and Trends

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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated used as HTF in the EU will be dominated by the market trends. As shown before, Terphenyl, hydrogenated plays a significant role as HTF in alternative energy technology (ORC and solar) supporting the EU's Green Deal[21]. Moreover, chemical recycling of PET and other polymers is increasing following the EU's Circular Economy action plan[22]. 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 Terphenyl, hydrogenated 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 approximately 16 931 tonnes per year by end of 2044.

The Dossier Submitter understands that the Gross Domestic Product (GDP) in the EU is considered to be significant below 5% on average[23] and for the years 2022 and 2023 the GDP in the EU should be in the area of 2.3 – 2.7%. The current pandemic situation and the war in Ukraine are leaving further question marks about the future development. However, it is important to note, that Terphenyl, hydrogenated is used in certain key renewable energy technologies such as CSP and ORC. 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

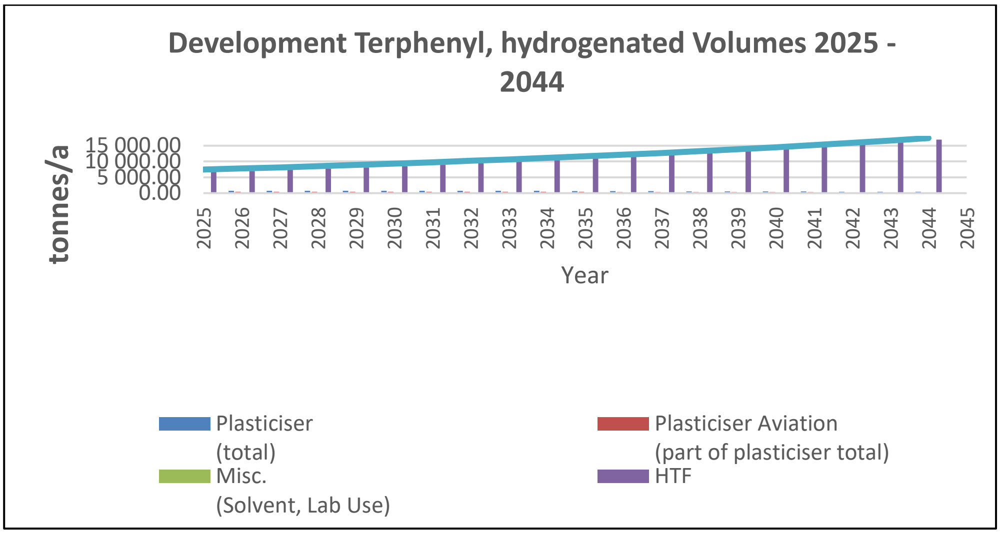
[21] Delivering the European Green Deal | European Commission (europa.eu)
[22] Circular economy action plan (europa.eu)
[23] EU GDP growth rate 2022 | Statista

from residual heat, for example for cost-effective power generation using waste or biomass heat from combustion or production processes.

Due to the Circular Economy, the EU Green Deal and the current energy crisis in Europe, these technologies are growing strongly and justifying a growth rate value above GDP.

Figure 2 below shows the estimated volume development in the EU between 2025 and 2044, based on the aforementioned growth rates.

Figure 2. Estimated trend of volume development of Terphenyl, hydrogenated 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 for applications where substitution can be achieved easily, resulting in a drop of the plasticiser use in the EU. The identification of a substance as a SVHC and its inclusion in the Candidate List triggers certain legal obligations for the importers, producers and suppliers of mixtures and articles that contain such a substance, which results in higher efforts to market the substance. In addition, SVHC substances are in general blacklisted by NGO or included in industry sector specific declaration or ban lists. 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 Terphenyl, hydrogenated as a plasticiser will be relocated outside the EU and that the volume of imported articles containing Terphenyl, hydrogenated into EU will increase. The high number of articles containing Terphenyl, hydrogenated 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.

1.4.2. Current Releases of Terphenyl, hydrogenated and Baseline Emissions

The current emissions of Terphenyl, hydrogenated 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 Terphenyl, hydrogenated, 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 (Appendix 1) 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 risk management measure that is used during the process.

The share of the total emissions was evaluated based on the market sector and summarised in **Table 15**. The exposure assessment shows that in the "high emission scenario" the largest source of Terphenyl, hydrogenated 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 48%). 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 15. Sources of Emission of Terphenyl, hydrogenated 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 16 the emissions for each compartment (air, water and soil) are displayed. These include the sum of estimated releases to air, water and soil. 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 16. Estimated total release for Terphenyl, hydrogenated 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 17 shows the estimated total release for Terphenyl, hydrogenated 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 Terphenyl, hydrogenated release of 925 tonnes in 2021.

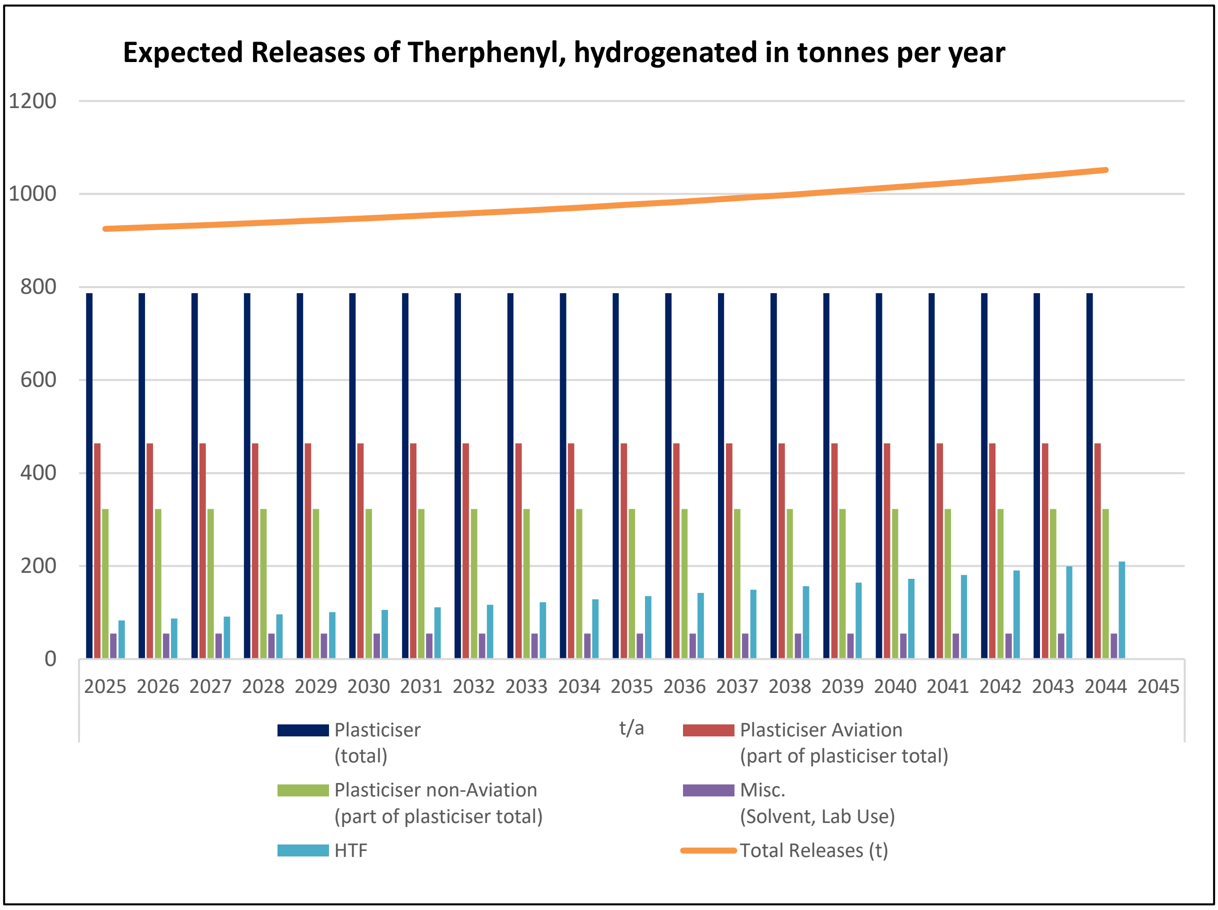
Table 17. Estimated total release for Terphenyl, hydrogenated based on market sector in EU in 2021 based on average release shares and average total volume.

