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Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Terphenyl, hydrogenated

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

ECHA/SEAC/[Opinion N°(same as opinion number)]

Draft date: 16 March 2023

16/03/2022

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

[Date]

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): **Terphenyl, hydrogenated**

EC No.: **262-967-7**

CAS No.: **61788-32-7**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Italy has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration on **20 June 2022**. Interested parties were invited to submit comments and contributions by **20 December 2022**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: **Laure Geoffroy**

Co-rapporteur, appointed by RAC: **Geneviève Deviller**

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on 16/03/2023.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.**]**

The opinion of RAC was adopted **by consensus**. of all members having the right to vote.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Marit Måge**

Co-rapporteur, appointed by SEAC: **Manuel Rodriguez Hernandez**

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **10 March 2023.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article 69(6)(a).**]**[4].

[The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.**] [**No socio-economic analysis, or the information which can contribute to one, were received from interested parties during the consultation in accordance with Article 69(6)(b).**]**.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration on **15/03/2023**. Interested parties were invited to submit comments and contributions by **15/05/2023**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and] 71(1)**]**[Error! Bookmark not defined.].

The opinion of SEAC was adopted **by [consensus.][a simple majority]**[Error! Bookmark not defined.] of all members having the right to vote. [The minority position[s], including their grounds,

are made available in a separate document which has been published at the same time as the opinion.]**Error! Bookmark not defined.**.

Contents

Tables

1. OPINION OF RAC AND SEAC[1]

The proposed wording of the restriction set out below aims to express the intention of the Dossier Submitter. Should a restriction be adopted then the final wording of the entry in Annex XVII of REACH will be decided by the European Commission.

Table 1 The restriction proposed by the Dossier Submitter

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 for the use and placing on the market as a heat transfer fluid, provided that such sites implement strictly controlled closed systems 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 not apply after entry into force +5

[1] Do not delete any of the headings in this document under any circumstances. This is important to keep in mind for the combination of the RAC and SEAC opinion towards the end of the opinion-making process.

	years, for the use and placing on the market in aerospace and defence applications and their spare parts, maintenance and repairs.

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **terphenyl, hydrogenated** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

RAC points out that o-terphenyl (the constituent of terphenyl hydrogenated that drives the restriction proposal due to its vPvB properties) may be present as constituent of other substances in addition to terphenyl hydrogenated. RAC recommends that the risks posed by o-terphenyl resulting from the use of these substances should be further investigated and addressed if confirmed.

The conditions of the restriction proposed by RAC are:

Table 2 The restriction proposed by RAC

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, or used, from [18 months after entry into force]: a) as a substance on its own. b) in other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w. c) in articles or any parts thereof in a concentration equal or greater than 0.1% w/w. 2. By way of derogation, Paragraph 1 shall not apply to the use and the placing on the market for use as a heat transfer fluid in industrial sites, provided that such sites have implemented strictly controlled

	closed systems with technical containment and organisational measures to prevent environmental emissions[1]. The implementation of the strictly controlled systems shall be monitored by a representative program. This derogation shall end by [x year(s) after entry into force of the restriction][2]. Paragraph 1 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force].

Explanatory notes:

[1] **Column 2, paragraph 2:** technical containment and organisational measures to prevent environmental emissions in strictly controlled closed systems shall comply with the organisational and technical requirements described in Appendix 5 in the Annexes of the Background Document by the date of entry into force of the restriction. Additionally, the industrial sites shall implement a monitoring program to assess environmental releases and confirm further the appropriateness and effectiveness of the operational conditions (OCs) and risk management measures (RMMs) in place.

[2] **Column 2, paragraph 2**: [x year(s)] to be considered by SEAC. RAC supports the shortest possible time limit to minimise environmental emission as much as possible.

1.2. THE OPINION OF SEAC

See SEAC opinion

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The restriction aims at reducing risks to health and the environment from the use of terphenyl, hydrogenated, which was identified by ECHA as a Substance of Very High Concern (SVHC) in 2018 because of its very persistent and very bioaccumulating properties (vPvB). This Substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) was assessed by evaluating the properties of 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.

Terphenyl hydrogenated is not manufactured in the European Union (EU), the imported volume is estimated to be 7 500 tonnes (2020). The main use, accounting for approximately 90% of the annual use volume is as a heat transfer fluid (HTF). When terphenyl, hydrogenated is used as an HTF, it is consistently contained within a closed system with limited discharges identified. However, exposure to the environment cannot be disregarded according to the Dossier Submitter. For all non-HTF uses, e.g. as a processing solvent and plasticiser, an unacceptable risk for the environment and human health has been identified.

According to REACH Annex I para 6.5, the risk to the environment and human health cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for such substances, nor can a threshold be determined for PBT/vPvB substances. Furthermore, as vPvB and PBT chemicals are treated as non-threshold substances, even low levels of emissions could pose a risk to the environment. Therefore, a REACH Restriction was identified as the most relevant and proportionate Regulatory Management Option (RMO) by the Dossier Submitter.

Three restriction options (RO1, RO2, RO3) are analysed in the impact assessment, all of which restrict the manufacture, use and placing on the market of terphenyl, hydrogenated in concentrations >0.1% by the end of a transition period of 18 months.

No feasible alternatives for terphenyl, hydrogenated are currently available, without creating a situation of regrettable substitution.

RO1 and RO2 both include derogations of varying scope and length for uses as HTF, i.e. by far the most important use. RO1 includes additional derogations for the use and placing on the market of terphenyl hydrogenated in aerospace and defence applications and in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats. Restriction option (RO3) does not include any derogations.

Based on an analysis of the effectiveness, proportionality, practicality and monitorability of the three restriction options, RO1 is proposed by the Dossier Submitter to be the most appropriate risk management option because it is effective and reduces potential risks to an acceptable level within a reasonable period of time.

2.2. Summary of opinion

2.2.1. RAC opinion summary

The Committee for Risk Assessment (RAC) supports a restriction on Terphenyl, hydrogenated.

Terphenyl, hydrogenated is used mainly as a HTF in industrial installations (90% of the total volume), in various articles from different sectors (i.e., electrical and electronic equipment (EEE) and in other minor uses (i.e., as a process solvent and a laboratory chemical). Releases and ongoing exposures in the environment and to humans have been confirmed by a limited

set of monitoring data. Due to large uncertainties in the quantitative assessment presented by the Dossier Submitter, RAC qualitatively evaluated the potential for releases from different uses, and the effectiveness of the proposed restriction to prevent such releases. The Committee concludes that releases to the environment are likely from all uses within the scope of the proposed restriction. This will lead to an increasing and irreversible environmental stock and further environmental and human exposure with unknown long-term effects. RAC concludes that current regulatory obligations do not directly lead to a reduction of emissions of terphenyl, hydrogenated and that a REACH authorisation would be less effective to control the risk considering the time required for the process and the exclusion of the articles. RAC is of the opinion that a broad EU-wide restriction with targeted derogations and transition periods is the most appropriated measure to reduce the risks of Terphenyl, hydrogenated.

RAC supports the proposed ban for uses where based on the current level of information, it is not possible to implement risk management measures to minimise emissions, especially during the service-life of various articles incorporating terphenyl, hydrogenated.

RAC supports a time-limited derogation under specified conditions for the placing on the market and for the main use as HTF in industrial installations. RAC is of the opinion that the mandatory compliance with strictly controlled closed systems with technical containment and organisational measures to prevent environmental emissions as described by the Dossier Submitter in a guidance document included in the Background Document (Appendix 5) is a minimum requirement for the industrial sites using HTF containing terphenyl, hydrogenated. Moreover, due to uncertainties with the effectiveness of the proposed conditions of use and risk management measures, RAC supports a mandatory monitoring program to assess the environmental releases at industrial sites. RAC also supports the derogation with a time limit to promote the development of safer alternatives.

RAC does not support the derogation for the use of terphenyl, hydrogenated in aerospace and defence applications. Overall, RAC considers this as potentially as a wide-dispersive use due to the professional use of various formulations. RAC notes that even if the volume of the substance related to aerospace and defence applications is not known with precision, it represents <10% of the imported tonnage range estimated at approximately 730 T/y. However, there is not enough risk-based information to ensure minimisation of emissions of terphenyl, hydrogenated from such formulations used in the aerospace and defence sector.

RAC does not support the proposed derogation for the use of terphenyl, hydrogenated in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats, noting that consumer uses are advised against in the registration dossier for terphenyl-hydrogenated. RAC considers the consumer use of thermostats as wide-dispersive use for which environmental releases are assumed and especially during the waste life cycle. RAC notes that there is no robust information on existing RMMs in the sector. RAC considers that there is not enough risk-based information to ensure minimisation of emissions of terphenyl, hydrogenated for the use of terphenyl hydrogenated in these articles (consumer use) to support a derogation. RAC notes that standard analytical methods for all matrices within the scope of the proposed restriction need to be developed which especially in articles could be challenging to achieve required concentration limits. However, based on the available analytical methods, RAC is of the opinion that it would be feasible to develop standardised analytical methods for the enforcement of this restriction.

RAC estimates that inconsistent information related to the various risk management measures in place to minimise the release of terphenyl, hydrogenated used as HTF and the lack of information regarding non-HTF uses constitute significant uncertainties in the risk and effectiveness assessment of this proposed restriction.

RAC concludes that overall, the proposed restriction will draw attention to the necessity for appropriate risk management measures, particularly for the use in HTF and is therefore effective in minimising the risks resulting from the use of terphenyl, hydrogenated and is enforceable.

RAC notes that this restriction proposal is focused on terphenyl, hydrogenated, because of its content of o-terphenyl. However, RAC points out that a wider restriction proposal focused on o-terphenyl and all other uses of o-terphenyl (in other substances) could have been more effective.

2.2.2. SEAC opinion summary

See SEAC opinion

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. RISK ASSESSMENT

3.1.1. Description of and justification for targeting (substance and use scope)

Summary of Dossier Submitter's assessment

The proposed restriction is primarily 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 Dossier Submitter considers that the proposed restriction is effective and will reduce potential risks to an acceptable level within a reasonable period of time.

Terphenyl hydrogenated is a UVCB- substance and was identified as a Substance of Very High Concern (SVHC) in 2018, because of its very persistent and very bioaccumulating properties (vPvB). The scope of the proposed restriction covers the UVCB 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.

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, the substance has not been registered under REACH.

RAC conclusion(s):

RAC considers that the scope and targeting of the proposed restriction are clear.

RAC notes that the scope of the risk assessment performed by the Dossier Submitter is limited to terphenyl hydrogenated while o-terphenyl is the constituent that drives the SVHC-status due its vPvB properties (see further discussion in section 3.4.1 and 3.5.1).

According to the evidence gathered by RAC, there are additional substances that may contain o-terphenyl as a constituent.

RAC considers that these substances could have been targeted in the present restriction proposal and that a broader restriction proposal focused on o-terphenyl and all other uses of o-terphenyl (in other substances) would have been more efficient.

Key elements underpinning the RAC conclusion:

1. The scope of the hazard assessment is justified

RAC considers that risks of PBT and/or vPvB substances cannot be adequately controlled and terphenyl, hydrogenated identified as vPvB may cause severe and irreversible adverse effects if released to the environment (see Section 3.1.2).

RAC takes note of the assessment and conclusions of MSC regarding the vPvB properties of terphenyl, hydrogenated. The MSC conclusions provide a reliable basis for concern and do not warrant further assessment by RAC. A risk assessment based on vPvB, i.e. environmental properties is enough to justify a restriction and therefore an assessment of potential human health hazards is not deemed necessary for the purpose of this restriction.

2. The substance within the scope of the risk assessment is clearly described by the Dossier Submitter

Terphenyl, hydrogenated was identified as a vPvB, and was included in the Candidate List on 27 June 2018. It was assessed by evaluating its constituents and at least one of these constituents (ortho-terphenyl / o-terphenyl) fulfils both the vP and vB criteria. Although o-terphenyl is the constituent that leads to terphenyl, hydrogenated meeting the criteria for a vPvB substance, the restriction proposal of the Dossier Submitter applies to the UVCB substance as a whole. The Dossier Submitter considers that o-terphenyl is part of the UVCB substance (as the other individual components) and cannot be considered separately. Consequently, the Dossier Submitter targeted the scope of the restriction on terphenyl, hydrogenated (CAS 61788-32-7) and argues that o-terphenyl (CAS 84-15-1) is not a chemical substance itself and is not marketed as a substance in the EU because it is not registered under the REACH regulation.

RAC concludes that the risk assessment as provided for terphenyl, hydrogenated has a clear scope. The Dossier Submitter has identified the risks for the substance terphenyl, hydrogenated.

Further to the Dossier Submitter's proposed scope and approach, RAC observes several aspects related to the potential risks arising from o-terphenyl:

a. o-terphenyl (purity > 99%, CAS 84-15-1), p-terphenyl (purity > 99%, CAS 92-94-4), m-terphenyl (purity 99%, CAS 92-06-8) are available on the market for laboratory uses. Moreover, the registration status of a substance is dependent of the quantity produced by the legal entity and the absence of registration does not mean that the substance is not marketed in the EU but that no legal entity places more than 1 tpa of o-, m- or p-terphenyl on the EU market individually.

b. On the ECHA website, in the ECHA 'search our chemicals' database[2], more than 100 entries contain the term terphenyl. Among them, o-terphenyl can be found alone or included in other reaction mass substances. One of these, reaction mass of o-terphenyl and m-terphenyl, that might contain p-terphenyl as an impurity, has been registered (EC 904-797-4) and is imported/manufactured in a volume lower than 100 tonnes per year.

c. The approach claimed by the Dossier Submitter is not in line with the ECHA document on 'Regulating substances based on constituents' presented to CARACAL (ECHA, 2020) in which it is supported to address the risk caused by constituents within the UVCB substance via targeting the constituent rather than the UVCB substance of which the constituents form a part.

