

**14 April 2021**

## Background document for terphenyl, hydrogenated

### Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV

*ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.*

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of terphenyl, hydrogenated in the Authorisation List or in the registration dossiers<sup>1</sup> as well as the MSC opinion<sup>2</sup> were taken into consideration when finalising the recommendation and are reflected in the present document.

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<sup>1</sup> As of the last day of the consultation, i.e. 5 June 2020

<sup>2</sup> Opinion of the Member State Committee on the draft tenth recommendation of the priority substances to be included in Annex XIV, adopted on 10 February 2021

## 1. Identity of the substance

Identity of the substance as provided in the Candidate List<sup>3</sup>:

Name: Terphenyl, hydrogenated  
EC Number: 262-967-7  
CAS Number: 61788-32-7

## 2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation<sup>4</sup>. Results of the prioritisation of all substances included in the Candidate List by July 2019 and not yet recommended or included in Annex XIV of the REACH Regulation are available at

[https://echa.europa.eu/documents/10162/13640/prior\\_results\\_cl\\_subst\\_march\\_2020\\_en.pdf](https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf).

The prioritisation results of the substances included in the draft 10<sup>th</sup> recommendation have been updated as necessary after the consultation. The updated results are available at [https://echa.europa.eu/documents/10162/13640/prioritisation\\_results\\_draft10threc\\_substances\\_april2021\\_en.pdf](https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft10threc_substances_april2021_en.pdf).

As stated above, registration information as available on the last day of consultation (5 June 2020) was considered. Therefore, the impact of the UK withdrawal from the EU (for which the transition period ended 31 December 2020) was not taken into account.

### 2.1. Intrinsic properties

Terphenyl, hydrogenated was identified as a Substance of Very High Concern (SVHC) according to Article 57(e) as it meets the criteria of a vPvB substance and was included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

### 2.2. Volume used in the scope of authorisation

The amount of terphenyl, hydrogenated manufactured and/or imported into the EU is according to registration data (ECHA, 2020) > 10,000 t/y. Part of this tonnage is exported outside the EU (based on registration information). All the uses appear to fall within the scope of authorisation, except some uses in scientific research and development, to the extent they fall under the generic exemption from authorisation requirement.

Taking into account the information available on the tonnage corresponding to those uses, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

### 2.3. Wide-dispersiveness of uses

Registered uses of terphenyl, hydrogenated in the scope of authorisation include uses at industrial sites (use in heat transfer fluids, use as solvent/process medium, formulation and use of adhesives and sealants, paints, coatings, inks, formulation and use of additives in plastics,

<sup>3</sup> For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

<sup>4</sup> Document can be accessed at [https://echa.europa.eu/documents/10162/13640/recom\\_gen\\_approach\\_svhc\\_prior\\_2020\\_en.pdf](https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf)

formulation of construction products) and uses by professional workers (heat transfer fluids, uses of adhesives and sealants, coatings/inks and paints) (ECHA, 2020).

Furthermore, according to registrations the substance is used in articles in volumes above 10t/y (e.g. plastic articles, coated articles).

More detailed information on uses is provided in Annex I.

## 2.4. Further considerations for priority setting

None<sup>5</sup>.

## 2.5. Conclusion

| Verbal descriptions and scores  |  |   | Total score<br>(= IP + V + WDU) |
|---|--|---|---------------------------------|
| Inherent properties (IP)  | Volume (V)   | Wide dispersiveness of uses (WDU)   |                                 |
| Terphenyl, hydrogenated is identified as vPvB meeting the criteria of Article 57 (e)<br><br>Score: 13 | The amount of terphenyl, hydrogenated used in the scope of authorisation is in the range of 1,000 - <10,000 t/y<br><br>Score: 12 | Terphenyl, hydrogenated is used at industrial sites and by professional workers.<br><br>Initial score: 10<br><br>Furthermore, the substance is used in articles in volumes >10 t/y<br><br>Refined score: 12 | 37                              |

### Conclusion

On the basis of the prioritisation criteria, terphenyl, hydrogenated receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, **terphenyl, hydrogenated is recommended for inclusion in Annex XIV**.

## 3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV<sup>6</sup> and as further specified in the practical implementation document<sup>7</sup>. The draft Annex XIV entries for all the substances that underwent consultation are available at

<sup>5</sup> At MSC-72 in December 2020, a member informed MSC about ongoing preparations of a restriction proposal for terphenyl, hydrogenated. However, to date, ECHA has not received a respective intention from any Member State, nor a request from Commission asking ECHA to prepare such a restriction (the status of the restriction intentions can be followed at <https://echa.europa.eu/registry-of-restriction-intentions>).