Market Sector of Use	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 approximately 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 Terphenyl, hydrogenated will be entering the EU via articles containing Terphenyl, hydrogenated as a plasticiser and will be released during service life**.**

Figure 3 shows an estimation of expected Terphenyl, hydrogenated releases on an annual basis from 2025 – 2044.

Figure 3. Estimation of expected Terphenyl, hydrogenated releases on an annual basis from 2025 – 2044.



The worst-case cumulative releases of Terphenyl, hydrogenated 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 18.**

Table 18. Cumulated and averaged expected releases from 2025 – 2044 per use.

Expected releases	Tonnes per year					Cumulated releases 20 years in tonnes	Average annual release in tonnes per year
	2025	2030	2035	2040	2044		
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 will increase 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 approximately 20% of total Terphenyl, hydrogenated 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) only identified negligible releases.

Over the examined 20 years, the whole plasticiser releases account on average for approximately 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.

2. Impact assessment

2.1. Introduction

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 **Annex E**: Impact Assessment, and **Annex G**: Stakeholder Consultation).

In summary, 139 responses were analysed for getting a better understanding of impacts for industry and society. 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.

Furthermore, the Dossier Submitter had several telephone interviews with the LR and Member Registrants as well as individual users of the substance via its consultant.

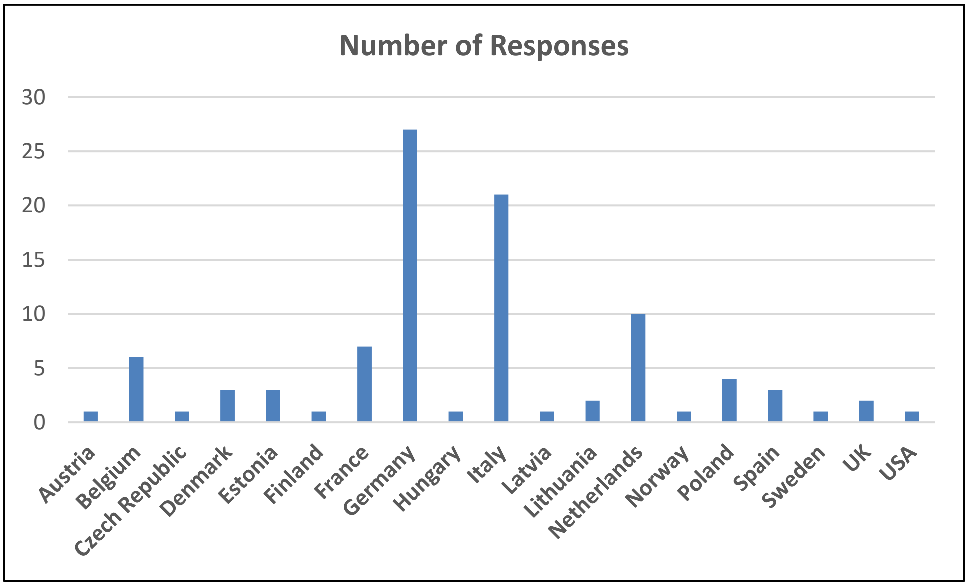
Table 19. Responses reviewed related to impacts on industry.

Type of Request/Response	Number of Responses
LR - SEA Questionnaire, 2018	24
Commission - Socio-Economic Impact Questionnaire, 2020[24, 25]	31
ECHA - Responses to 10th Recommendation, 2020	55
Dossier Submitter - SEA Questionnaire, 2021	29
Total	**139**
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 Terphenyl, hydrogenated has the highest installed base.

Figure 4 does illustrate these numbers in a schematic diagram.

Figure 4. Schematic diagram to illustrate the number of responses per country



2.2. Analysis of alternatives

This section draws on **Annex E.2.** which provides further details on the analysis of the alternatives to Terphenyl, hydrogenated for its different uses. Detailed information can be consulted in this Annex.

[24] Circabc (europa.eu)
[25] Circabc (europa.eu)

The overall goal of this analysis is to support informed decisions regarding the advantages and disadvantages of different alternatives to Terphenyl, hydrogenated. These alternatives 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, the identification process has been divided in three general steps:

- Screening of information sources
- Assessment on the technical suitability of the alternatives, considering the different uses of Terphenyl, hydrogenated.
- Assessment of the hazard profile of the alternatives

The first step (screening of information sources) consisted in the revision of available literature and bibliography, information from stakeholders, and responses to the SEA questionnaires.

The main alternatives to Terphenyl, hydrogenated, based on technical documentation on specifications for plant construction and the RMOA conducted by the Finnish Safety and Chemicals Agency (Tukes, 2020), are 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).

Considering the classification of HTFs (Pirobloc, 2021), possible alternatives to Terphenyl, hydrogenated for this use could be mineral fluids, other synthetic fluids, and silicones. However, in the comparative temperature ranges of the mineral and synthetic fluids, silicon fluids are unlikely to be choices for most process applications due to performance and cost factor disadvantages (they are used in specialised heat transfer applications). For this reason, they are discarded as potential alternatives to Terphenyl, hydrogenated.

Regarding the synthetic fluids and based on the information obtained from the responses to the SEA questionnaires, the following substances could be also considered as potential alternatives to Terphenyl, hydrogenated for the use as HTF:

- 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 Terphenyl, hydrogenated because it cannot be legally marketed and used in EU in the required quantities.

Concerning the substitution of Terphenyl, hydrogenated 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 "*Terphenyl, hydrogenated 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 Terphenyl, hydrogenated "*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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated. There are no direct replacements in many critical applications and replacement would likely involve significant redesign and requalification and recertification activities in this industry*".

A literature search revealed, that recently novel monomeric and oligomeric dibenzoate plasticizers have been introduced. These new plasticizer solutions have been specially tailored for polysulfide sealant applications. They have been found to be high-performing, low-fogging alternatives to traditional chemistries used in polysulfides. Additionally, they are expected to be less hazardouse compared to chemistries such as chlorinated paraffins and phthalates.

It was found in addition, that substitution of Terphenyl, hydrogenated in epoxy-based adhesives is taking place already. Product literature from an adhesives company[26] does demonstrate, that Hydrogenated terphenyls were removed from their products to address global regulatory concerns regarding its vPvB properties. While it's not a regulatory requirement yet, the company is revising the chemistry in many of their hydrogenated terphenyl containing products. A comparison of the formulations via the old[27] and the new[28] safety data sheet of one of the adhesives reveals, that Terphenyl, hydrogenated has been replaced by Diethylene glycol bis(3-aminopropyl) ether (CAS-No. 4246-51-9). According to the website of the company, they are selling into the aviation industry[29,30] but others as well.