Therefore, RAC considers that the use of o-terphenyl as a constituent in substances other than terphenyl, hydrogenated could have been considered by the Dossier Submitter, at least as a restriction option. In addition, RAC performed a preliminary screening and has identified several petroleum substances as well as other substances from the terphenyl group that would indicate that the presence of o-terphenyl at relevant concentrations in substances other than terphenyl, hydrogenated is relevant.

The scope is targeted to the exposure situations that are of most concern for the use of terphenyl, hydrogenated, i.e., its use as a plasticiser and the life-cycle stages of articles containing terphenyl, hydrogenated.

RAC supports the general approach that the restriction proposal covers the uses resulting from the presence of terphenyl, hydrogenated in substances and/or in mixtures in a concentration equal to or greater than 0.1% w/w and in articles in a concentration equal to

[2] ECHA website, search for chemicals, "terphenyl", 31/01/2023, Search for Chemicals - ECHA (europa.eu). The results of this request do not distinguish active/inactive registered substances, meaning only that the substance had been quoted in the IT system

or greater than 0.1% w/w, because this triggers the information requirement under REACH Article 31. However, RAC notes that the Dossier Submitter did not assess the scenario setting a lower or higher concentration limit, whereas the measurement of terphenyl, hydrogenated is based on its constituent o-terphenyl, for which the highest concentration of 7.1% (detected by GC/MS analysis) is assumed (see section 2.7.2 of the Background Document).

3.1.2. Hazard(s)

Summary of Dossier Submitter's assessment:

The hazard assessment of the Dossier Submitter is based on the assessment of the ECHA Member State Committee, carried out for the purpose of identifying terphenyl, hydrogenated as a Substance of Very High Concern (SVHC) in 2018, on the basis of the presence of o-terphenyl which fulfils both vP and vB criteria. 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 to be considered a vPvB substance according to Article 57 (e) of REACH (see Annex B4).

According to REACH Annex I para 6.5, the risk to the environment and to human health cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold, can be determined for PBT/vPvB substances. Due to these intrinsic substance properties, terphenyl, hydrogenated may cause severe and irreversible adverse effects on the environment and on human health if the releases are not minimised.

RAC conclusion(s):

RAC takes note of ECHA's Member State Committee decision that terphenyl, hydrogenated meets the REACH Annex XIII criteria for very persistent and very bioaccumulative substances (vPvB) based on the conclusion on the constituent o-terphenyl.

Key elements underpinning the RAC conclusion(s):

The RAC opinion on the hazard of terphenyl, hydrogenated is based on Section 1.2.4 of the Background Document, Annex B.4 and the information submitted in the consultation. The decision by ECHA's Member State Committee and is not further evaluated by RAC in this opinion. According to the Support Document for identification of the substance as an SVHC because of its vPvB properties (ECHA, 2018a): "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".

3.1.3. Emissions and exposures

Summary of Dossier Submitter's assessment:

Terphenyl hydrogenated is widely used in the EU and is imported to the EU as a substance, in mixtures and in articles. There are currently 6 active registrants of terphenyl, hydrogenated under REACH. There is no manufacture of terphenyl, hydrogenated within EU after Brexit (see section 1.1 of the background document and Annex A.1)

Based on information received from stakeholders, the global volume of terphenyl, hydrogenated manufactured in 2020 is approximately 32 000 tonnes per year. The total volume imported in 2020 into the EU is assumed to be up to 7 500 tonnes per year which includes as well estimates of imports in articles and formulations in the order of 100 tonnes per year.

Exposure of terphenyl, hydrogenated mainly occurs from releases to air and water from point

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

Terphenyl, hydrogenated's main use in the EU (90% of annual use volume) is as a high-temperature Heat Transfer Fluid (HTF) in industrial installations, a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source. 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.

The second main use in the EU (10% of total annual use volume) is as a plasticiser for the production of coatings, sealants, and adhesives and in polymer applications. The final coatings, sealants, and adhesives are used in a wide variety of sectors, for example the aerospace industry. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables).

The remaining registered uses (both industrial and professional) involve less than 1% of the amount of substance imported into the EU. According to the lead registrant, all uses as HTF should be considered as industrial and no uses are considered professional. Consumer uses and intermediate uses have not been registered. 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.

Specific information on the releases to the environment of terphenyl, hydrogenated during its use as HTF at industrial sites is obtained in the Exposure & Release Questionnaire (2018). In order to obtain updated information on potential environmental emissions of terphenyl, hydrogenated from industrial uses as HTF, a monitoring program was designed and developed at a number of industrial sites that use terphenyl hydrogenated in this application. 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 (see section B.9.3.3).

Very little specific 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 consultations issued for this substance: the Lead Registrant Socio-Economic Analysis questionnaire from 2018, the socio-economic impact questionnaire from the European Commission 2020, the responses to the 10th Recommendation received by ECHA in 2020[3], and the Dossier Submitter Socio-Economic Analysis questionnaire from 2021. Also, the Dossier Submitter did not find information regarding these uses via internet search.

Taking into account the (lack of) available information two type of assessments were conducted: a quantitative estimation of releases into the environment as well as a qualitative assessment. For the main identified uses with a potential to be widely dispersive, the quantitative information to minimise exposure was missing. In these cases, where no effective RMMs can be expected or information on RMMs was lacking, the qualitative assessment is applied.

Quantitative assessment

For each exposure scenario, the Dossier Submitter provided an overview table with the input parameters and the resulting emissions to air, water and soil (see Annex B9 of the Background Document).

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

The environmental exposure assessment is based on the default release factors in accordance with ECHA Guidance R.16 (ECHA, 2016). In general, the high emission scenario represents a worst-case assumption whereby e.g., the above default release factors are used. Hence, thisemission scenario is generally regarded as a very conservative approach overestimating the actual exposure. The low emission scenario considers more specific information from, e.g., SpERCs, made available through the Exposure & Release Questionnaire (2018) by the Lead Registrant and/or via the consultation on the Annex XV dossier.

Qualitative assessment

Taking into account the available information, including the information received via the consultation on the Annex XV dossier, a qualitative assessment was performed for various uses, which were arranged based on the market sector as follows:

- HTF uses at industrial sites,
- adhesives/sealants,
- coatings/inks,
- miscellaneous uses, and
- consumer use as HTF in thermostats.

The qualitative assessment is based on estimated use in the market sector and likelihood of possible release in relation to availability and possible effectives of risk management measures (see section B.9.23 in the Annex to the Background Document). The prioritization of the market sectors and their respective contribution to the identified risk are listed in Table 65 of section B.9.23.2 of the Annex to the Background Document.

RAC conclusion(s):

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, due to insufficient justification provided, various inconsistencies in reporting between different sections of the Background Document and significant data gaps for some use scenarios.

Based on a qualitative evaluation of the available information (section 3.4.3), 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).

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter has used information for the main use as HTF and relevant life cycle stages of terphenyl, hydrogenated from the REACH registration dossier (ECHA, 2021a). Currently, there is one joint registration for terphenyl, hydrogenated (active since 2010 and last updated in October 2022) covering six active registrants. RAC agrees in principle with this approach but notes that the Dossier Submitter has not considered it necessary to address the manufacturing life cycle stage in the context of this restriction proposal. The reason is that only the lead registrant is manufacturing terphenyl, hydrogenated at a plant in UK (Newport) but since the UK left the EU (Brexit), terphenyl, hydrogenated is not manufactured anymore within the EU. However, RAC notes that the properties of terphenyl, hydrogenated i.e. persistency, bioaccumulation, adsorption to soil and sediment, raise a concern of potential long-range transport via suspended particles in air.

Additionally, the Dossier Submitter has not taken into account the potential use of HTF at

professional sites, which based on information received from the REACH lead registrant of the substance is known to occur.

Finally, RAC notes that the consumer use is advised against in the REACH registration dossier and that the Dossier Submitter has correctly considered based on the review of the SCIP database and manufacturer declarations available online that the use as HTF in thermostats in electromechanical temperature controls takes place in ovens and stoves. The Dossier Submitter's assessment is only of qualitative character and no quantitative estimation of environmental release has been made.

Quantitative assessment

Where no specific information was available, the Dossier Submitter based their assessment of environmental emissions on default release factors (ERC in accordance with ECHA Guidance R.16) further referred to as "upper estimate". For most of the identified uses, the exposure assessment has been refined using applicable SpERCs, OECD Emission Scenario Document and specific information from stakeholder consultations i.e. the Lead Registrant Exposure and Release Questionnaire (LR - SEA 2018), the Commission - Socio-Economic Impact Questionnaire (COM, 2020) and the Dossier Submitter - SEA Questionnaire, (DS SEA 2021), and the results from a monitoring program performed at industrial sites using HTF. Table 3 presents the use scenarios considered in the exposure assessment, their input data and release estimates as reported in the Background Document and the accompanying Excel sheet detailing the calculations (Further estimation for the Expo Ass).

Table 3 Overall assumptions of the Dossier Submitter for release estimations

Life-cycle stage	Covered uses	Total volume input	Share of total volume input	Amount used to estimate releases (T/y)	Upper estimate: Release fractions and Total Release (TR)	Lower estimate: Release fractions and Total Release
Formulation	Formulation, transfer, and packing of PHT used as solvent/process medium or as laboratory chemical	Imported volume (7 471 T/y)	0.49%	36.5	ERC 2 Air: 0.025 Wastewater: 0.02 Soil: 0.0001 Solid waste: none TR= 1646 kg/y	None
	Formulation of adhesives and sealants	Imported volume (7 471 T/y)	6.42%	480	ERC 2 Air: 0.025 Wastewater: 0.02 Soil: 0.0001 FEICA / EFCC SpERC 2.1a.v3 Solid waste: 0.03 TR= 36048 kg/y	FEICA / EFCC SpERC 2.1a.v3 Air: 0.0008 Wastewater: 0.0002 Soil: 0 Solid waste: 0.002 TR= 1440 kg/y
	Formulation of coatings or inks	Imported volume (7 471 T/y)	3.4%	254	ERC 2 Air: 0.025 Wastewater: 0.02 Soil: 0.0001 CEPE SpERC 2.1c.v2 Solid waste: 0.01 TR= 13995 kg/y	CEPE SpERC 2.1c.v2 Air: 9.5E-5 Wastewater: 5E-5 Soil: 0 TR= 37 kg/y
Uses at industrial sites	Use as HTF	Theoritical installed volume in the EU (taking into account the installed volume at the largest plant ofn1 200 T and a number of sites of 100.	100 %	120 000	ERC 7 Air: 0.05 Wastewater: 0.05 Soil: 0.05 Solid waste: none TR= 18 000 T/y	Exposure&Release Questionaire (2018) Monitoring program Air: 0 Wastewater: 0 Soil: 0 Solid waste: None TR= 0 T/y
	Use as adhesive and sealants	Imported volume (7 471 T/y)	5.14%	384	ERC 5 Air: 0.5 Wastewater: 0.5 Soil: 0.01 FEICA SpERC 5.1a.v3 Solid waste: 0.06 TR= 410880 kg/y	FEICA SpERC 5.1a.v3 Air: 0.017 Wastewater: 0 Soil: 0 Solid waste: 0 TR= 6528 kg/y
	Use as solvent or process medium	Imported volume (7 471 T/y)	0.47%	35	ERC 4 Air: 1 Wastewater: 1 Soil: 0.05 Solid waste: 0.05 TR= 7350 kg/y	ESVOC SpERC 4.1.z.v2 Air: 0.00001 Wastewater: 0.00001 Soil: 0.0001 Solid waste: 0.05 TR= 175 kg/y
	Use for coatings or inks applications	Imported volume (7 471 T/y)	2.73%	204	ERC 5 Air: 0.5 Wastewater: 0.5 Soil: 0.01 CEPE SpERC 5.1a.v2 Solid waste: 0.52 TR= 312120 kg/y	CEPE SpERC 5.1a.v2 Air: 0.015 Wastewater: 0 Soil: 0 Solid waste: 0.1 TR= 23460 kg/y
	Use in laboratory analysis (use of HTF at industrial sites)	Based on the assumption that each site within the EU sends a 1 L sample for analysis (0.15 T/y)	100 %	0.15	ERC 6b Air: 0.001 Wastewater: 0.05 Soil: 0.00025 Solid waste: none TR= 7.7 kg/y	Exposure&Release Questionaire (2018) Air: 0.001 Wastewater: 0 Soil: 0.00025 Solid waste: None TR= 0.19 kg/y
Uses by professional	Use as adhesive and sealants	Imported volume (7 471 T/y)	1.28%	96	ERC 8f (outdoor) Air: 0.15 Wastewater: 0.05 Soil: 0.005	FEICA / EFCC SpERC 8f.1a.v2 Air: 0 Wastewater:

					FEICA / EFCC SpERC 8f.1a.v2 Solid waste: 0.25 TR= 43680 kg/y	0.015 Soil: 0 Solid waste: 0.04 TR= 5280 kg/y
	Use for coatings or inks applications	Imported volume (7 471 T/y)	0.68%	50	ERC 8c (outdoor) Air: 0.15 Wastewater: 0.05 Soil: 0.005 CEPE SpERC 8f.3a.v2 Solid waste: 0.3 TR= 25520 kg/y	CEPE SpERC 8f.3a.v2 Air: 0 Wastewater: 0.02 Soil: 0.02 Solid waste: 0.09 TR= 6500 kg/y
	Use as laboratory chemical	Imported volume (7 471 T/y)	0.02%	1.5	ERC 9a Air: 0.05 Wastewater: 0.05 Soil: 0 Solid waste: none TR= 150 kg/y	None
Article service life (workers only)	Articles produced from use of coatings and inks	Imported volume (7 471 T/y)	3.4%	254	ERC 10a Air: 0.0005 Wastewater: 0.032 Soil: 0.032 Solid waste: none TR= 127 kg/y	None Migration modelling to confirm HES (polysulfide sealant in aerospace industry)
	Articles produced from use as plasticizer in adhesives and sealants	Imported volume (7 471 T/y)	6.24%	480	ERC 10a Air: 0.0005 Wastewater: 0.032 Soil: 0.032 Solid waste: none TR= 15360 kg/y	None Migration modelling to confirm HES (epoxy topcoat used in aerospace industry and cable joint sealant)

Use as a heat transfer fluid in industrial installations

The main use of terphenyl, hydrogenated is as a HTF in industrial installations of various sectors, which accounts for approximately 90% of the total tonnage used (according to stakeholder information). A HTF is a liquid or a gas that is specifically manufactured for the transmission of heat. RAC notes that no emission assessment for the formulation of HTF is reported in the Background Document because terphenyl, hydrogenated does not need to be formulated in order to be used as HTF.