Diethylene glycol bis(3-aminopropyl) ether has been REACH-registered in the volume band 100 – 1 000 t/a[31]. The uses include industrial and professional applications in adhesives and coatings. According to PubChem[32] the function of the substance in adhesives and coating can be as plasticiser and viscosity adjustor.

As potential plasticiser substitutes little attention to Orthophthalates was given due to their intrinsic properties. But a more in-depth analysis revealed that there are classes of phthalates, different from orthophthalates, which are in general less hazardous, such as Isophthalates and Terephthalates. There is an ECHA document on the Assessment of Regulatory Needs (ECHA 2021f) that reports information on this group of phthalates. While for some substances the need

[26] https://webaps.ellsworth.com/edl/Actions/?document=50412&language=en
[27] Safety Data Sheet is available to the Dossier Submitter
[28] ResinLab EP1290 Clear Epoxy Adhesive
[29] ResinLab - The Leading Resin Manufacturer
[30] How to Choose a Static Mixer - ResinLab
[31] Registration Dossier - ECHA (europa.eu)
[32] 4,7,10-Trioxa-1,13-tridecanediamine | C10H24N2O3 - PubChem (nih.gov)

for further studies is highlighted, for others the results indicate that, due to the unlikely hazard of these substances, there is currently no need for further EU regulatory risk management.

In conclusion, it seems that technical alternatives are available, such as Diethylene glycol bis(3-aminopropyl) ether, dibenzoates, ortho-, iso- and terephthalates or chlorinated paraffins. However, it is not easy to find out the technical suitability and for which sector (e.g. aviation) in which application these substances could be used.

After the first step of the identification process (screening of information sources) an initial list of potential alternatives to Terphenyl, hydrogenated was defined. This list is shown in **Table 20**:

Table 20. List of potential alternatives to Terphenyl, hydrogenated

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	-	-
13	Dibenzoates	-	-
14	Orthophthalates	-	-
15	Chlorinated paraffins	-	-
16	Iso- and Terephthalates	-	-
17	Diethylene glycol bis(3-aminopropyl) ether	4246-51-9	224-207-2

The second step of the identification process assess the technical suitability of the alternatives considering their uses.

Alternatives to Terphenyl, hydrogenated for the HTF use 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 per technical definition 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 Terphenyl, hydrogenated, because they require the pressurization of the heat transfer system.

For this reason, this analysis ruled out alternatives 3, 4, 6, 7, 8 10, and 11 because the values of their boiling points are not suitable for the conditions of use of Terphenyl, hydrogenated as HTF (they are lower than 325°C). This conclusion is aligned with the analysis performed on these substances in the RMOA developed by the Finnish CA (Tukes, 2020).

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 Terphenyl, hydrogenated in those specific conditions (Tukes, 2020).

Finally, mineral fluids based hot oils (alternative 12) are not recommended to be used above a temperature of 315-320°C (Damiani MR, 1998). These substances decompose as well disproportionally as well at lower temperatures. Due to the insufficient thermal stability at the temperature required, they are not used above their real limit. Therefore, mineral fluids cannot be considered as alternative to Terphenyl, hydrogenated as HTF for technical reasons. It should be noted that ca. 75% of the annual built HTF systems are based on mineral oils, while just ca. 25% for aromatic fluids (like Terphenyl, hydrogenated), because operating temperatures are too high.

Regarding the other uses of Terphenyl, hydrogenated, alternatives 2, 9, 13, 14 and 15 could be used as plasticiser; alternatives 6, 7, 8 and 9 as solvent or process medium; alternatives 9, 13, 14 and 15 as additive in adhesive and sealants; 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, alternatives 3, 10, and 11 have been completely discarded.

The summary of potential alternatives per use is detailed in **Table 21**:

Table 21. List of potential alternatives per use

Use	**Alternatives**
HTF	1, 2, 5
Plasticiser	2, 9, 13, 14, 15, 16, 17
Solvent or process medium	6, 7, 8, 9
Additive in adhesive and sealants	9, 13, 14, 15, 16, 17
Laboratory chemicals	4, 6, 7, 8, 9
Additive in coatings, paints, and inks	9, 17

The last step of the identification process (assessment of the hazard profile) discarded alternatives 2 and 4 due to their classification as reprotoxic, and alternative 5 due to its PBT properties. In the case of alternatives 13 (benzoates), 14 (orthophthalates) and 15 (chlorinated paraffins), that could be potential substitutes of Terphenyl, hydrogenated as plasticiser and additive in adhesive and sealants from the technical point of view, however, alternatives 14 and 15 carry similar concerns to Terphenyl, hydrogenated in terms of their hazard properties and environmental behaviour (see **Annex E.2.2.3.**). For this reason, they should be discarded as potential alternatives to Terphenyl, hydrogenated, in order to avoid a situation of regrettable substitution.

Related to dibenzoates it needs to be taken into account, that an Assessment of Regulatory Needs has been conducted[33], because some of the substances in this group have reproductive toxicity properties Cat. 1b. Therefore the right compound needs to be selected, since some substances of this group do not carry these properties. Concerning Iso- and Terephthalates an Assessment of Regulatory Needs (ARN) has been conducted too[34]. For some of the substances in these two groups ECHA stated, that no human health or environmental hazards are expected based on the currently available information and that there is currently no need for further regulatory risk management. Diethylene glycol bis(3-aminopropyl) ether is neither classified as CMR Cat 1 nor as a PBT/vPvB substance or meets the equivalent level of concern criteria, so would not be eligible for SVHC classification.

The final list of alternatives to Terphenyl, hydrogenated and their potential uses is detailed in **Table 22**:

Table 22. Final list of potential alternatives to Terphenyl, hydrogenated

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
13	Dibenzoates	Plasticiser, adhesive and sealants
16	Iso- and Terephthalates	Plasticiser, adhesive and sealants
17	Diethylene glycol bis(3-aminopropyl) ether	Plasticiser, adhesive and sealants, additive in coatings, paints, and inks

The uses are independent from each other and as such, some alternatives may be suitable replacements for some uses, but not for others. For this reason, an analysis of the risk reduction, technical and economic feasibility, and availability of these potential alternatives to Terphenyl, hydrogenated has been done (see detailed information in **Annex E.2.3.**).

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 Terphenyl, hydrogenated. It may therefore be the case that some of the uses of Terphenyl, hydrogenated are not covered in this analysis of alternatives.

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33 76e478b2-5533-3114-e175-8d5ee71a5b6b (europa.eu)
34 d4d52e3a-578d-0944-d1c3-e3b489a7e82c (europa.eu)

The analysis is specific for each potential alternative and use, and it comprises the following:

- Availability of alternative
- Human health risks related to alternative
- Environment risks related to alternative
- Technical and economic feasibility of alternative
- Other information on alternative

Since Terphenyl, hydrogenated 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 Terphenyl, hydrogenated and its potential 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

In the case of alternative 1, its PBT status is still under assessment but there are well-founded suspicions that this behaviour will be confirmed in the near future. Therefore, the substitution of Terphenyl, hydrogenated by this alternative when used as HTF in non-pressurised liquid phase systems could result in regrettable substitution.

The case of alternative 6 is similar to the above one, but in this case the main concern is the potential status as CMR substance, because it is currently under assessment. If it is confirmed in the future, the substitution of Terphenyl, hydrogenated by this alternative as solvent or process medium could lead to a regrettable substitution.

The result of the analysis of alternative 8 indicates that it cannot be considered an adequate substitute for Terphenyl, hydrogenated as a solvent or process medium due to technical reasons (high unsaturated degree), and because the registered volumes are not sufficient to fully replace Terphenyl, hydrogenated for this function.

Alternative 9 has been assessed as a potential alternative to Terphenyl, hydrogenated for the uses as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent, or process medium, and laboratory chemical. However, as the PBT status of this substance is still under assessment, the substitution of Terphenyl, hydrogenated by this alternative could become a regrettable substitution if it is confirmed in the future.

Finally, only alternative 7 shows features that could be compatible for its use as solvent or process medium, mainly as a textile dyestuff carrier. However, the feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

In summarising, an alternative to Terphenyl, hydrogenated that covers the IU of this substance has not been found when used as HTF, plasticiser, adhesive and sealants, paints and coatings, and ink and toners (because most of them could lead to a regrettable substitution), and only one potential alternative has been found for the use as solvent or process medium (biphenyl), although there is some uncertainty as to whether this alternative would be technically and economically suitable for this application.

As stated in **Annex E.2.3.3.**, biphenyl could be a potential alternative to Terphenyl, hydrogenated for its use as solvent or process medium, mainly as textile dyestuff carrier. The LR of this substance, which is also the LR of Terphenyl, hydrogenated, is placing on the market biphenyl as process media or solvent in many industries, including chemicals and petrochemicals (Eastman, 2022a). However, the company does not recommend or market Terphenyl, hydrogenated as solvent or process medium (Eastman, 2022b). This is an indication that both substances are not substitutable in this use.

Furthermore, no information on the technical and economic feasibility of biphenyl as alternative to Terphenyl, hydrogenated in this use has been reported during the different public consultations on Terphenyl, hydrogenated.

It should be noted that, in general terms, the responses to the SEA questionnaires (appendix 4) on potential alternatives have been very scarce and poor. Since no specific technical and economic data related to the potential alternatives have been provided by the impacted actors, it is assumed that this assessment of alternatives for the functions of Terphenyl, hydrogenated 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.

2.3. Risk Management Options

Various regulatory risk management options have been assessed to identify the options that are most appropriate to Terphenyl, hydrogenated. Discarded ROs as well as other union-wide measures are set out in **Annex E.1.2** and **Annex E.1.3** respectively, whilst the ROs included in the SEAs are set out below.

All considered ROs, defined in Annex E.1.1, restrict the manufacture, use and placing on the market of Terphenyl, hydrogenated as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months. Whilst the strictest RO (RO3) does not include any derogations, RO1 and RO2 include derogations of varying scope and length for uses as HTF and as plasticiser in the production of aircrafts. A summary of the considered derogations is provided in

Table 23. Restriction options

	RO1	RO2	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.			
Derogation for the use and placing on the market for industrial sites as HTF.	Implementation of strictly controlled closed systems with technical containment and organisational measures to minimise environmental emissions.	Implementation of strictly controlled closed systems with technical containment and organisational measures to minimise environmental emissions.	None
Derogation for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts.	EiF + 5 years	None	None

The analysis in **Annex E.8** shows that RO3 (the most stringent RO) has the highest emission reduction potential but at much higher costs than the other risk management options. RO2 has a higher emission reduction capacity than RO1 but a lower C/E. RO1 has a high C/E coupled with a high emission (risk) reduction capacity.

Therefore, RO1 is considered the most appropriate risk management option because it is effective and reduces potential risks to an acceptable level within a reasonable period of time.

The proposed restriction is targeted to the exposure that are of most concern, e.g., the use of Terphenyl, hydrogenated as a plasticiser. 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.

2.3.1. Definition of the strictly controlled closed systems (SCCS)

RO1 and RO2 include a derogation that shall apply for the use and placing on the market of Terphenyl, hydrogenated 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 in **Appendix 5** of the Annexes to this restriction report.

Compliance with **Appendix 5** will be mandatory for all current and future heat transfer systems using Terphenyl, hydrogenated as HTF to comply with the derogation conditions of the HTF use in this restriction.

The general approach described in **Appendix 5** can be applied to other organic HTFs, alike to Terphenyl, hydrogenated, if similar REACH Restrictions are introduced for other HTFs in the future.

Costs for the implementation of SCCS have been obtained during the stakeholder consultations via questionnaires and over telephone. This is illustrated in the Annex of the initial Annex XV Dossier on page 191, Chapter E.4.2. Costs for applying Strictly Controlled Closed Systems (SCCS) were communicated by industry in the range of EUR 10 000–30 000. Therefore an average costs of EUR 20 000 was considered, resulting in a total cost for 1 500 plants of EUR 30 Million. We assume that most of the costs is related to organizational matters, rather than structural measures. The feedback from the public consultation on the restriction proposal received is basically confirming this assumption.

2.4. Restriction scenario(s)

This section draws on **Annex E.3** which provides further details on the analysis of the restriction scenarios.

The restriction scenarios are defined by the anticipated behaviour of affected actors (current downstream users of Terphenyl, hydrogenated) in response to the ROs. These scenarios constitute the basis for assessing the socio-economic costs and benefits associated with the restriction.

The behavioural options deemed most plausible are:

- Switch to alternative substances, resulting in transfer of market shares between EU actors (to the benefit of companies switching first).
- Business reallocation outside the European Economic Area (EEA)[35], if the companies have customers outside the EU.
- Company would abandon business related to Terphenyl, hydrogenated globally.

The behavioural responses are based on information received from stakeholders through the 2021 SEA questionnaires (Appendice 4).

Considering the behavioural responses received in relation to the different industrial sectors that are using Terphenyl, hydrogenated as HTF in their production process, the proportion is the following:

Table 24. 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%	0.0%
Cement	0.0%	0.0%	100.0%
Steel	100.0%	0.0%	0.0%
Paints	50.0%	50.0%	0.0%
Total	**64.7%**	**17.6%**	**17.6%**

According to the information detailed in Annex E.3, the assumed behavioural responses for the use of Terphenyl, hydrogenated as plasticiser in the production of aircrafts are to switch to an alternative by 100%. Furthermore, this is the assumed behavioural response for the other uses of Terphenyl, hydrogenated.

[35] The EEA includes EU countries and also Iceland, Liechtenstein, and Norway.

2.5. Economic impacts

Economic impacts are concerned with costs or cost savings comparing the "proposed restriction" scenario with the "baseline" scenario.

The costs of the three ROs (RO1, RO2 and RO3) are estimated based on the behavioural assumptions set out in **Annex 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. The exact procedure and all details on costs and economic impacts considered are described and explained in detail in **Annex E.5**.

The estimated total costs for RO3 are in the range of 10.6 billion €. Around 98% of these costs are allocated to the use as HTF, followed by about 1.6% 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 0.1%.

Table 25 provides the summary of the costs.

Table 25. Total costs for RO3.

Type of Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in million €		
Substitution & Investment	3.00	2.00	10 032.62
Profit Losses	165.72	0.00	451.80
Enforcement costs	0.37	0.37	0.37
Subtotals	169.09	2.37	10 484.79
% of Total costs	1.59	0.02	98.39
Total Sum	**10 656.24**		

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., self-inspections, training) improvements of the plants, as needed. The derogation will apply, provided that such sites implement strictly controlled closed systems with technical containment and organisational measures to minimise environmental emissions.