Environmental releases of terphenyl, hydrogenated from use as a HTF at industrial sites have been estimated by the Dossier Submitter, who assumed that these would only occur through spills/leakages and during periodic quality checks of HTF (sampling/analysis). Nevertheless, RAC notes that other potential activities are relevant as sources of release, e.g. the periodic collection of degradation products and top-up (or refill) operations, the complete draining of the heat transfer system and the dismantling of the installation, for which no emissions are estimated in the Background Document. As these operations are identified by the Dossier Submitter as managed outside of the heat transfer system but have the potential to lead to emissions of terphenyl, hydrogenated, RAC considers that these releases are closely associated and are also relevant.

The release estimation from leakage for the use of HTF at industrial sites is based on the worst-case installed volume of terphenyl, hydrogenated of 12 000 000 tonnes (12 000 tonnes per site * 1000 sites). However, RAC identified contradictory information in the Background Document considering the worst-case installed volume (1 300 tonnes at industrial site S-02 of the monitoring programme) and the number of sites in the EU (1 300 and 100 sites are cited). Moreover, the estimated EU installed base of terphenyl, hydrogenated in industrial sites using HTF was estimated at approximately 25 000 tonnes based on feedback from the stakeholder consultations and individual communications (e.g. Table 4, Annex of the Background Document). RAC notes that it is unclear whether the estimated installed volume is expressed on a yearly basis and assumes that a higher yearly tonnage can be used at a site than the installed volume due to refill, draining and leakage processes. Similarly, the total

tonnage used in laboratory analysis is set at 0.15 T/y based on the assumption that 150 sites within the EU sample 1 L/y of terphenyl, hydrogenated in the HTF system for analysis. Therefore, it is not clear to RAC if the Dossier Submitter has taken the most relevant values for the release calculations.

The assumption of negligible emissions at industrial sites using HTF is considered reliable by the Dossier Submitter based on:

- the answers provided by companies from various industrial sectors via the Exposure & Release Questionnaire (LR SEA 2018);
- the consultation to the Annex XV report (44 HTF-users) and supported by;
- the results of the monitoring programme at industrial sites presented in the Background Document.

RAC notes that the information provided by the companies, claims that RMMs are in place to avoid leakages or manage them to avoid environmental release at industrial sites. However, RAC notes the absence of monitoring data provided by the responding companies to support this statement and identifies that some companies mention releases directed to their wastewater treatment plants (#3637, #3665). RAC estimates that the assumption that spills of terphenyl, hydrogenated are properly managed is in contradiction with the results of the monitoring programme at industrial sites that reports unmanaged leakage or soil contamination with terphenyl, hydrogenated at 2 of the 13 monitored HTF systems. This could indicate that releases of terphenyl, hydrogenated from HTF at industrial sites do occur and cannot be considered as isolated incidents. Furthermore, the assumption that there is no solid waste generated during the use of terphenyl, hydrogenated as HTF at industrial sites is not supported by the information provided by the Dossier Submitter and the responders to the consultation of the Annex XV report, on:

- the collection of accidental spills on sealed areas with absorbent material;
- the use of equipment for laboratory analysis and
- the management of dismantled HTF installations.

RAC considers that the monitoring dataset available for industrial sites is not sufficiently representative for the EU (1% of the sites and 9.8% of the installed volume) and is insufficiently reliable due to the monitoring design and lack of information[4] to assess the emissions of terphenyl, hydrogenated from HTF systems but demonstrate that the 0% release factors cannot be applied to all existing installations. RAC notes that the use of the ESVOC 7.13a.u.v2 SpERC release fractions for HTF use at industrial sites would provide a more reliable estimation of the releases than the use of the monitoring data chosen by the Dossier Submitter, since ESVOC 7.13 SpERC is designed for functional fluids in closed systems and is applicable to heat transfers agents and covers release from waste. RAC notes that it has been used to estimate the releases in the REACH registration dossier. RAC is of the opinion that the Dossier Submitter has not sufficiently justified why it considers that this applicable SpERC is not suitable for its assessment.

Use in articles – plasticiser

Concerning the use of terphenyl, hydrogenated in articles, the Dossier Submitter identified the use of the substance as a plasticiser for the production of coatings, adhesives & sealants and in polymer application as the second relevant use and assessed the release from two main categories: adhesives & sealants and coatings & inks.

The Dossier Submitter recognises that very little information regarding the use of terphenyl, hydrogenated as a plasticiser, for the production of coatings, paints and inks, and as additive in plastic applications, was provided in the different consultations (LR SEA 2018, COM 2020,

[4] e.g. relevance of air sampling, low number of samples; analytical method validation for terphenyl, hydrogenated in air and soil, detection of o-terphenyl representing <1% of terphenyl, hydrogenated.

DS SEA 2021). Similar default release factors (ERC in accordance with ECHA Guidance R.16) were used for both categories but the "upper estimates" were refined using applicable SpERCs for adhesives & sealants (FEICA / EFCC SpERC) and coatings & inks (CEPE SpERCs) except for the article service life scenarios. A total volume input (i.e., imported tonnage) of 7471 T/y and an overall share of the total volume input of 30% for the uses in adhesives & sealants and coatings & inks (i.e., formulation, industrial and professional uses and articles service life) has been used to estimate the amount used to estimate the releases. RAC notes that this is not in line with the information in the Annex XV report mentioning an imported volume of 6700 T/y and a share of only 9% for plasticiser uses.

The Dossier Submitter commented that 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. Nevertheless, in December 2022, the SCIP database contained more than 24 000 notifications[5] related to terphenyl, hydrogenated. The Dossier Submitter reported that the majority of SCIP notifications relate to the following article categories:

- Electrical machinery and equipment and components thereof
- Base metals and articles of base metal
- Machinery and mechanical appliances and components thereof
- Vehicles, aircraft, vessels and associated transport equipment and parts thereof
- Components and accessories of optical, photographic, cinematographic, measuring instruments and apparatuses
- Articles of stone, plaster, cement, asbestos, mica or similar materials
- 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

A relevant mixture category incorporated in notified articles is the use as HTF in electrical machinery and equipment and base metals/ articles of base metal. Further investigation of these entries via a web search revealed that terphenyl, hydrogenated is used as a HTF in articles for consumer use i.e in thermostats of household ovens (different models from different brands). The Dossier Submitter has considered the use of terphenyl, hydrogenated as HTF in the electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats and assessed qualitatively its environmental releases).

Additional information was also received during the consultation on the Annex XV dossier: two responses from the Aerospace, Security and Defence Association of Europe (#3655, #3707) and one response from a downstream user using different formulations to manufacture various types of articles (#3662). Their responses indicate that terphenyl, hydrogenated is used as an ingredient in formulations for catalysts, adhesives, encapsulants paints and varnishes in the aerospace and defence (A&D) industry and also in some medical, scientific and industrial applications. Terphenyl hydrogenated is present at various concentrations in the mixtures for the different uses (e.g. 5-10% in catalysts for encapsulant resins on probe stems of meters used in medical, scientific & industrial applications and for adhesives in medical & aerospace magnetic applications; 10-30% in catalysts for adhesives in aerospace power supply applications and in adhesives in circuit card assemblies in motor controllers; 20-50% in varnishes applied to vibration monitoring unit housings for unmanned

[5] This number includes duplicates and double counting as it includes dossiers with "referencing and Simplified SCIP notification (SSN). More information on SSN and referencing can be found in the manual "Tools to refer to SCIP data already submitted to ECHA" available at: https://echa.europa.eu/documents/10162/13567/tools_to_refer_to_already_submitted_sip_data_en.pdf/50ca0226-83d4-d967-f45e-203d04717ddd.

defence aircraft in extreme environments; up to 50% in sealant/adhesive formulations used by the A&D sector. Some manufacturing may take place outside of the EU, final products are exported to the EU. The technical function of terphenyl, hydrogenated in the aerospace and defence industry seems to be predominantly the use as a plasticiser, but in addition uses as a dispersant or a carrier were reported.

RAC considers that it is uncertain if the assessment performed by the Dossier Submitter properly addresses all the types of articles potentially affected by the restriction. RAC notes that, based on the notifications to the SCIP database, the origin of articles containing terphenyl, hydrogenated and whether they are imported into the EU or exported to third countries is uncertain. The concentration ranges of terphenyl, hydrogenated ordinarily applied in articles to retain its function is not known in most cases.

RAC concludes that overall, the lack of information regarding articles brings a significant uncertainty in the release and risk assessment of terphenyl, hydrogenated.

Additionally, RAC agrees with the Dossier Submitter that there is a significant data gap related to the information on the waste life-cycle stage of articles. RAC points out that generally the waste stage can be expected to be the source of highest emissions of all the life-cycle-stages of articles containing PBT/vPvB substances. This has already been thoroughly discussed in previous restriction cases on PBT/vPvB substances such as Dechlorane Plus. Migration modelling was conducted by the Dossier Submitter to assess the net mass transfer of terphenyl, hydrogenated from articles into another medium (i.e. air and soil) in order to confirm the estimated releases based on the default factors in the service life of articles scenarios. However, RAC is of the opinion that the migration scenario used to confirm the releases resulting from the service life of articles produced from use of coatings and inks is not relevant as it is based on an article containing a sealant (i.e. polysulfide sealant used in the aerospace industry) and not a coating or ink. Similarly, RAC considers that the migration scenario used to confirm the release resulting from the service life of articles produced from use of adhesives and sealants is not relevant as it is based on the leaching of a special epoxy topcoat used in the aerospace industry and not an adhesive or sealant.

RAC has evaluated the following migration scenarios for the use scenarios as described in the Table 4.

Table 4 Upper and lower release estimates for service life of articles produced from use of adhesives/sealants and coatings/inks

Use scenario	Migration scenario	Upper release estimate (based on ERC)	Lower release estimate (based on migration modelling)
Service life of articles produced from use as plasticizer in adhesives and sealants	Migration from polysulfide sealant used in the aerospace industry to the air	0.05% (0.24 T/y released from 480T/y total volume)	10 years: 0.03% (0.5T released from 1800T used) 20 years: 0.044% (1.6T released from 3600T used)
Service life of articles produced from use as plasticizer in adhesives and sealants	Migration from a plasticiser use in joint seals for underground cables into the soil	3.2% (15.36 T/y released from 480T/y total volume)	10 years: 80% (80T released from 100T used) 20 years: 85% (85T released from 100T used)

Service life of articles produced from use of coatings and inks	Leaching of a special epoxy topcoat used in aerospace industry into the air	0.05% (0.127 T/y released from 254 T/y total volume)	10 years: 8% (200T released from 2500T used) 20 years: 11% (550T released from 5000T used)

The migration modelling confirms the considered release fraction in air for the articles produced from use in adhesives and sealants but not for the release fraction in soil from the same type of article nor the release fraction in air from articles produced from use of coatings and inks.

Overall, RAC considers that the quantitative assessment of environmental releases for the uses of terphenyl, hydrogenated suffers from a number of information gaps, unrealistic assumptions and a number of uncertainties.

Qualitative assessment

A qualitative assessment was performed by the Dossier Submitter using the results of the quantitative assessment if specific information was lacking and information received via the consultation on the Annex XV report.

- Use of HTF in industrial installations:

According to the information from the Dossier Submitter, no releases of HTF take place at industrial installation or they can be considered negligible. The volume for this use represents 90% of all uses of Terphenyl, hydrogenated. More than 44 companies have responded via the LR - SEA Questionnaire (2018) and the Public Consultation that OCs and RMMs are in place in their industrial installations to avoid release of HTF. However, RAC notes that although the industrial use of HTF takes place in closed systems, some companies have reported leakages in their installations. In addition, no monitoring data are presented to support the absence of emissions at industrial sites. RAC concludes that releases cannot be considered negligeable due to the uncertainties regarding the occurrence of leakages during use, noting the high volume of terphenyl, hydrogenated used as HTF.

According to the information from the Dossier Submitter no emissions result from the sampling and laboratory analysis of terphenyl, hydrogenated used as HTF at industrial sites. RAC notes that the RMMs in place at industrial sites to support the absence of releases for the sampling operations are not described in the Background Document. In response to the consultation of the Annex XV report, only one company (#3709) refers to the use taking place under Strictly Controlled Conditions. However, RAC agrees that the total volume of sampling is expected to be small compared to the other uses and therefore the environmental releases can be considered as negligeable.

- Use as HTF in thermostats in electromechanical temperature controls of ovens and stoves (consumer use):

As reported in the Background Document, the quantity sold on this market is assumed to be <1 T/y, equivalent to 100 000 thermostats or 100 000 ovens per year, according to the lead registrant.

RAC is of the opinion that this volume is low compared to HTF use in industrial installations but significant compared to other uses of terphenyl, hydrogenated. Moreover, RAC anticipates a widespread release due to the consumer uses of these products.

The Dossier Submitter supposes that during the use of the product by consumers, there is no relevant release of terphenyl, hydrogenated since it is contained in a closed vessel which is installed in the end product.

RAC agrees with this assumption even if spills from thermostats and accidental releases cannot be disregarded. It is assumed that at the end of their service life, ovens and stoves are collected through take-back schemes at their end-use location. Requirement at the end-of life of electrical and electronic equipment are laid down by waste legislation, specifically the WEEE Directive (2012/19/EU) and related national implementing legislation. The Dossier Submitter assumes that any risk is mitigated by the compliance with this legislation. RAC acknowledges that household ovens are in the scope of the WEEE Directive which requires the Member States to ensure proper treatment i.e. removal of all fluids and a selective treatment in accordance with Annex VII. RAC notes that hydrocarbons are listed in Annex VII to the WEEE Directive, hence terphenyl, hydrogenated needs to be removed and treated separately. However, the Dossier Submitter did not provide any information on current practices in the Member States and therefore RAC cannot conclude on the environmental release at waste disposal from ovens and stoves.

- Use in articles- plasticiser

These uses represent 9% of all uses of terphenyl, hydrogenated. The Dossier Submitter estimates that releases during formulation and industrial use are assumed to be minor due to the RMMs that should be in place, but no information is provided in the Background Document to support this assumption. The Dossier Submitter also assumes that professional use (especially the outdoor use) and service life of articles are associated with emissions in the environment in the absence of specific information on the RMMs. Overall, RAC agrees with this assessment and notes that the information provided during the consultation of the Annex XV restriction report for the Aerospace and Defence sector (#3655, #3707) confirm the assumptions on RMMs at industrial sites. Overall, RAC considers the aerospace and defence applications as a potentially wide-dispersive use due to the professional use of various formulations at a wide range and number of sites. RAC concludes that releases cannot be considered negligeable for the use of articles and service-life including waste disposal is anticipated to be of major concern. Nevertheless, RAC notes that the service-life including waste disposal for articles was only scrutinized, i.e. on the applicability of the WEEE directive for the use as HTF in ovens and stoves.

- Miscellaneous uses

These uses represent 1% of all uses of Terphenyl, hydrogenated and includes solvent/process medium and laboratory chemical (professional use). In the absence of information on RMMs for those uses, the Dossier Submitter concludes that formulation, industrial use as solvent/process medium and use as laboratory chemical by professionals can generate releases into the environment. RAC concludes that releases cannot be considered negligeable for these uses in the absence of information on RMMs in place at industrial and professional sites.

Prioritization of uses based on qualitative assessment of releases

RAC does not agree with the prioritization of uses performed by the Dossier Submitter based on the qualitative assessment of their contribution to the identified risk. The Dossier Submitter did not appear to take into account the major volume of terphenyl, hydrogenated used as HTF in industrial installations. For HTF at industrial sites, even accidental leakages can bring significant releases compared to the other uses since this use represents 90% of the total volume used in the EU. Further details of RAC's qualitative evaluation are reported in the section 3.4.3 "Effectiveness in reducing the identified risks".

3.1.4. Risk characterisation

Summary of Dossier Submitter's assessment:

The Dossier Submitter states under section 1.2.6 of the Background Document that it is neither relevant nor scientifically possible to perform a quantitative risk assessment of vPvB substances. This is due to the uncertainties regarding long-term fate and behaviour, 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. The overall aim for vPvB substances is to minimise the emissions and any exposures to humans and to the environment (Annex I, para 6.5 of REACH).

RAC conclusion(s):

- RAC agrees that the risk assessment of terphenyl, hydrogenated cannot be described on a quantitative basis due to the vPvB properties of the substance.
- RAC concludes that total releases of terphenyl, hydrogenated into the environment should be used as a proxy for risk.
- RAC considers that the uncertainties in the share of total emission of terphenyl, hydrogenated for the different uses and scenarios does not allow to estimate realistically which activities result in the highest emissions and hence the highest risk.
- RAC concludes that based on the information provided in the Background Document, it is evident that current uses cause emissions and exposures and hence, there is a risk to address. RAC notes that terphenyls and hydrogenated terphenyls have been detected in several compartments of the environment and human food, confirming that emissions have led to environmental and human exposures.
- 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 likely (i.e., current information specifying operational conditions and risk management measures cannot guarantee that releases are controlled under the conditions of use).

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 1.2.6 and Annex B.10.

It is not possible to derive a reliable threshold for the effects of PBT/vPvB substances. Therefore, any releases should be regarded as a proxy for risk to the environment and human health. Manufacturer or importers of PBT/vPvB substances should recommend risk management measures for downstream users to minimise exposure and emissions to humans and environment throughout the lifecycle of the substance that results from manufacture or identified uses (Annex I para 6.5 of REACH[Error! Bookmark not defined.]). As discussed in the hazards section, the vPvB properties of terphenyl, hydrogenated result in an intrinsic hazard. A continuous and irreversible exposure of the environment and humans may lead to unpredictable long-term adverse effects. A risk characterisation where releases and exposures are regarded as a proxy for a risk to the environment and human health is appropriate. The emission and exposure assessment of the uses of terphenyl, hydrogenated performed by the Dossier Submitter (section 3.1.3) contains many uncertainties (section 3.1.6) impairing the accurate identification of the risks related to each activity and which human populations or environmental compartments are most at risk. Releases of vPvB substances should be minimised in all sectors of use to reduce adverse effects.

3.1.5. Existing risk management measures and operational conditions

Summary of Dossier Submitter's assessment:

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) to the Background Document. 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. The Dossier Submitter considered that a HTF installation should comply with strictly controlled closed systems as are defined in Appendix 5 of the Annexes to the Background Document.

Concerning the use of terphenyl, hydrogenated in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations for which it was reported, the Dossier Submitter considered that there are currently no alternatives available. Terphenyl, hydrogenated is used due to their ease of application, ease of field repair, flexibility, solvent and chemical resistance, low moisture permeability, and adherence to many metals, composite, and coated substrates. The Dossier submitter did not provide any further information on the RMMs concerning the use of terphenyl hydrogenated in the aerospace industry.

Concerning the release of terphenyl hydrogenated from ovens and stoves the disposal of EEE is regulated by the WEEE Directive (2012/19/EU)[6] and the Waste Framework Directive 2008/98/EC[7]. Large household appliances like electric stoves, the 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. According to the Dossier Submitter, 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).

When terphenyl, hydrogenated is used as a plasticiser it may be released into the environment during the various life cycle steps, including incorporated into/onto an article. During the disposal at a waste treatment plant terphenyl, hydrogenated may be released into the environment. The Dossier Submitter assumes, that at the waste life-cycle stage of articles, due the wide-spread, complex and partly unknown use, the operational conditions and risk management measures are not sufficient and effective enough to control the risks of terphenyl, hydrogenated.

Therefore, a complete restriction of terphenyl, hydrogenated use in articles (> 0.1% w/w) is the most appropriate risk management measure, except for the article use of terphenyl, hydrogenated as plasticiser in the aviation industry (with a 5-year derogation (after EiF)) and for the use as HTF in thermostat.

RAC conclusion(s):

- RAC is of the opinion that the risk management measures and operational conditions currently in place at industrial sites using HTF systems, are not sufficient to minimise

[6] EUR-Lex - 02012L0019-20180704 - EN - EUR-Lex (europa.eu)
[7] EUR-Lex - 32008L0098 - EN - EUR-Lex (europa.eu)

the releases of terphenyl, hydrogenated and control the risk. RAC supports the implementation of strictly controlled conditions as described in REACH article 18.4 for the use of HTF at industrial sites to prevent environmental emissions.

- RAC concludes that the reported information for the use of adhesives and sealants in aerospace and defence applications is insufficient to assume negligeable emissions. Emissions are expected during the service life and waste disposal of the articles.

- RAC considers that it is not possible to conclude, based on the limited information provided by the Dossier Submitter, if the requirements of the WEEE Directive (respectively the national transpositions) are currently sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided.

- RAC notes that there is no information on existing risk management measures and operational conditions related to the uses of terphenyl, hydrogenated as a solvent/process medium, laboratory chemical (professional use) and as part of mixtures incorporated in articles allowing to conclude on their capacity to control the risk.

- RAC agrees that articles containing terphenyl, hydrogenated may lead to significant releases to the environment at the end of life and final disposal.

- RAC concludes that the measurements of terphenyl, hydrogenated in the environment and other media demonstrate that current risk management measures and operational conditions are not sufficient to control the risk.

Key elements underpinning the RAC conclusion(s):

Use as HTF in industrial installations

The Dossier Submitter assumes that HTF at industrial installations is included in closed systems and that potential releases to the environment can be considered negligible based on the 27 responses received to its SEA questionnaire (2021) and the 44 responses received during the consultation on the Annex XV report. The responses received represent approximatively 6% of the industrial sites using HTF (of a total of 1300 sites in the EU). RAC agrees that the described RMMs and OCs may be efficient to reduce the release of terphenyl, hydrogenated into the environment. However, those RMMs and OCs are not always comparable between the different sites. For example, the sampling of HTF for periodic quality control occurs weekly in one site (#3656) when a yearly sampling occurs in two sites (#3698, #3658) and the latter is assumed as the general case by the Dossier Submitter in their assessment. Also, disposal of the exhausted terphenyl, hydrogenated is not always treated through licensed waste handling companies but can be directed into the site wastewater treatment plant (#3637, #3665). The frequency of HTF system leakages is also not very clear, and the results of the monitoring programme presented in the Background Document show that unmanaged leakage or soil contamination occurred in 15% of the monitored sites. The Dossier Submitter refers to the Pressure Equipment Directive (PED 2014/68/EU) as the main European legislation that should be considered and to national guidelines as technical requirements for the design, construction, adaptation, and operation of HTF installation (DIN 4754-1). However, RAC notes that the objectives of these legislations are not targeted specifically to minimise environmental release of HTF but to protect safety of persons or property. If some conditions contribute to reduce the environmental release, such as the provisions for the resistance of the equipment material and for filling and discharge of HTF, they cannot be compared to strictly controlled conditions under REACH. Additionally, strong legal restrictions are only applicable to systems with high potential for danger (Art. 14 PED). So, HTF systems are rated into modules and if they are not in high module, they will be inspected only according to the manual of the manufacturer. Also, the majority of HTF systems were installed before the entering into force of these legislations and can be aged up to 40 years as demonstrated by the monitoring program in industrial sites. There is no

reference to former PED in the Background Document, so the baseline number of compliant installations is unknown.

Representative monitoring data are missing to support the Dossier Submitter's assumption of negligeable emissions in all industrial sites. RAC concludes that the risk managements measures and operational conditions currently in place in all HTF installations using terphenyl, hydrogenated cannot be considered sufficient to control the risk.

- Aerospace and Defence applications:

No feedback was received during the stakeholder consultations (LR SEA 2018, COM 2020, DS SEA 2021) on RMMs and OCs for these applications. During the consultation of the Annex XV report, the Aerospace and Defence Association of Europe (ASD) and the Aerospace Industrial Association (AIA) submitted some basic information on RMMs and OCs at factory/industrial settings including repairs at airports. They include trained workers, compliance with the SDS, no wastewater releases for sealant/adhesive formulations which are not water-miscible, waste management during formulation and repair/maintenance procedures. Formulation and mixing of polysulfide sealants/adhesives also containing octylphenol ethoxylate (OPE) are managed according to the RMMs and OCs of the REACH authorisation (AfA 0203-02). However, as OPE is only present at <0.1% in the sealants etc. they are not further subject to authorisation and information on the service life is sparse. As already noted, the waste disposal of the articles is expected to be the major source of releases for these uses. RAC also notes that environmental release of OPE during service life is assumed to be low due to its interaction with the matrix and that no re-use and hazardous waste treatment at the end of the service life are performed as part of aviation requirement. However, there is not sufficient information to assume that the RMM/OCs in place for the polysulfide sealants can be extrapolated to all formulations used in the A&D sector that include not only sealants/adhesives but also finished paints and topcoats. Moreover, terphenyl hydrogenated is more volatile and used at far higher concentration than OPE in the formulations which could potentially lead to an increased environmental release. Overall, RAC is of the opinion that the information on risk for Aerospace and Defence applications are insufficient to assume negligeable emissions which are expected to be likely during the service life and waste disposal of the articles.

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

There is no information in the Background Document related to the RMMs and OCs applied by companies that are using terphenyl, hydrogenated as HTF in thermostats of ovens and stoves. The Dossier Submitter assumed that at the end of their service life, ovens and stoves are disposed according to the WEEE Directive (2012/19/EU) and that any risk is covered. RAC is of the opinion that it is not possible to conclude, based on the limited information provided by the Dossier Submitter, if the WEEE requirements (respectively the national transpositions) are sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided.

- Other uses:

No specific risk management measures and operational conditions are described in the Background Document for the other uses of terphenyl, hydrogenated as sealant/adhesive and coating/paint mixtures incorporated in articles, as solvent/process medium and as laboratory chemical (professional use). In particular, there is no information on the end of the article's service life representing a specific concern of release and accumulation in the environment over long periods of time. RAC agrees with the Dossier Submitter that the final disposal of these articles could lead to uncontrolled risk.

A screening programme conducted in 2018 by NILU and NIVA (NILU, 2018), shows that terphenyl, hydrogenated was found in marine sediments, surface water and buildings and it was recommended that the chemical should consequently be studied in more detail.

Additionally, Moh et al. (2002) describe accidental contamination of food items with terphenyl, hydrogenated, and Sturaro et al. (1995) detected the substance as contaminant in food cardboard packages made from recycled material containing carbonless copy paper. Based on these results, RAC concludes that current risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk.

3.1.6. Uncertainties in the risk assessment

Summary of Dossier Submitter's assessment:

Relevant uncertainties concern the release factors used for different environmental compartments and uses (see Annex F.2 of the Background Document). Only for the use of HTF some measurement data were used. For the other uses of terphenyl, hydrogenated, volumes associated with the identified uses are uncertain, llimited information is available. In the absence of specific information, the Dossier Submitter used a combination of appropriate default release factors from ECHA Guidance R.16, OECD Emission Scenario Documents (ESD) and industry Specific Environmental Release Categories (SPERCs).

RAC conclusion(s):

- RAC concludes that there are significant uncertainties related to the total use volume, operational conditions, and environmental releases for the use of HTF in industrial installations.