In comparison to RO3, the total costs of RO2 have been significantly reduced to an amount of about **202 million €**. The cost contribution of HTF uses is now at about 15% and the majority of the costs is carried by the Aviation plasticiser use (>80%). The remaining uses carry about 1%. **Table 26** is summarizing the costs for RO2.

Table 26. Total costs for RO2.

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use
	in million €		
Substitution & Investment	3.00	2.00	30.00
Profit Losses	165.72	0.00	0.00
Enforcement costs	0.37	0.37	0.37
Subtotals	169.09	2.37	30.37
% of Total costs	83.78	1.17	15.05
Total Sum	**201,82**		

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 Terphenyl, hydrogenated from their manufacturers and importers to formulators of sealants and adhesives will be reduced.

As a profit loss about 83 million € was taken into account 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 Terphenyl, hydrogenated as plasticiser in the aviation sector. Terphenyl, hydrogenated was included in the Candidate List in June 2018[36], thus providing more than 10 years of time for reformulation and re-certification (Supplemental Type Certificates). The aviation industry would carry more than 70% of the costs, followed by the HTF use (ca. 25%) and around 2% by the remaining uses.

Table 27 summarises the costs for RO1.

Table 27. Total costs for RO1.

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use
	in million €		
Substitution & Investment	3.00	2.00	30.00
Profit Losses	82.86		0.00
Enforcement costs	0.37	0.37	0.37
Subtotals	86.23	2.37	30.37
% of Total costs	72.48	1.99	25.53
Total Sum	**118.96**		

Table 28 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 90-times higher than RO1 and 50-times higher than RO2. Substitution and investment costs in

[36] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

RO3 account for > 90%, in particular for the HTF sector. In RO2 and RO1 there is a shift towards profit losses, with share of > 80% for RO2 and ca. 70% for RO1, especially at the expense of the aviation industry.

Table 28. 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	82.86	165.72	617.52
Enforcement costs	1.10	1.10	1.10
Total Costs (in million €)	**118.96**	**201.82**	**10 656.24**

RAC and SEAC box

SEAC agrees with the approach taken for estimating costs but notes that the estimated costs are subject to significant uncertainty. SEAC considers that the cost of a full ban for the uses of the substance as HTF and in the aviation and defence sector are significantly underestimated by the Dossier Submitter. SEAC considers that there is convincing evidence to suggest that the cost associated with this restriction in all other sectors is low.

A further elaboration on this can be found in the the RAC and SEAC opinion.

2.6. Human health and environmental impacts

This section draws on **Annex E.5**. In 2018 Terphenyl, hydrogenated 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.

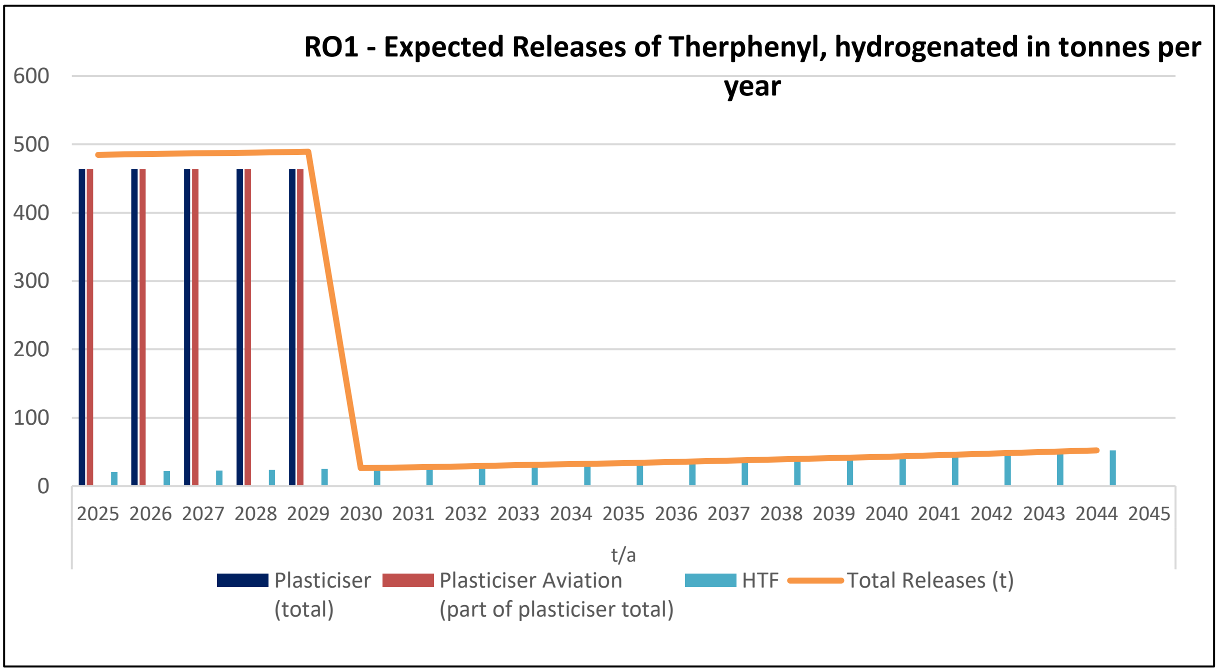
Terphenyl, hydrogenated is chemically stable in various environmental compartments with minimal or no abiotic degradation (see **Annex B.4.1**) and is very bioaccumulative, which means that the concentrations in the environment may increase over time (see **Annex B.4.3**). Quantification of risks is 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. The potential benefits will be linked to the environmental stock and therefore also reduction in emissions. SEAC 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).

As described in the baseline scenario of Terphenyl, hydrogenated in Annex D.3, the continued use of Terphenyl, hydrogenated was estimated as illustrated in

Figure 3. It should be noted that emissions prior to 2025 were not considered. Furthermore, the model assumes that emissions ceases when the use of Terphenyl, hydrogenated is baned for a certain use. 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 (approximately 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.

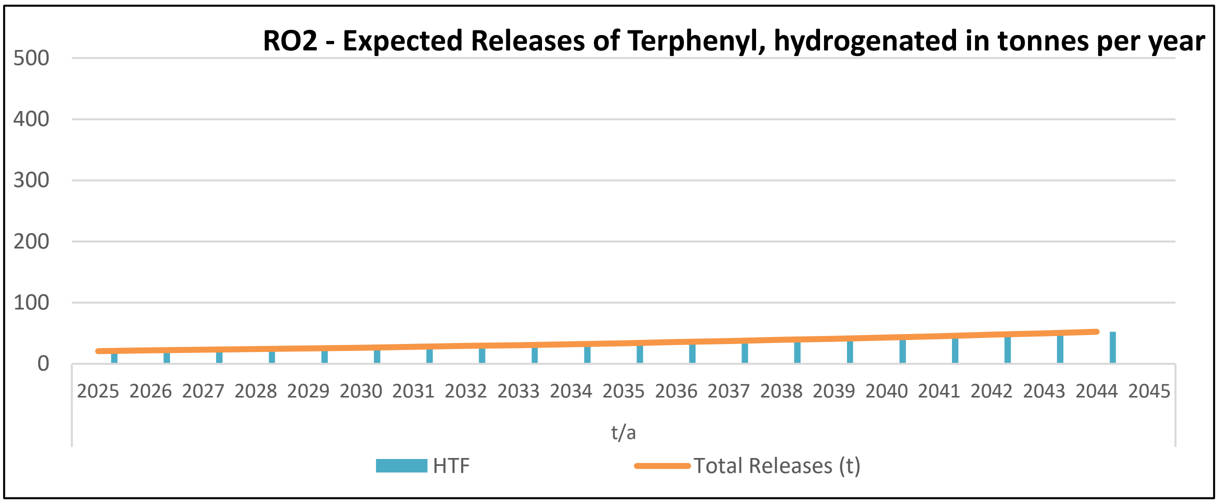
Figure 5 illustrates the trend of expected emissions for RO 1 where a derogation exists for plasticiser uses in the aviation industry (5 years after EiF) and a general derogation for HTF uses, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

Figure 5. Expected releases of Terphenyl, hydrogenated for RO1.