- RAC considers that significant uncertainties arise for the risk assessment of HTF related uses as the Dossier Submitter did not consider all identified sources of releases from the use of HTF in industrial installations in the assessment, i.e., the periodical collection of degradation products and the top-up (or refill) operations, the complete drain of the heat transfer system and the dismantling of the installation. The Dossier Submitter did neither consider the use of HTF in articles.

- RAC is of the opinion that the lack of information regarding non-HTF uses brings major uncertainties in the risk assessment of terphenyl, hydrogenated.

- RAC concludes that all identified information gaps, unrealistic assumptions and a number of uncertainties in the emission and exposure assessment of terphenyl, hydrogenated bring significant uncertainty in its risk assessment.

Key elements underpinning the RAC conclusion(s):

Key elements underpinning the RAC conclusions are presented in section 3.1.3.

3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

Summary of Dossier Submitter's assessment:

The Dossier Submitter concluded that action is required on a Union-wide level based on the following considerations':

1. The overall aim for vPvB substances such as terphenyl hydrogenated 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. 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)

2. The uses of terphenyl hydrogenated are broad and the main use as HTF as well as the use of terphenyl, hydrogenated as plasticiser and as other uses containing terphenyl, hydrogenated are imported into the EU and are placed on the market in all EU member states

3. Potential national regulatory actions are not considered adequate to manage the risks, in particular the risk on the plasticiser 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.

RAC conclusion(s):

Based on the key principle of ensuring a high level of protection across the Union and of maintaining the free movement of goods within the Union, RAC supports the view that any necessary action to address risks associated with terphenyl, hydrogenated should be implemented in all Member States.

Key elements underpinning the RAC conclusion(s):

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. Moreover, an increasing trend of terphenyl volumes used in the EU in the future is assumed. The results of the monitoring program at industrial sites clearly shows that releases of terphenyl, hydrogenated from HTF could be relatively frequent (i.e. 15% of the monitored HTF systems).

The Dossier Submitter considers that long-range transport of terphenyl, hydrogenated is unlikely based on its semi to non-volatile profile (estimated by a boiling point of 342 °C at 1013 hPa) not meeting the key pre-conditions for long-range transport chemicals. RAC notes that the boiling point alone is not sufficient to assess the volatility of a substance and considers that long-range transport can also occurs via migratory species based on the Stockholm convention criteria. The screening programme results performed in Norway (NILU, 2018 and COWI AS, 2020) shows that hydrogenated terphenyl congeners are found in house dust, sewage water and sludge, landfill, marine sediments, marine fish and freshwater benthic biota. It is also the case for terphenyls, including ortho-terphenyl, and they have also been detected in surface water. The sources of emissions haven't been identified but the detection in surface water, marine sediment and biota show the potential for transfer to a receiving environment. Additionally, Moh et al. (2002) describe accidental contamination of food items with terphenyl, hydrogenated, and Sturaro et al. (1995) detected the substance as contaminant in food cardboard packages made from recycled material containing carbonless copy paper. Based on these monitoring results, RAC considers that properties of persistence and, bioaccumulation, combined with adsorption to soil and sediment and its detection in various environmental matrices are of sufficient concern in their own right.

RAC concludes that the current risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk and that action is required on a Union wide basis.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3. ANALYSIS OF ALTERNATIVES

3.3.1. Approach to the analysis of alternatives

Summary of Dossier Submitter's assessment:

The Dossier Submitter has performed an analysis regarding the advantages and disadvantages of different alternatives to terphenyl hydrogenated. The Dossier Submitter states that 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 Dossier Submitter process of identifying alternatives has been divided into 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

After the first step of the identification process (screening of information sources) an initial list of potential alternatives to terphenyl hydrogenated was defined.

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.).

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.2. Availability and technical and economic feasibility of alternatives

Summary of Dossier Submitter's assessment:

The Dossier Submitter concluded that there is not a universal alternative to terphenyl hydrogenated that covers all the identified uses of this substance.

The Dossier Submitter states that a suitable alternative to terphenyl hydrogenated that covers all the identified uses 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).

Only one potential alternative, commercially available in the required quantities, has been found for the use as solvent or process medium (biphenyl), mainly as textile dyestuff carrier. It is worth noting that the Lead Registrant of this substance, which is also the Lead Registrant of terphenyl, hydrogenated, is placing on the market biphenyl as process media or solvent in many industries, including chemicals and petrochemicals (Eastman, 2022b). However, the company does not recommend or market terphenyl hydrogenated as solvent or process medium (Eastman, 2022c). This is an indication that both substances are not substitutable in this use.

The Dossier Submitter states that it lacked the required information to assess technical and economic suitability of this alternative with certainty because in stakeholder surveys specific technical and economic data related to the potential alternatives have not been provided by the impacted actors. Despite the absence of more precise information on technical and economic feasibility, the Dossier Submitter assumed that this assessment of alternatives for the functions of terphenyl, hydrogenated and its conclusions are still valid.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.3. Conclusion on analysis of Alternatives (RAC)

Summary of Dossier Submitter's assessment:

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 summarising, an alternative to terphenyl, hydrogenated that covers the uses 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 Lead Registrant of this substance, which is also the Lead Registrant 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.

RAC conclusion(s):

Based on the data presented in the Background Document by the Dossier Submitter, RAC understands that no suitable alternatives to terphenyl, hydrogenated was found by the dossier submitter for HTF, because they considered that candidates could lead to regrettable substitution mainly due to PBT or CMR properties.

Based on the data presented in the Background Document by the Dossier Submitter RAC notes that no information is available on the alternatives to terphenyl, hydrogenated used in articles. This represents a significant uncertainty regarding the proposed restriction, considering the wide variety of the article uses and hence potential high number of alternatives.

RAC considers that alternative with a better hazard profile compared to terphenyl,

hydrogenated might exist for adhesives uses for aerospace industry sector, pending further evaluation

Key elements underpinning the RAC conclusion(s):

The main alternatives to Terphenyl, hydrogenated in HTF (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). 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene is identified by the Dossier Submitter as the unique potential alternative of terphenyl, hydrogenated for the HTF use. Nevertheless, this substance is under PBT assessment and the substitution of terphenyl, hydrogenated by this alternative when used as HTF in non-pressurised liquid phase systems could result in regrettable substitution.

RAC noted that the reaction mass of m- and o-terphenyl (CAS 904-797-4) is quoted in Table 20 in the background document as potential alternatives to terphenyl, hydrogenated for HTF uses. In the last step of the identification process, this substance had been discarded by the dossier submitter due to its PBT properties. In the RMOA conducted by Finland (Tukes 2020) this substance "reaction mass of m-and o-terphenyl" was not considered as potential alternative because it contains o-terphenyl as constituent. In case of time limited derogation for HTF uses, other substances can be used as alternative to terphenyl, hydrogenated in low temperature (<300-325 °C), non-pressurised heat transfer systems. However, these alternatives have not been assessed in above mentioned FI RMOA as they cannot be considered direct alternatives in high temperature, non-pressurised heat transfer systems.

Most of the respondents of the consultation on the Annex XV report claimed the absence of reliable alternatives for this use (#3637, #3659, #3666, #3669, #3672, #3679, #3687, #3689, #3690, #3693, #3697, #3698, #3701, #3706, #3709, #3710, #3714, #3716, #3717, #3720). Some respondents also indicate that alternatives with other parameters and potentially with lower environmental concern cannot provide the same heat exchange and resistance capability and will lead to a significant redesign of the installation (#3658; #3675, #3676, #36791, #3695). Furthermore, it is not known in how many industrial installations terphenyl, hydrogenated is used in low temperature (<300-325 °C) conditions.

RAC notes that no information is available on the alternatives to terphenyl hydrogenated used in articles in the background document or submitted during the consultation on the Annex XV dossier. This represents a significant uncertainty regarding the proposed restriction.

For aerospace industry uses, the aerospace industry (#3655, #3662, #3707) claims, that no direct replacement is possible, and the alternatives need to contain terphenyl hydrogenated. The Dossier Submitter notes that a comparison of the formulations via the old[8] and the new[9] 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 ECHA's website[10], no harmonised classification exists for this substance, but data submitters broadly recognised this substance as a skin sensitiser. According to the website of the company, they are selling this alternative not only to the aviation industry[11,12] but to other sectors as well. RAC took note of this data and considers that Diethylene glycol bis(3-aminopropyl) ether might be an alternative of terphenyl, hydrogenated for adhesives use with a better hazard profile. Diethylene glycol bis(3-aminopropyl) ether is neither classified as CMR

[8] Safety Data Sheet is available to the Dossier Submitter.
[9] ResinLab EP1290 Clear Epoxy Adhesive.
[10] Brief Profile - ECHA (europa.eu) (20/02/2023)

[11] ResinLab - The Leading Resin Manufacturer.
[12] How to Choose a Static Mixer - ResinLab.

Cat 1 nor as a PBT/vPvB substance or meets the equivalent level of concern criteria, so would not be eligible for SVHC classification.

For uses other than aerospace industry and HTF, the Dossier Submitter identified and presented a list of alternative substances in Table 22 of the Background Document. RAC notes that several listed alternatives could result in regrettable substitution for these uses, including:

- Diphenyl ether as a potential alternative to terphenyl, hydrogenated for the use as solvent or process medium, and laboratory chemicals but its CMR status is under assessment.

- Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues 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, the PBT status of this substance is under assessment.

- Cyclohexylbenzene classification is notified under CLP regulation as Aquatic Acute 1, H400 and Aquatic Chronic 1 H410 and could be considered compatible for solvent and laboratory chemical uses, but the Dossier Submitter concluded that it cannot be considered a suitable alternative for terphenyl, hydrogenated as on the basis of its hazard classification. However, RAC noted that the hazard profile of this substance is more favourable than that of terphenyl, hydrogenated. A conclusion regarding the relevance of this substitution can only be reached through a risk assessment requiring knowledge of the processes and the quantities involved to estimate a potential release. Since these data were not presented by the Dossier Submitter, the RAC cannot conclude on the environmental risk that this substitution would represent.

- The Dossier Submitter considers that Biphenyl could be compatible for its use as solvent or process medium, mainly as a textile dyestuff carrier, and as laboratory chemical. This substance is registered under the REACH Regulation for solvent and laboratory chemical uses and classified under CLP \regulation as Aquatic Acute 1 H400. A conclusion regarding the relevance of this substitution can only be reached through a risk assessment requiring knowledge of the processes and the quantities involved to estimate a potential release. Since these data were not presented by the Dossier Submitter, RAC cannot conclude on the environmental risk that this substitution would represent. However, RAC noted that the hazard profile of this substance is more favourable than that of terphenyl, hydrogenated.

- Dibenzoates could be potential substitutes of terphenyl, hydrogenated as plasticiser and additive in adhesive and sealants from the technical point of view, however, some of the substances in this group present reprotoxicity property and are classified as Rep cat 1b, leading to potential regrettable substitution.

- The iso- and terephtalates- are not considered hazardous by the Dossier Submitter and it is indicated that they could be used as plasticizer, additive sealants and adhesives in the aerospace industry although neither additional information nor evidence is provided.

3.3.4. Conclusion on analysis of alternatives (SEAC).

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

3.4.1. Targeting of the proposed restriction

Summary of Dossier Submitter's assessment:

The proposed restriction (RO1) is targeted to the exposure that is 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.

The aim of the proposed restriction is to minimise the emissions of terphenyl, hydrogenated in Europe.

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 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 5:

Table 5 Overview of restriction options considered by the Dossier Submitter

	RO1	RO2	RO3
A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.			
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 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, maintenance and repair.	EiF + 5 years	None	None
Derogation for the use and placing on the market in applications of electromechanical		None	None

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).			

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.

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 should 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 Dossier Submitter considered RO1 the most appropriate risk management option because it is effective and minimises the risks within a reasonable period of time.

RAC conclusion(s):

- RAC agrees that a broad EU-wide restriction is the most appropriate measure to reduce the risks of terphenyl, hydrogenated. RAC notes that the potential risks resulting from the use of additional substances containing o-terphenyl have not being assessed by the Dossier Submitter and are not included in the scope of the restriction proposal and that this may need to be assessed in the future.

- RAC supports derogations which would not affect the effectiveness of the proposed restriction but is not in favour of unlimited derogation for the use as HTF at industrial sites which would impair the substitution of SVHCs substances targeted by REACH. RAC is of the opinion that for such PBT/vPvB substances as terphenyl, hydrogenated, the time period should be as short as possible to guarantee the smallest possible increase of the environmental stock during the derogation.

- RAC supports time limited derogations for the use of HTF in industrial sites, provided that such sites have implemented strictly controlled, closed systems. The implementation of the strictly controlled systems shall be monitored by a representative program to assess the environmental emissions.

  RAC does not support a time limited derogation for the use in aerospace and defence applications. RAC considers the aerospace and defence applications as a wide-dispersive use due to the professional use of various formulations. RAC notes that there is not enough information on the risks at relevant life cycle stages to ensure minimisation of emissions of terphenyl, hydrogenated from all formulations used in the aerospace and defence sector.

RAC does not support a derogation for electromechanical control of ovens and stoves. RAC considers that the proper treatment of HTF by waste holders is unclear and in the absence of any further information on current practices in the Member States cannot conclude on the environmental release at waste disposal from ovens and stoves. Moreover, RAC notes that the Dossier Submitter's derogation also include electrical capillary thermostats for which no information at all was provided. RAC therefore supports a restriction for the use of terphenyl, hydrogenated in thermostats.

Further evaluation of the use/sector-specific derogations is integrated into the subsequent section of this opinion on the section 3.4.3 'Effectiveness in reducing the identified risks'.

Key elements underpinning the RAC conclusion:

The Dossier Submitter has targeted the restriction proposal to terphenyl hydrogenated based on the assumption that the constituents of terphenyl hydrogenated are not present in other substances or exist as substances as such. RAC does not agree with this assumption taking into account that the substance "reaction mass of m-terphenyl and o-terphenyl "(EC 904-797-4) is registered under REACH and o-terphenyl (EC 201-517-6) and terphenyl (EC 247-477-3) are notified under the CLP regulation. RAC notes that the potential risks resulting from the use of these substances containing o-terphenyl have not being assessed by the Dossier Submitter and are not included in the scope of the restriction proposal. This leads to uncertainties regarding the baseline calculations and the effectiveness of the restriction proposal.

Emissions of terphenyl, hydrogenated occur from all uses based on RAC's qualitative assessment detailed in section 3.4.3. Considering the broad use of the substances in many sectors, a broad restriction covering all uses, articles, and mixtures, with carefully selected and justified derogations where emissions are confirmed to be managed using appropriate operational conditions and risk management measures, is RAC's view from a risk perspective an effective measure. A broad restriction would also cover potential future uses. Articles, specifically imported ones, cannot be efficiently targeted by a risk management option under REACH other than a restriction. However, RAC does not agree that all the proposed restricted uses and derogations have been justified by the Dossier Submitter.

The Dossier Submitter proposed to target the restriction of the use of terphenyl, hydrogenated as a plasticiser since they considered that the largest source of terphenyl, hydrogenated emission to the environment in the EU is attributed to the use in adhesives/sealants and the "Service life of articles produced from use as plasticiser". Nevertheless, RAC notes that the uncertainty linked to the estimation of the releases and their sources does not permit to conclude on the relevance of the targeted use and sector.

For RAC to conclude that a proposed derogation would not affect the effectiveness of the proposed restriction, emissions from the use should be either negligible or the operational conditions and risk management measures must have been justified to be appropriate and effective to minimise residual emissions as low as possible. However, the exposure assessment (section 3.1.2) show that releases are not minimised by OCs/ RMMS currently in place for the use of terphenyl, hydrogenated as HTF in industrial installations proposed to be derogated. RAC notes that derogation for this use shall only be granted for the sites complying with minimum OCs/RMMs described in Appendix 5 of the Annexes to the Background Document. Those are expected to minimise the environmental releases. However, RAC is of the opinion that the appropriateness and effectiveness of the technical measures and operational conditions cannot be confirmed before a representative monitoring program of environmental releases would be conducted at industrial sites. Additionally, as pointed in response to a comment received in the consultation on the Annex XV report (#3719), derogations without a time limit would hamper the aim to promote a progressive substitution when suitable alternatives become available. Further evaluation of the use/sector-specific

derogations is integrated into the subsequent section of this opinion on the section 3.4.3 'effectiveness in reducing the identified risks'.

SEAC conclusion(s):

[Text]

Key elements underpinning the SEAC conclusion:

[Text]

3.4.2. Other regulatory risk management options

Summary of Dossier Submitter's assessment:

The Dossier Submitter considered national regulatory actions not to be adequate to manage the risk of terphenyl, hydrogenated. Union-wide action is proposed by the Dossier Submitter to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States (Annex XV restriction report, section 1.3).

A short description of different Union-wide legislative options that may have the potential to influence emissions of terphenyl, hydrogenated to the environment is presented in Annex E.1.3 to the Annex XV report. These legislative options concern Waste Framework Directive, authorisation, Water Framework Directive, RoHS Directive and Industrial Emissions Directive.

However, the Dossier Submitter concludes that these presented options are not considered to have the potential to minimise the emission of terphenyl, hydrogenated, as they are currently not considered to be feasible, are not considered as an appropriate risk management option, or not effective in reducing the risk.

Concerning other REACH instruments, the analysis of Authorisation as RMO – against the restriction route demonstrates that the Restriction route would be the most appropriate option to deal with the potential risks derived from the manufacture and use of terphenyl, hydrogenated in the EU. In contrast, authorisation would be a disproportionate, less practical, and less effective provision due to the lack of suitable alternatives for the vast majority of the volume used; and therefore, it should not be selected as a RMO for this substance (see section E.1 of the Annex).

RAC conclusion(s):

RAC considers that the data in the Background Document on emissions, despite major uncertainties, and the environmental monitoring data available demonstrate that existing regulatory risk management instruments are not sufficient to address the risk.

RAC concludes that current obligations under the CLP regulation, the Water framework directive, the Industrial Emissions Directive, and the Waste Framework Directive do not directly lead to a reduction of emissions of terphenyl, hydrogenated.

RAC is of the opinion that a REACH authorisation would be less effective to control the risk due to the continuation of emissions considering the time required for the process and the non-inclusion of the articles.

Key elements underpinning the RAC conclusion(s):

The available data on emissions and exposure as well as data from environmental monitoring show that current regulatory risk management measures applying for part of the uses are not sufficient to minimise the releases, exposures and the risk resulting from the use of terphenyl,

hydrogenated.

RAC notes that terphenyl, hydrogenated is currently neither included in the Annex VI of the CLP regulation nor identified as priority substances or priority hazardous substances under EU Water framework directive (WFD). The manufacture and some uses of terphenyl, hydrogenated are covered by the Industrial Emissions Directive (IED) based on best available techniques (BAT) reference documents however, not all uses are included. Under the Waste Framework Directive, suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA (SCIP notification obligation) to ensure that the information on articles containing SVHC is available throughout the whole lifecycle of products and materials, including at the waste stage. However, these obligations do not directly lead to a reduction of emissions. Pursuing the authorisation regime route would result in the continuation of emissions as long as the applications are under assessment. A large number of applications for authorisation would be expected to be received due to the very high number of the sites using HTF, so this period could be long.

A REACH authorisation would be less effective to control the risk due to the continuation of emissions considering the time required for the process of the inclusion of the substance into the Annex XIV to REACH and the subsequent application process for authorization of the 1300 different industrial sites using HTF. Additionally, an authorization obligation would not cover the import of articles containing terphenyl, hydrogenated, which seems significant based on the SCIP database. A restriction of those uses could only follow based on a restriction proposal by ECHA according to Article 69(2) of REACH once the substance is added to Annex XIV. Therefore, further time would be required, meaning more environmental release of terphenyl, hydrogenated, before the risk from articles is controlled. RAC acknowledges that a REACH authorization would lead to information on environmental emissions at industrial sites however the mandatory monitoring program included in the RAC opinion is proposed to provide a similar level of information.

All these elements underpin the conclusion that a REACH restriction is the most appropriate EU wide measure to address the identified risk from the uses of terphenyl, hydrogenated.

RAC notes, however, that the Dossier Submitter did not propose a restriction and neither assessed the risks for other substances containing o-terphenyl (see section 3.1.1). It is unknown to RAC how effective the proposed restriction is compared to a restriction proposal which would have covered all substances containing o-terphenyl.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.3. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

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).

The continued use of terphenyl hydrogenated is described in the baseline scenario of terphenyl hydrogenated in Annex D.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 banned for a certain use. A significant share of the emissions occurs at the end-of-life stage. Furthermore, if the use as terphenyl hydrogenated 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)

RAC conclusion(s):

- RAC agrees that following from the RAC conclusion on the quantitative emissions assessment, the baseline scenario with/without the restrictions reported in the Background Document (i.e., the basis of the estimated quantitative effectiveness) are not considered to be robust enough to draw any quantitative conclusion.

- Instead, RAC qualitatively evaluated the effectiveness of the proposed restriction from the point of view of the overall objective to minimise the releases and exposures.

- RAC concludes that overall, the proposed restriction is effective in minimising the risks resulting from the use of terphenyl, hydrogenated (see Table 6 below)

Table 6: Use specific conclusions of the qualitative emission assessment of RAC

Sector	Subsector	Alternatives available	RAC conclusion on uses, release, and emission minimisation	Derogation / longer / TP / higher concentration limit supported
Heat Transfer fluid	Industrial sites	Yes, but are suspected to be PBT, (Finnish RMOA)	Main use (90%) of Terphenyl, hydrogenated Environmental releases are likely based on available information presenting inconsistency probably due to different level OC/RMMs in the industrial sites using HTF. RAC concludes that the compliance of industrial sites with the OC and RMM requirements described in the Appendix 5 of Annex XV report Annexes is appropriated to reduce the environmental releases and the risk.	RAC supports a derogation for HTF provided that the industrial sites implement, strictly controlled closed systems with technical containment measures, as outlined in Appendix 5 of the Annexes to the Background Document, to prevent environmental emissions. RAC concludes that the sites must also implement a representative monitoring program to confirm the effectiveness of the OC and RMM to reduce environmental releases as much as technically and practically feasible. RAC supports a time-limit derogation to promote the development of safer alternatives. The time-limit shall be as short as possible.
	Thermostats (consumer use)	There is no information available to conclude whether there are suitable alternatives.	Wide-dispersive use (consumer use). Environmental releases are assumed at all life cycle stages and especially during the waste life cycle. No robust information on existing RMMs in the sector. Based on the available information, RAC cannot conclude on environmental emissions for this use.	No

			RAC therefore, supports a restriction for HTF incorporated in articles.	
Plasticiser	All uses including Formulation Industrial and professional uses (including articles production) Incorporation in articles	There is no information available to conclude whether there are suitable alternatives.	Wide-dispersive use (industrial and professional use) with environmental release assumed at all life cycle stages and especially during the waste life cycle of articles. SPERCs described for the formulation, industrial and professional uses of adhesives /sealants (FEICA/EFCC) and coatings/inks (CEPE) confirm the releases to water, air, soil and solid waste considering specific OCs and RMMs applied in the sector. RAC considers that environmental emissions would be inevitable due to the limited potential for containment of releases at the waste/recycling life-cycle stage. RAC therefore, supports a restriction for plasticiser uses.	No
	Aerospace and Defense applications	Three alternatives for the use as additive in adhesive and sealants: dibenzoates, phthalates and chlorinated paraffins. Nevertheless, regarding the hazard properties of these alternatives, RAC cannot exclude regrettable substitutions.	RAC assumes a wide-dispersive use due to professional uses and in the absence of further information. Environmental releases are assumed at all life cycle stages (except for the polysulfide sealant formulations containing also octylphenol ethoxylate which are subject to REACH Authorisation) and especially during service life cycle of the articles containing terphenyl, hydrogenated at concentration > 0.1% w/w.	No

			No robust information on existing OC/RMMs in the sector (except for the polysulfide sealant formulations containing also octylphenol ethoxylate which are subject to REACH Authorisation). RAC therefore, supports a restriction for aerospace and defence applications.	
Solvent/process medium	Industrial use		RAC cannot conclude if it is a local or wide-dispersive use based on the available information. Environmental releases are assumed by default and specific release factors. No information to conclude on the application of the SpERC conditions of use for this specific use sector or EU level regulatory measures in place to ensure minimisation of emissions RAC therefore, supports a restriction for solvent/process medium.	No
Laboratory chemical	Professional uses		RAC assumes a wide-dispersive use due to the use by professionals and in the absence of further information. Environmental releases are assumed by default release factors and information provided by the users. No information to conclude on the application of the SpERC conditions of use for this specific use sector or EU level regulatory measures in place to ensure minimisation of emissions	No

			RAC therefore, supports a restriction for the use as laboratory chemical by professionals.	

Key elements underpinning the RAC conclusion(s):

The quantitative assessment of the effectiveness of the proposed restriction reported by the Dossier Submitter cannot be considered to be robust based on the RAC conclusion on the emissions assessments detailed in section 3.1.3. Therefore, RAC qualitatively evaluated the effectiveness of the proposed restriction from the point of view of the overall objective to minimise the releases and exposures.

Qualitative assessment

- HTF industrial use

In the background document, the use of terphenyl, hydrogenated as HTF in industrial sites is reported to represent approximately 90% of the total imported tonnage in the EU (appr.6700 t/y in 2020). According to the data obtained from the stakeholders, the total number of closed loop manufacturing systems using terphenyl, hydrogenated, is estimated by the Dossier Submitter to be close to 1300 systems installed in 24 EU Member States.

Sectors using terphenyl, hydrogenated as HTF representing an installed base volume in EU of 25 000 t, are Chemicals, specialities and petrochemicals (48%), Renewable energy (Organic Ranking Cycle, Concentrated Solar Power) (22%) Polymers and plastics (20%), oil and gas processing (5%), Process equipment heating (5%) (Table 4 of the background document).

During the consultation on the Annex XV report and in the Background Document, use of terphenyl, hydrogenated as an HTF is described as being constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated in 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 controls 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. The Dossier Submitter considers that 5% of the imported tonnage were used for top-up and refill. A respondent to consultation on the Annex XV report indicated that 3% of the total quantity used is dedicated to top-up and refill (#3679). Approximately 35% of that volume (2 275 tonnes) was used for complete replacements in existing plants, at the end of the HTF service life. The service life is considered to be 20 years. 60% (approximately 3 900 tonnes) account for filling new installed plants in the EU.

To estimate the emission, RAC notes that in Table 26 of Annex B.9.3.3., the Dossier Submitter reports measurements from 13 sites, although no specific information about the heat transfer systems has been received from Site S-09 (basic chemicals producer). The remaining 12 sites include 17 heat transfer systems installed with a total volume of 2 356 tonnes (2 336 m3) of terphenyl, hydrogenated. RAC noticed that 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.) and considers this percentage not high enough to be representative.

The Dossier Submitter proposes a derogation, provided that sites using HTF, implement strictly controlled closed systems with technical containment and organisational measures to prevent environmental emissions. Appendix 5 in the Annex to the Background Document describes how to reach strictly controlled closed systems conditions in heat transfer systems using terphenyl, hydrogenated as HTF. This appendix intends to be a guidance based on existing EU legislation or guidance documents and cover all expected conditions of use in industrial installations using HTF. RAC is of the opinion that overall, the OCs and RMMs

described in the Appendix 5 are adequate to minimise the risk resulting from environmental releases of terphenyl, hydrogenated.
However, RAC notes that the proposed OC/RMMs are only optional and cannot be assessed for each HTF user. Therefore, RAC considers that the only way to ensure the effectiveness of the strictly controlled conditions described by the DS is to implement a representative monitoring program covering the different conditions of use of the HTF system. Provision of the representative monitoring results to the enforcement authorities would allow for better evaluation of the situation at the industrial sites and would confirm further or not the appropriateness and effectiveness of OCs and RMMs in place.