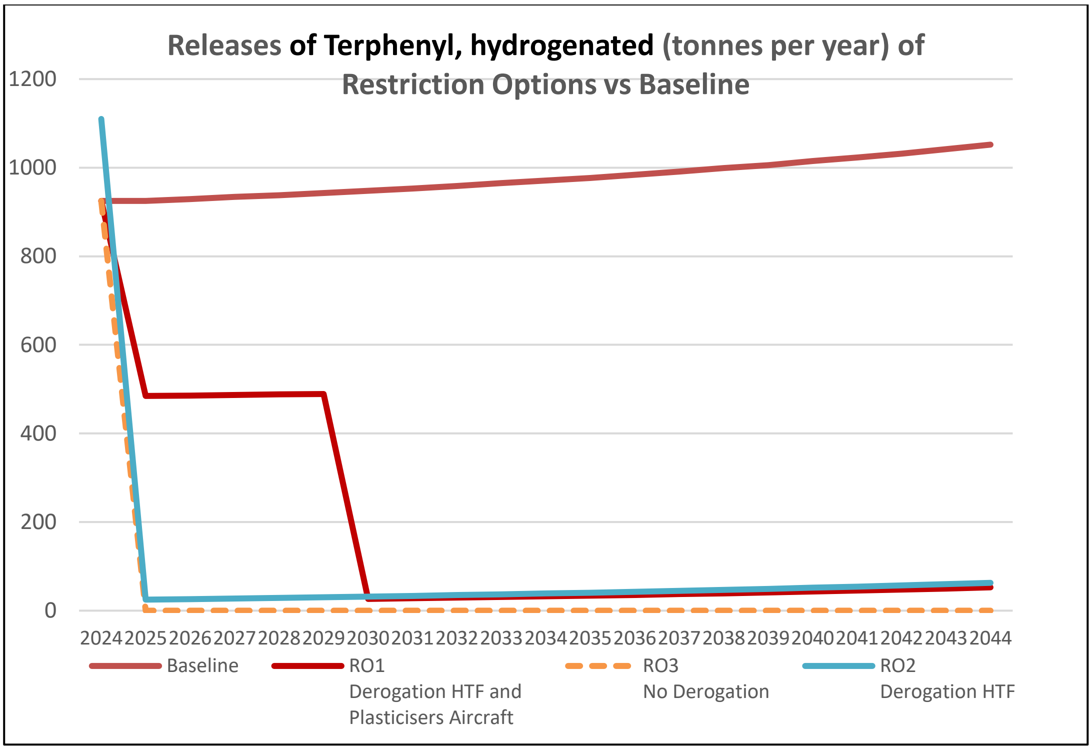
Since the HTF emissions are likely to be an overestimate as mentioned before, the introduction of controlled closed systems with engineered containment measures to minimise environmental emissions was considered with an emission reduction of 75% compared to the baseline scenario. **Figure 6** shows the expected releases for RO2, where the derogation exists only for the use of Terphenyl, hydrogenated as HTF. Consequently, emissions will only arise from the use of HTF.

Figure 6. Expected releases of Terphenyl, hydrogenated for RO2.



In case of RO3, where no derogations exist, all emissions will cease in 2025. **Figure 7** does exhibit the expected emissions of each ROs in comparison to the baseline scenario.

Figure 7. Expected emissions of each RO in comparison to the baseline scenario.



RAC and SEAC box

Given RAC's conclusions regarding the Dossier Submitter's estimation of emissions, SEAC considers that a cost-effectiveness approach is not possible in this case and follows a qualitative approach like the approach used in the PFHxA restriction. SEAC bases its evaluation of benefits on i) concern on persistency of terphenyl, hydrogenated, ii) emission minimisation used as a proxy for risk reduction/benefits assessment and iii) the potential for regrettable substitution.

A further elaboration on this can be found in the the RAC and SEAC opinion.

2.7. Other impacts, practicability and monitorability

2.7.1. Other 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 Terphenyl, hydrogenated, societal impacts may vary significantly. A complete restriction leading to a practical ban of all uses of Terphenyl, hydrogenated (RO3) would have a significant impact down the supply chain, particularly related to potential job losses in many industries that rely on Terphenyl, hydrogenated as an HTF. In contrast, RO1 would allow the continued use of Terphenyl, hydrogenated in this application (provided operations are undertaken under certain containment measures) and therefore the impact would be limited.

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 the extent to which 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 Terphenyl, hydrogenated would be **2 074**. The Dossier Submitter assumes, that for the Terphenyl, hydrogenated use as plasticiser in the **aviation industry** due to its complex value chain, approximately **1 500 jobs could be lost** for a total Terphenyl, hydrogenated ban in this industry. Putting the lost revenues of the "**non-aviation plasticiser and other uses**" into perspective with the aviation plasticiser use, the percentage is approximately 1.6%. This would result in approximately **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), 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[37] 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 29**. The Societal Loss was calculated by the number of lost jobs, multiplied by 2.7. The SEAC paper on the costs of unemployment[38] agreed on the 32nd SEAC Meeting describes how the various components of the costs of unemployment – lost output, leisure time, scarring etc – can be calculated, based on a methodology set out by Dubourg (2016).[39] This methodology recognises that unemployment is generally a temporary phenomenon, reflecting the time it takes for labour resources to be reallocated from one use

37 The average gross salary was estimated based on an average EU gross earning of € 13.7 per hour uplifted to 2020 (Eurostat), 40.3 hours work weeks (Eurostat, 2018b) and 33 holidays per year (European Data Portal, 2016).

38 af3a487e-65e5-49bb-84a3-2c1bcbc35d25 (europa.eu)

39 https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf

to another. The methodology is based on an explicit consideration of how long each source of impact of unemployment is likely to last. The SEAC paper reviews the results presented by Dubourg (2016) to propose a "rule of thumb", whereby the costs of one person being made unemployed is approximated by a figure equal to 2.7 times the previous gross wage of the individual. This rule of thumb is assumed to cover all of the costs associated with unemployment, until the person involved is re-employed.

Table 29. 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	0.00	0.00	0.00	0.00	2 074	140.00
Plasticiser Aviation	750	50.63	1 500	101.25	1 500	101,25
Plasticiser non-Aviation and Other Uses	24	1.62	24	1.62	24	1.62
Total per RO	**774**	**52.25**	**1 524**	**102.87**	**3 598**	**242.87**

Related to **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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated.

Moreover, in case of a complete Terphenyl, hydrogenated 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, Terphenyl, hydrogenated 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.