- Non HTF industrial/professional use

The Dossier Submitter assumes that the non-HTF uses represent approximately 10% of the total EU imported volume (appr. 771 t/y) based on stakeholders' consultation. RAC notes that it is not specified if HTF use relates only to industrial and professional uses or if it also includes HTF mixtures incorporated in articles. The split of volumes per use based on information provided by stakeholders is presented in Table 2 of the Background Document. Plasticiser uses in sealants, adhesives, castings, and coating make up for ca. 95% of the non-HTF uses, while the remaining ca. 5% are used as processing solvents, 0.5% as part of corrosion inhibitor oils and 0.2% as laboratory chemicals (i.e., analytical standards and microscope immersion oils).

In December 2022, the SCIP Database had a total number of almost 25 000 database entries[13] and the received stakeholder information indicates that some of the registrants are importing mixtures from non-EU countries into the EU. An internet search by the Dossier submitter led to the finding of 66 Safety Data Sheets (SDSs) in EU and USA format for non-HTF products, mainly plasticiser formulations. The concentration levels of terphenyl, hydrogenated within these mixtures are ranging from < 1% to up to 60%.

- HTF in the electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats (consumer use)

The use of terphenyl, hydrogenated in these cases is as HTF in the electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats. Widespread release is assumed due to the consumer use of these articles. RAC notes that there is currently no information on sector specific RMMs and OCs or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from this use during article production and service life. RAC assumes no relevant release of terphenyl, hydrogenated during service life of the ovens/stoves since HTF is contained in a closed vessel however spills from thermostats and accidental releases cannot be disregarded without further information.

At the end of life, RAC acknowledges that household ovens and hydrocarbons are in the scope of the WEEE Directive (2012/19/EU) which requires the Member States to ensure proper treatment i.e., removal of all fluids and a selective treatment in accordance with Annex VII. For HTF use in ovens, waste holders are required to treat the fluid as hazardous waste based on its classification. If no harmonised classification is available, the waste holder should employ its best efforts to assign a classification, based on the published self-classifications in the C&L inventory and taking particular notice of the classification transmitted via the SDS of the operator generating the waste. RAC notes that there is no harmonised classification for terphenyl, hydrogenated and various self-classification for aquatic chronic 4 (569 notifiers), aquatic chronic 2 (48 notifiers), aquatic acute 1/chronic 1 (4 notifiers) and aquatic chronic 1 (1 notifier) and not classified (15 notifiers) are available. Therefore, RAC considers that the proper treatment of HTF by waste holders is unclear and in the absence of any further

[13] This number corresponds to the number of entries disseminated on ECHA website (SCIP dissemination portal) and includes double counting as it includes entries based on "referencing".

information on current practices in the Member States cannot conclude on the environmental release at waste disposal from ovens and stoves. Moreover, RAC notes that the Dossier Submitter's derogation also include electrical capillary thermostats for which no information at all was provided. RAC therefore supports a restriction for the use of terphenyl, hydrogenated in thermostats.

- Plasticiser

RAC notes that limited information regarding the use of terphenyl, hydrogenated as a plasticiser is provided by the Dossier Submitter. In the Background Document, the use of the substance as a plasticiser is described as the second most relevant use, involving around 10% of the imported tonnage range (730 T/y). Terphenyl, hydrogenated is used as a plasticiser mainly for the formulation of sealants/adhesives, coatings/ paints/ inks, construction products as well as additives in plastics and polymer preparations which are incorporated in articles used in a wide variety of sectors. Among those categories, adhesives/sealants is the main mixture category incorporated in articles notified to the SCIP database followed by inks, polymer and paints/coatings. The main category of articles incorporating those mixtures is "Vehicles, aircraft, vessels and associated transport equipment" followed by "Electrical machinery and equipment and components thereof", "Products of the chemical or allied industries" and "Machinery and mechanical appliances".

The Dossier Submitter assumes that articles notified to the SCIP database are small and components of very complex products such as vehicles (e.g., cars, trains, planes), electrical and electronic equipment (e.g., for the protection of joints of buried high voltage cables), construction and building components, or furnishings. Downstream sectors (Gifas and the Aerospace Industries Association) confirmed the use of the substance in their sector in sealants in the Draft background document for terphenyl, hydrogenated (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020) and the Annex XV public consultation (see the Aerospace and Defence comment #3655). One individual company commented on its use of terphenyl hydrogenated as ingredient in formulation of a bitumen-based polyurethane used for expansion joints in concrete constructions and filling compound for underground high voltage joints up to 550 kV (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020).

The use of terphenyl, hydrogenated as plasticiser is wide-dispersive and its supply chain can be characterised by the following actors: formulators, users at industrial sites (including articles producers), professional workers and users of articles. No precise and up-to-date information is available on the total number of industrial sites where the substance is currently used. However, this number was expected to be well above 100 in the Draft background document for terphenyl, hydrogenated (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020). Consumer uses (as additive in sealant and adhesive applications, in plastic applications and in coatings, paints and inks) were previously reported in registrations dossiers but are not supported anymore in the current active registrations (ECHA, 2019).

Environmental releases of terphenyl, hydrogenated are assumed to occur during all life-cycle stages of the use of the substance as a plasticizer (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020). Similar default release factors in water, wastewater and soil, are assumed by the Dossier submitter for the formulation (ERC 2), industrial uses (ERC 5), professional uses (ERC 8f) and articles service-life (ERC 10a) of sealants/adhesives and coatings/inks. Specific Environmental Release Categories (SPERCs), described in the Background document for the formulation, industrial and professional uses of adhesives /sealants (FEICA/EFCC) and coatings/inks (CEPE) confirm the releases to water, air, soil and solid waste considering specific operational conditions and

RMMs applied in the sector (even if they are generally reduced compared to the default release factors).

RAC notes that there is currently no information on sector specific RMMS and OCs or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from plasticizer uses including from articles during waste life cycle. RAC is aware that the waste stage is the source of highest emissions of all the life-cycle-stages of produced articles based on the previous restriction cases on PBT/vPvB substances (e.g. Dechlorane Plus).

Described articles are complex products which are composed of multiple components for which separation and properly management of terphenyl, hydrogenated containing parts in the waste phase seems unrealistic. 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. RAC therefore supports a restriction for plasticiser uses.

- Plasticiser use in Aerospace and Defence applications

Terphenyl, hydrogenated is used in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations. During the consultation of the Annex XV report, a comment on these applications was received (comment # 3655) from the Aerospace and Defence industries association of Europe (ASD) and the Aerospace Industries Association (AIA).

ASD and AIA explained that their members still rely on the use of terphenyl, hydrogenated in formulations used in the EEA for both production and repair of aerospace and defence (A&D) products. ASD and AIA members also import articles containing PHT (>0,1%) into the EEA. The following (non-exhaustive) A&D uses of terphenyl, hydrogenated in sealants/adhesives are described where, terphenyl, hydrogenated is used to manufacture, repair and maintain A&D products:

• as encapsulants
• around rivets/fasteners
• in jet engine compressors
• for smoothing/levelling
• to seal fuel tanks
• to seal pressurised aircraft cabins, military aircraft cockpits
• for electrical and thermal potting
• in repair schemes for aircraft that are expected to be in service for decades
• in specific confidential uses in defence and security programs and uses for the manufacture and repair of other safety-critical parts.

Terphenyl, hydrogenated is present as a constituent of sealant/adhesive formulations used by the A&D sector in concentrations up to 50% in one half of a two-part component system. It remains in the finished articles, within the cured sealants/adhesives. Uses of terphenyl, hydrogenated are also required in some finish paints/topcoats used by the A&D sector. Industrial and professional users of formulations containing Terphenyl, hydrogenated are trained workers following the information on the SDS and local laws. The affected sealant/adhesive formulations are not water-miscible and as such no release of hardener or sealant to wastewater from the facility during sealant mixing, and related cleaning and maintenance activities are expected.

RAC notes that some of these formulations, i.e. polysulfide sealants, are subject to current

REACH Authorisation (application number 0203_02[14]) where they also contain(ed) Octylphenol ethoxylate (OPE). As demonstrated in the dossier for the formulation of the polysulfide sealants, there is no release to air due to the volatility of OPE, no release to water due to the absence of water use nor liquid waste generated, no direct or indirect release to soil and all wastes are discarded as hazardous waste i.e., collected and disposed via licensed waste contractors. RAC considers the RMMs and OCs for the formulation of polysulfide sealants also effective to control the release of Terphenyl, hydrogenated in the environment. However, it is worth to note that they will only apply until OPE will be substituted (the review period is 24/12/2024) and they do not cover the application of the sealants and the service-life of articles incorporating such formulations. In the REACH authorisation, the release of OPE during maintenance (service life) is assumed to be controlled by the collection and disposal as hazardous waste of the removed sealant and RAC is of the opinion that it is also applicable to Terphenyl, hydrogenated release. On the other hand, during service life, release by migration into water is assumed for OPE but it is expected to be low due to its interaction with the cross-linked matrix and its encapsulation in the article. RAC considers that it is unknown whether these assumptions are also applicable to Terphenyl, hydrogenated and notes that finish paints/topcoats formulations also used by the aerospace and defence sector will be more exposed to raining water and leaching. RAC also notes that it is more volatile than OPE and its concentration in articles is higher (i.e. > 0.1% w/w when OPE concentration is < 0.1 % w/w) which could potentially led to increased environmental releases. As already noted, the waste disposal of the articles is expected to be the major source of releases for these uses. However, RAC notes that the authorisation specifies, that at end of life all A&D products must, as part of aviation requirement to avoid being used as suspect unapproved parts, be destroyed to avoid reuse as counterfeit parts. At the end of life, parts are collected in designated, secure boxes and sent to a licensed scrap dealer who treats the metals according to EU and national requirements. RAC is of the opinion that these rules are applicable for the entire aerospace and defence sector and therefore no release is expected from waste at the end of life.

Overall, RAC considers the aerospace and defence applications as a wide-dispersive use due to the professional use of various formulations. RAC notes that even if the volume of the substance related to aerospace and defence applications is not known with precision, it represents <10% of the imported tonnage range estimated at approximately 730 T/y. However, there is not enough information to ensure minimisation of emissions of terphenyl, hydrogenated from all formulations used in the aerospace and defence sector. RAC concludes that a general derogation for the use of Terphenyl, hydrogenated in aerospace and defence applications cannot be supported.

- Solvent/process medium

This use is reported in the Background Document at industrial sites, but no information is available on the number of sites in the EU to conclude on a local or wide dispersive use.

In the Background Document, default release factors (ERC 4) and Specific Environmental Release Categories (ESVOC SpERC 4.1.z.v2) assume releases in air, wastewater, soil, and solid waste even if the conditions of uses considered in the SpERCs allow to reduce significantly some emissions (by a factor of 100 000 for air and wastewater and a factor of 500 for soil).

RAC notes that there is currently no information to conclude on the application of the conditions of use assumed in the SpERC for this specific use sector or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from this

[14] See also: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/52405/del/200/col/synonymDynamicField_1512/type/asc/pre/2/view.

use. RAC therefore supports a restriction for solvent/process medium use.

- Laboratory chemical

This use is reported in the Background Document at industrial and professional sites. Use for laboratory analysis of HTF samples are related to the use as HTF at industrial sites and its qualitative assessment is included in the generic scenario for this use.

Terphenyl, hydrogenated is also used as laboratory chemical (e.g., as microscope immersion oils) by professionals. Wide-dispersive use is assumed due to the use by professionals in the absence of information on the number of users.

In the Background Document, default release factors at industrial sites (ERC 6b) assume releases in air, wastewater and soil and releases only in air and wastewater at professional sites (ERC 9b). The LR SEA questionnaire (2018) indicates that no release to wastewater occurs at industrial sites, but it confirms that release occurs in air and soil.

RAC notes that there is currently no information on RMMs and OCs for the use of laboratory chemicals by professionals or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from laboratory chemical uses. RAC therefore supports a restriction for laboratory chemical uses. However, RAC supports a derogation for the laboratory analysis of HTF samples if the restriction includes strict controlled conditions to minimise environmental emissions at industrial and professional sites using HTF.

3.4.4. Socioeconomic analysis

3.4.4.1. Costs

Summary of Dossier Submitter's assessment:

Text

Summary of proposed derogations:

Text

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.4.2. Benefits

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

Summary of proposed derogations:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.4.3. Other relevant impacts

Summary of Dossier Submitter's assessment:

Text

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.4.4. Proportionality

Summary of Dossier Submitter's assessment:

Text

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.5. Practicality, including enforceability

Summary of Dossier Submitter's assessment:

The Dossier Submitter considers the proposed restriction to be practical because it is affordable, implementable, enforceable and manageable.

Regarding enforceability, the Dossier Submitter considers that enforcement authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. They consider that analytical methods can be easily adapted from the methods to analyse o-terphenyl. Given that such methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

RAC conclusion(s):

RAC concludes that overall, the restriction is implementable, enforceable, and manageable.

RAC agrees with the Forum advice regarding the derogation for terphenyl, hydrogenated used as HTF in industrial installations to define in more detail in the legal text strictly controlled closed systems and the obligations of the end user.

RAC is of the opinion that a representative monitoring program to assess environmental releases in air, water and soil is implementable by industrial users of terphenyl, hydrogenated as HTF and enforceable by the enforcement authorities for a better evaluation of the appropriateness and effectiveness of RMMs and OCs.

RAC agrees with the Forum opinion on monitorability that the sampling of products on the

market should be feasible but that a standard analytical method is required. RAC notes that they are some uncertainties related to the standard analytical method development.

Key elements underpinning the RAC conclusion(s):

The Forum considered the enforcement of the proposed restriction as generally practicable but that inspections may vary a lot depending on the personal involved (e.g., non-professional personal of the end user, competent technical bodies, additional experts) and the documentation available (e.g., manual of the manufacturer). RAC agrees with the Forum that, as a consequence, the derogations in Paragraph 2 and 3 of the proposed restriction entry by the Dossier Submitter would require further elaboration in order to provide sufficient basis for the enforcement of the requirements. The Dossier Submitter has provided a definition of strictly controlled closed systems, recommended technical measures and points of inspection and training for enforceability in Appendix 5 of the Annex XV Annexes. However, RAC noted that the different criteria described in the Appendix 5 are only optional and their implementation would differ between the industrial installations using HTF. Therefore, RAC is of the opinion that the strictly controlled closed systems should be confirmed by monitoring environmental releases which shall be checked by the inspectors. These conditions should be added in the restriction entry in order to make the derogation possible.

RAC is of the opinion that the industrial installations must implement a yearly representative monitoring program with the samples taken at relevant points of the circuit to assess the environmental releases in air, water, and soil, under normal conditions and at each intervention on the circuit. Additionally, all solid waste which had been in contact with terphenyl, hydrogenated shall be collected and disposed of as hazardous waste in line with applicable regulations. The information from the monitoring program (including waste management), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken, shall be documented, maintained, and be made available by the industrial sites, upon request, to the competent national authority of the Member State where the site is located.

The industrial sites may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that release to the environment has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific condition of use function appropriately.

Where the frequency of a monitoring programme has been reduced, any subsequent changes to the operational conditions or risk management measures that may affect the release to the environment at each of the sites where the use takes place shall be documented. The industrial sites shall assess the impact of such changes by monitoring to demonstrate that exposure of the environment continues to be reduced to as low a level as technically and practically possible.

There is currently no specific analytical method for the determination of terphenyl, hydrogenated but a reference analytical method by GC-MS for o-terphenyl in air (NIOSH method 5021) as reported in the background document. For enforcement of the restriction, the Dossier Submitter recommends to monitor o-terphenyl and estimates indirectly the concentration of terphenyl, hydrogenated assuming a concentration of 7.1% of o-terphenyl based on the highest concentration provided in the REACH registration dossier. RAC is of the opinion that this approach could bring significant uncertainties in the identification and quantification of terphenyl, hydrogenated and recommends to develop analytical methods which could differentiate o-terphenyl from other terphenyl isomers present in the UVCB and guarantee the distinction between ortho-terphenyl from terphenyl, hydrogenated or from other sources. RAC notes that NILU NIVA (NILU, 2018) has developed non-standardised GC-MS analytical methods to monitor different hydrogenated terphenyls and terphenyls congeners (including o-terphenyl, m-terphenyl and p-terphenyl) in air, water, biota and solid (sediment, sludge and dust) samples. In scarcity of any available standards for the broad

group of congeners of hydrogenated terphenyls, a synthesis of 13C6-dicyclohexylbenzene was undertaken. The major congener, $^{13}C_6$-sH12pTP was extracted and purified by crystallization. to serve as standard solution for spiking samples prior to extraction and quantify all hydrogenated terphenyls congeners. Two other publications which are not referred to in the Background Document report further monitoring studies. The screening programme 2019 (COWI AS, 2020) analysed Terphenyl, hydrogenated in wastewaters, sludge, passive samplers, sand trap, sediment, fish and house dust in various locations in Norway by GC-MS/MS (triple quad) along with other semi-volatile compounds but no details on the methodology are provided. The other report refers to an accidental release of Therminol 66, with terphenyl, hydrogenated as main component, in a Norwich fjord (NIVA, 2012 in Norwegian). Samples of mussels were analysed by a commercial laboratory. A known amount of sample of the soft parts was added to isopropanol, cyclohexane and internal standard (d10-phenatrene) and then treated with ultrasound, shaking and centrifugation. The organic phase was extracted and washed with saline solution, before removal of polar components with Bond Elute. The extract was run on GC-MS in SIM/Scan mode. To determine the uncertainty of the analysis, a so-called "spiking" test was carried out in which a known amount of Therminol oil was added to a “reference sample” and analysed. The detection limit of 0.1 mg/kg was calculated from the spiked reference sample. Therminol oil was also found in the reference sample without addition leading to higher detection limit and uncertainty than expected if Therminol-free material had been used in the spiking tests. A sample of the oil was analysed to determine retention times and ion ratios. From the probable fragmentation pattern, five different peaks were identified by the author to be the different isomers of the terphenyl, hydrogenated compound.

Based on the information on available analytical methods, RAC assumes that it should be feasible to develop standardised analytical methods for the enforcement of this restriction.

RAC recognizes the relevance of the concentration limit of 0.1% w/w of Terphenyl, hydrogenated proposed by the Dossier Submitter because it triggers the information requirement under REACH article 31 for substances and mixtures and 33 for articles. However, RAC agrees with the Forum that a standardised analytical method with a limit of detection below 0.1% w/w shall be elaborated in order to sampling of liquid mixtures and articles for the uniform enforcement of the restriction. The limit of detection for o-terphenyl are 2 µg/sample of air in the reference analytical method dated 1994 and 1 µg/m3 for air in the monitoring program at industrial sites reported in the Background Document annexes. Limit of detections are not reported in the NILU report from 2018 but concentrations of 1/0.1 ng/m3 of air, 3/1.8 ng/L of water and 1/0.3 ng/g of sediment were measured for hydrogenated terphenyls/ terphenyls, respectively. The method was able to differentiate o-, m- and p-terphenyls and had LoDs in the range of ng (ng/m3, ng/g or ng/L depending on the relevant sample types). However, as raised by the Forum, it is uncertain whether these limits of quantifications are applicable to sampling of liquid mixtures or articles under the scope of this restriction.

RAC agrees with the Forum that a sample preparation for articles would need to be elaborated as well.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.6. Monitorability

Summary of Dossier Submitter’s assessment:

The Dossier Submitter considers the proposed restriction to be monitorable.

Analytical methods for quantitative determination of terphenyl, hydrogenated are available. 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.

RAC conclusion(s)

RAC notes that the tonnage band declared in the REACH registration or imported on industrial sites, (information in SDS), could be used for monitoring the use of terphenyl hydrogenated.

RAC is of the opinion that standard analytical methods needs to be develop in liquid mixtures, articles and environmental samples to assess the effectiveness of the restriction.

RAC notes that monitoring is based on o-terphenyl and concludes that the standard analytical methods should be able to differentiate o-terphenyl from terphenyl, hydrogenated or from other substances containing o-terphenyl. Therefore, there is a need for the users of the latter substances to indicate they do not use terphenyl, hydrogenated.

RAC is of the opinion that the implementation of a representative monitoring program is necessary for the enforcement authorities to assess the appropriateness and effectiveness of RMMs and OCs to minimise environmental releases at industrial sites using terphenyl, hydrogenated as HTF.

Key elements underpinning the RAC conclusion(s):

Key elements underpinning the RAC conclusions are presented in section 3.4.1.

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 by the dossier submitter in its monitoring campaign 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. 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.

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. This is not a direct method for the identification and quantification of Terphenyl, hydrogenated, since this substance is a UVCB.

The Dossier Submitter did not address the presence of o-terphenyl in other substances (as e.g., a constituent), the Dossier Submitter considered that o-terphenyl (CAS 84-15-1) is not a chemical product itself and is not marketed as an individual substance globally.

RAC has reservations on this statement (see section 3.4.1) as the proposed method would capture o-terphenyl where it may be present as a constituent of other terphenyl substances that are not in scope of the proposed restriction.

RAC therefore considers that during the enforcement for example, the declaration of the quantity and the identity of the substance containing terphenyl should be verified to examine compliance with the proposed restriction. Furthermore, RAC highlights that the main issue of the proposed restriction (RO1) is the lack of monitoring requirements in the guidance on

strictly controlled closed systems for HTF derogation. Although the Dossier Submitter considered that o-terphenyl (CAS 84-15-1) is not a chemical product itself and is not marketed as an individual substance globally, RAC notes that on the ECHA website o-terphenyl can be found as such or included in other substances and that other substances may be commercially available in the EU, even though no registration dossiers are available, when they are manufactured or imported at a tonnage below 1 t/y per legal entity.

RAC notes that the reaction mass of o-terphenyl and m-terphenyl is registered in the tonnage band 10-100 tonnes per year and that this quantity could interfere with the global volumes marketed for terphenyl hydrogenated. Therefore, RAC notes that during the enforcement for example, the declaration of the quantity and the identity of the substance containing o-terphenyl should be verified to exclude the substance that are out of the scope of the suggested restriction.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.7. Conclusion whether the suggested restriction is the most appropriate EU-wide measure

RAC conclusion(s):

RAC concludes that the proposed restriction is with some modifications the most appropriate EU wide measure.

The revised proposed restriction with some modifications is effective in minimising the risk.

A time limited derogation on the use as a HTF in industrial installations is supported provided that strictly controlled closed systems are implemented and the requirement to implement a representative monitoring program is foreseen as part of the restriction.

The restriction is generally practicable, enforceable and monitorable. Further development of the analytical methods is recommended.

RAC points out that o-terphenyl (the constituent of terphenyl hydrogenated that drives the restriction proposal due to its vPvB properties) may be present as constituent of other substances in addition to terphenyl hydrogenated. RAC recommends that the risks posed by o-terphenyl resulting from the use of these substances should be further investigated and addressed if confirmed.

Key elements underpinning the RAC conclusion(s):

RAC concludes for the reasons set out in section 3.1.1 that the scope of the restriction is not optimal.

Due to significant uncertainties on the emission estimates and the uses of Terphenyl, hydrogenated, RAC cannot give a robust view on the effectiveness of the restriction on a quantitative basis. However, the qualitative analysis performed by RAC demonstrates that emissions can be expected for all the identified uses (see section 3.4.3) and the overall need for action given the vPvB properties of the substance.

Other regulatory risk management options have been disregarded in section 3.4.2 because they do not address terphenyl, hydrogenated or, all its uses or, they would delay the minimisation of environmental releases compared to a broad restriction. RAC concludes that a restriction is the preferred regulatory measure compared to other, REACH and non-REACH, actions.

RAC considers that the use of HTF in industrial installations can be derogated if the sites are compliant with specific OCs and RMMs described in Appendix 5 of the Annex of the Annex XV Dossier. The derogation will be valid a minimum length of years after the entry into force of the restriction in order to allow the development of safer alternatives.

In section 3.4.1, RAC concludes that the restriction is implementable, enforceable and manageable. RAC is of the opinion that the industrial installations using terphenyl, hydrogenated must implement a representative monitoring program to assess the environmental releases without delay. Provision of the results of the representative monitoring results to the enforcement authorities will allow for a better evaluation of the situation at the industrial sites and inform further the appropriateness and effectiveness of RMMs and OCs.

RAC notes that analytical methods are limited and need more development for the enforcement of the restriction proposal.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.5. SUMMARY OF UNCERTAINTIES

3.5.1. Uncertainties evaluated by RAC

Summary of Dossier Submitter's assessment:

A number of uncertainties have been identified and described by the Dossier Submitter in the Background Document (section 3 and Annex F). The Dossier Submitter considered the input parameters on volumes and uses (Annex A) as well as the number of sites using terphenyl, hydrogenated to be quite accurate, since consistent data was provided from industry during the stakeholder consultations and direct interviews with the concerned parties

Owing to a lack of site-specific exposure information for the EU, a generic approach closely aligned with ECHA Guidance R16 has been used for the exposure assessment. The approach involves a number of assumptions and, where appropriate, a realistic worst-case approach has been chosen in line with ECHA Guidance R16. Uncertainties in the use factors, for the plasticiser use, is a driving factor for the results of the exposure assessment. The limited information on volumes for certain uses combined with the lack of information on fractions of terphenyl Hydrogenated released to air, water, and soil from the various processes using terphenyl hydrogenated and lifecycle stages, creates uncertainties in the exposure 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 Dossier Submitter considered the result of the high emission scenario as not reliable since the actual emission associated with the industrial use of terphenyl, hydrogenated is unrealistic and overestimates

the actual emission.

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.

RAC conclusion(s):

RAC estimates that inconsistent information related to the total use volume, operational conditions and environmental release factors for the use of HTF in industrial installations constitute significant uncertainties in the risk assessment of terphenyl, hydrogenated.

RAC is of the opinion that the lack of information regarding non-HTF uses brings major uncertainties in the risk assessment of terphenyl, hydrogenated.

RAC concludes that all identified information gaps, unrealistic assumptions and uncertainties in the emission assessment of terphenyl, hydrogenated add uncertainty to the effectiveness of this proposed restriction.

RAC is of the opinion that there is uncertainty on the effectiveness of this proposed restriction in minimizing releases to the environment of o-terphenyl, the vPvB constituent of terphenyl, hydrogenated, as it could also be present in other substances outside the scope of this restriction.

RAC notes that analytical methods are limited and need more development, making the monitorability of the restriction uncertain.

RAC concludes that overall, given the vPvB properties of terphenyl hydrogenated couples with the wide dispersive uses, the identified uncertainties would not impact the effectiveness and enforceability of the restriction as proposed by RAC.

Key elements underpinning the RAC conclusion(s):

Key elements underpinning the RAC conclusions are presented in section 3.1.1, 3.1.3.; 3.4.1; 3.4.2.

Despite the uncertainties identified, the qualitative assessment outcome clearly shows that a restriction is needed, whereas for other uses operation conditions and risk management measures can be proposed that are appropriate and effective in limiting the risk for as far as technically possible.

RAC proposes some modifications to the restriction proposed by the Dossier Submitter in order to reduce the uncertainties related to the risk of terphenyl, hydrogenated used in aerospace and defence applications and as HTF in industrial installations and concludes that overall, the identified uncertainties would not impact the effectiveness and enforceability of the restriction as proposed by RAC.

3.5.2. Uncertainties evaluated by SEAC

Summary of Dossier Submitter's assessment:

Text

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

4. REFERENCES

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