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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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.

2.7.2. Practicality and monitorability

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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated, would be complex to implement and manage for many users of Terphenyl, hydrogenated. 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated as a plasticiser in this sector. To be implementable within a reasonable timeframe, a restriction should be designed in such a way 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.

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 ones 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated in this sector and implementation of inspections by the relevant Member States. The second action would be related to the import of Terphenyl, hydrogenated 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 Terphenyl, hydrogenated.

The SCIP Database could potentially be useful to identify if new articles that do contain Terphenyl, hydrogenated have been notified after the restriction in order to identify non-compliance. 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 Terphenyl, hydrogenated 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 for articles containing Terphenyl, hydrogenated. However, this limit would be also applicable to Terphenyl, hydrogenated as a substance and in mixtures.

Terphenyl, hydrogenated as a pure UVCB substance (100% concentration) meets the criteria for classification as hazardous in accordance with CLP Regulation because it is classified by co-registrants as Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects). For this reason, and according to Article 31 of the REACH Regulation, its SDS must be available and the suppliers shall provide it to the customers.

This classification must be considered when Terphenyl, hydrogenated is placed in the market as a mixture. As the substance has not a defined M factor (default value of 1) and according to Part 4 of Annex I to CLP Regulation, any mixture containing Terphenyl, hydrogenated will be classified due to environmental hazards if the concentration of Terphenyl, hydrogenated is ≥ 2.5% w/w. However, according to Article 31 of the REACH Regulation, any mixture containing a vPvB substance in a concentration ≥ 0.1% w/w must be its SDS available, even if the mixture does not meet the criteria for classification as hazardous in accordance with CLP Regulation. Therefore, the suppliers of any mixture containing Terphenyl, hydrogenated in a concentration ≥ 0.1% w/w must be the SDS available and it shall be provided to the customers at their request.

In conclusion, the concentration of 0.1% w/w can be considered the concentration limit for Terphenyl, hydrogenated as a substance and in mixtures, because it triggers the information requirement under REACH Article 31.

There is no specific analytical method for the determination of Terphenyl, hydrogenated. This can be checked, as example, at the website of the United States Department of Labour, in which no monitoring method has been defined for PHT[40]. Regarding the components of Terphenyl, hydrogenated (o-terphenyl, m-terphenyl and p-terphenyl), only o-terphenyl has an accepted analytical method for its determination (NIOSH 5021)[41].

The analytical method used has been the NIOSH 5021 for o-terphenyl using a PTFE filter and analysis by GC/MS. The sampling and analysis have been carried out on a best effort basis using this method, with semi-quantitative analysis by GC/MS using o-terphenyl as a calibration standard. In this way, it has been possible to identify any terphenyl peaks present and quantify them as o-terphenyl.

This method has been applied to air samples (PTFE filters for the sampling of inhalable dust) and soil samples (bulk). The methodology used for the collection of these samples is described in **Annex B.9.3.3**. The reporting limits are 0.4 µg for air samples and 1.0 µg for soil samples. No determination of o-terphenyl in liquid samples was performed during the exposure measurements, although the method used in the analysis of liquid samples would be the same.

There are limitations with this method, as it is possible to report what terphenyls are 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 can be not detected.

There are no standard analytical methods for the identification of the other main individual components of Terphenyl, hydrogenated, as m-terphenyl or p-terphenyl. In fact, the NIOSH pocket guides to chemical hazards for o-terphenyl, m-terphenyl and p-terphenyl (CDC, 2019) refer to the NIOSH 5021 analytical method for o-terphenyl as common measurement method.

For this reason, the DS recommends assuming the highest concentration of o-terphenyl (7.1%, detected by GC/MS analysis) provided in the REACH registration dossier of Terphenyl, hydrogenated (ECHA, 2021b) to calculate the concentration of Terphenyl, hydrogenated from the results obtained for o-terphenyl. Although this is not a direct method for the identification and quantification of Terphenyl, hydrogenated, it can give an idea of the concentration of Terphenyl, hydrogenated in the samples.

This indirect method can be used for enforcement because, according to the available bibliography to the DS, o-terphenyl is not component of other substances than Terphenyl, hydrogenated. The US National Library of Medicine states that o-terphenyl is usually shipped as a mixture with its isomers m-terphenyl and p-terphenyl that is commonly used as a heat transfer fluid, being this the definition of Terphenyl, hydrogenated[42].

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[40] https://www.osha.gov/chemicaldata/444
[41] 5021.new (cdc.gov)
[42] https://pubchem.ncbi.nlm.nih.gov/compound/O-Terphenyl

O-terphenyl (CAS 84-15-1) is not a chemical product itself and it is not marketed as an individual substance globally. Furthermore, it has not been registered under REACH. In the ECHA website o-terphenyl can be found alone or included in other reaction mass substances. Only one of these reaction masses has been registered (EC 904-797-4). This means that the other substances cannot be commercially available in the EU and, therefore, they cannot be used in any European site and no detection of o-terphenyl should be expected from them.

Regarding the only registered substance, it is a reaction mass of o-terphenyl and m-terphenyl, that might contain p-terphenyl as impurity. The substance is only imported in a volume lower than 100 tonnes per year, very far of the volumes marketed for PHT (1 000 to 10 000 tonnes). Therefore, any interference between both substances during the determination of o-terphenyl (e.g., during enforcement) can be considered highly unlikely.

It has to be noted that the application of this restriction could push the European laboratories to develop a specific analytical method and a standardized protocol for the determination of Terphenyl, hydrogenated itself, instead of the current indirect method of o-terphenyl determination. This should guarantee the uniform enforcement of the restriction and compliance assurance of industry. Moreover, the current analytical method uses carbon disulphide, which is a STOT RE1 and Repro Cat. 2 toxicant. From this perspective the development of a new analytical method using less hazardous chemicals should be elaborated and taking advantage of the rapid developments of analytical chemistry.

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.

2.8. Proportionality (including comparison of options)

As highlighted in **Annex 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. 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 Terphenyl, hydrogenated 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 highest 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 Terphenyl, hydrogenated 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 Terphenyl, hydrogenated 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 30 provides a comparison of environmental emissions versus expected costs, jobs at risk and the social impacts for the different ROs evaluated.

Table 30. 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	118.96	52.25	171.21	3 006	85
RO2	201.82	102.87	304.69	686	96.5
RO3	10 656.24	10 899.11	10 899.10	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 31 shows the C/E estimates for each RO. The proposed RO1 has a high C/E (10 €/kg Terphenyl, hydrogenated emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1.

Table 31. Cost Effectiveness of all ROs.

	Total Economic Impact (€)	**Total Emissions** (tonnes)	**Total Emissions** (kg)	**Terphenyl, hydrogenated Reduced against Baseline** (kg)	**C/E** (€ per kg Terphenyl, hydrogenated)
Baseline		19 584	19 584 000	-	-
RO1	171 205 000	3 006	3 006 000	16 578 000	**10**
RO2	304 690 000	686	686 000	18 898 000	**16**
RO3	10 899 105 000	0	0	19 584 000	**557**

The C/E falls within the benchmark zone for being acceptable.

RO2 has, with 96.5%, a higher emission reduction capacity but a lower C/E ratio with a factor of 1.6 (16 €/kg Terphenyl, hydrogenated emissions avoided) compared to RO1. RO3 as the most stringent RO has the highest emission reduction potential but at much higher costs (557€/kg Terphenyl, hydrogenated emissions avoided), which are a factor of ca. 58 compared to RO1.

Please note that the high and low volume emission scenarios were averaged to an estimated Terphenyl, hydrogenated release of 925 tonnes in 2021, potentially a slight overestimate. The DS agrees that it is debatable, if an 85% emission reduction for a vPvB substance is sufficient. 5 years after Entry into Force of the Restriction (e.g., 2030), the plasticiser use in aviation will cease, which will limit the emissions to the HTF use, which is marginal.

The proposed RO1 has a high C/E coupled with an acceptable emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1 in order to respect the proportionality principle.

The main trade-off on a societal level is the potential environmental benefits associated with reducing emissions of Terphenyl, hydrogenated 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 Terphenyl, hydrogenated.

Table 32 compares C/E values of other recent restrictions. RO1 is with a ratio of 90 €/kg at the lower level compared to other substances.

Table 32. C/E ratios of recent (including 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

REACH Restriction	**€/kg**
PFOA Substances	734

RAC and SEAC box

SEAC stresses that there are arguments in favour of proportionality, based on available, overall qualitative information in the Background Document, information provided during the consultation of the Annex XV report as well as RAC's conclusion on uses and emission minimisation per sector or identified use. In this respect, SEAC recognises that there are large uncertainties on the exact magnitude of the socio-economic impacts of the restriction and of the emissions for specific sectors.

A further elaboration on this can be found in the the RAC and SEAC opinion.

3. Assumptions, uncertainties and sensitivities

All key variables, input parameters and assumptions used for the exposure assessment and the SEA are set out and described in detail in **Annex F.1**. Volumes and Uses (**Annex A**) as well as number of sites using Terphenyl, hydrogenated are considered to be accurate, since consistent data was provided from industry during the stakeholder consultations. Assumptions on Exposure Assessment (**Annex B.9.**) have been referenced in the respective tables.

The current emissions of Terphenyl, hydrogenated to the environment from various sources and sectors were derived according to **Annex B.9.** (Exposure Assessment). The environmental releases of the high emission scenarios are based on the default release factors in accordance with ECHA Guidance R.16 (ECHA, 2016). In case other information on the releases was available to the Dossier Submitter and applicable for Terphenyl, hydrogenated, 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 (Appendix 1 to the Annex) by the LR, which was initiated to update the Exposure Assessment of the Registration Dossier. Release information as indicated by SpERCs, OECD ESD and the Exposure & Release Questionnaire is used for the low emission scenarios.

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 risk management measure that is used during the process.

The share of the total emissions was evaluated based on the market sector. The exposure assessment shows that in the "high emission scenario" the largest source of Terphenyl, hydrogenated 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 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%).

A differentiation between plasticizer (non-aviation) and plasticizers for use in aviation was not made and the expected releases are just based on the volumes used in these sectors.

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. It is expected that the decrease in volume as of 2036 will be 5% per annum. 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 **Annexes E.4.** and **E.6**.

The lack of information on fractions released to air, water, and soil from the various processes during the lifecycle of Terphenyl, hydrogenated creates significant uncertainties in the exposure assessment. The PECs have been estimated using ECHA Guidance. The approach used is generic and uncertainties arise in modelled outputs from a number of sources. Moreover, it is to be noticed that the number of articles containing Terphenyl, hydrogenated imported into the EU and exported from the EU is not known. In addition, it is an uncertainty if a restriction of imported articles with Terphenyl, hydrogenated 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%. This is an uncertainty since it is not clear, how many articles with concentration levels <0.1% of Terphenyl, hydrogenated are being imported and if those imported articles would pose a risk of environmental exposure.

Please note that the SCIP Database was referenced as an additional data source for estimating volumes and trends in conjunction with the Baseline Emissions. The Baseline describes the expected trends that would occur without the introduction of any new regulatory measure. So a restriction on Terphenyl, hydrogenated is not included in this trend scenario.

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. This methodology has been described in detail in **Annex E.4.** (Economic Impacts). 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.

As highlighted in **Annex 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 the quantitative data on emissions and release estimates versus those associated with exposure estimates in HTF uses, 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. Due to the high uncertainty of the quantitative release estimations, a qualitative assessment was conducted. In addition, strictly controlled closed systems and associated RMMs and OCs were defined. Moreover, another key uncertainty is related to the plasticisers uses in aviation and non-aviation related to availability of alternatives as well as uses of Terphenyl, hydrogenated in non-plasticiser applications, since no feedback could be obtained during stakeholder consultations. Furthermore, treatment of waste as well as treatment of articles at the end of their service lifetime is not certain.

Table 33 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 33. Sensitivity of key uncertainties.

Parameter tested	**Impact on Emissions**	**Impact on Costs**	**Impact on C-/E-Ratio**
Quantitative data on HTF emissions underestimated	↑	None	↓
Non-availability of alternatives for plasticiser and non-plasticiser applications	↓	↑	↑
EoL management of articles	↓↑	Unknown	↓↑
Market growth rate underestimated	↑	None	↑
Market growth rate overestimated	↓	None	↓
Cost overestimation	None	↓	↓
Cost underestimation	None	↑	↑

4. Conclusion

To identify the most appropriate measure to address the risks of the Terphenyl, hydrogenated 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 situations that are of most concern, e.g., the use of Terphenyl, hydrogenated as a plasticiser and the service life of articles containing Terphenyl, hydrogenated. 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.

This derogation has been proposed in accordance with other restriction proposals in which placing on the market and use of a substance has been permitted when strict operational conditions and risk management measures are adopted, as in the case of Decamethylcyclo-pentasiloxane (D5) when use in closed systems (ECHA, 2019). Although in this case the volumes of Terphenyl, hydrogenated used as HTF cannot be considered low, the lack of suitable alternative substances or technologies that could lead to an overall reduction in the risk and the low proportion of releases to the aquatic compartment, coupled with high socio-economic benefits, make this measure applicable.

The conditions and requirements that a HTF installation shall comply with to be considered as a strictly controlled closed system are defined in the **Appendix 5** of the Annexes to this restriction report.

Compliance with **Appendix 5** will be mandatory for all current and future heat transfer systems using Terphenyl, hydrogenated as HTF to comply with the derogation conditions of the HTF use in this restriction. This will as well overcome the uncertainties on real emissions.

Regarding the control of the current installations, most of the systems are compliant with PED (see details in **Annex E.3.4**). This Directive requires the initial legalization of the pressure equipment and periodical regulatory inspections. To achieve conformity with PED, the conformity assessment of pressure equipment must be certified by a notified body, which will ensure that the technical and safety conditions of the installation are maintained. The objective of these inspections is to verify that this equipment complies with the mandatory safety conditions. For this purpose, different types of checks, inspections with non-destructive testing, hydrostatic tests, or other substitute tests are carried out.

Furthermore, any chemical facility in the EU needs to have a permit to operate, issued by local, regional, or national Authorities. These competent authorities regularly assess this permit through periodic inspections and audits.

Finally, the two standards cited in **Appendix 5** are national and non-EU-wide, but they constitute the general rules for the plant basic design in all of the EU countries. As an indication of its recognition and use, the German standard DIN 4754-1 was originally issued in 1973 and it has been periodically modified to be adapted to technical progress (the last version is dated 2015).

All of the above exposed are indicative of the high level of control of this type of installation at present, which will be increased once all the measures described in **Appendix 5** are implemented.

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