<sup>6</sup> General approach can be accessed at [https://echa.europa.eu/documents/10162/13640/recom\\_gen\\_approach\\_draft\\_axiv\\_entries\\_2020\\_en.pdf](https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf)

<sup>7</sup> Practical implementation document can be accessed at [https://echa.europa.eu/documents/10162/13640/recom\\_gen\\_approach\\_draft\\_axiv\\_entries\\_impl\\_doc\\_2020\\_en.pdf](https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf)

[https://echa.europa.eu/documents/10162/13640/10th\\_recom\\_draft\\_axiv\\_entries\\_en.pdf](https://echa.europa.eu/documents/10162/13640/10th_recom_draft_axiv_entries_en.pdf).

The final draft Annex XIV entries that ECHA recommends are available at [https://echa.europa.eu/documents/10162/13640/10th\\_axiv\\_recommendation\\_april2021\\_en.pdf](https://echa.europa.eu/documents/10162/13640/10th_axiv_recommendation_april2021_en.pdf).

### 3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for terphenyl, hydrogenated:

**Latest application date (LAD): Date of inclusion in Annex XIV plus 21 months**

**Sunset date: 18 months after LAD**

In each recommendation, the LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances included in the recommendation to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain.

Comments were received during the consultation (ComRef, 2021) requesting to postpone the sunset date for terphenyl, hydrogenated in a way that it would coincide with the sunset dates of other alternative substances<sup>8</sup> that might be included in future in Annex XIV. Other comments requested to set the LAD of terphenyl, hydrogenated in a way that its analysis of alternatives can take into account the outcome of ongoing data generation for alternative substances. Furthermore, some comments claimed that the typical authorisation timeframes (LAD, SD, review periods) are not suitable for the use as heat transfer fluid<sup>9</sup> as the life cycles/ investment cycles are typically longer.

ECHA has seen no reason to diverge from its proposal for latest application dates and sunset date based on the comments received (see detailed response in RCOM, 2021). The MSC is of the opinion that the LAD allocation proposed by ECHA is appropriate<sup>10</sup>.

ECHA made the final LAD allocation using all available relevant information including that received in the consultation.

A summary of the information available for terphenyl, hydrogenated is provided in Annex I.

### 3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for terphenyl, hydrogenated.

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

<sup>8</sup> See Annex I, section 2

<sup>9</sup> The main use of terphenyl, hydrogenated according to information provided in consultations (ComRef, 2021),

<sup>10</sup>[https://www.echa.europa.eu/documents/10162/13576/msc\\_opinion\\_10th\\_draft\\_rec\\_adopted\\_10022021\\_en.pdf/dee677cc-4c9d-de87-3397-dfa0c2703e65](https://www.echa.europa.eu/documents/10162/13576/msc_opinion_10th_draft_rec_adopted_10022021_en.pdf/dee677cc-4c9d-de87-3397-dfa0c2703e65)

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of terphenyl, hydrogenated.

### 3.3. Uses or categories of uses exempted from authorisation requirement

#### 3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for uses of terphenyl, hydrogenated on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the consultation (ComRef, 2021), exemption requests were received by various comment submitters for uses of terphenyl, hydrogenated, as heat transfer fluid/heat exchanger fluid/heat carrier oil (later on generally referred to as HTF). Some comment submitters further specified the uses to be exempted e.g. as follows:

- HTF in closed systems
- HTF in closed tight systems without any possibility of leakage
- HTF in close system without any contact with the other installation and equipment
- HTF in closed systems at industrial sites
- HTF in closed, tight, non-pressurised systems requiring an operational temperature of 300 to 345 °C in industrial processes, provided that operators are trained with respect to Safety and Environmental guidelines published on the Material Safety Data Sheet and that all potential risks are assessed and deemed manageable.

ECHA assessed the requests made and concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of terphenyl, hydrogenated (see detailed response in Section C, in particular C.2, of the response document (RCOM, 2021)).

MSC is of the opinion that exemptions under Article 58(2) are not warranted for terphenyl, hydrogenated.

ECHA therefore **does not recommend exemptions** for uses of terphenyl, hydrogenated on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

#### 3.3.2 Exemption of product and process oriented research and development (PPORD)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of terphenyl, hydrogenated for PPORD.

During the consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of the consultation.

ECHA therefore **does not recommend exempting any use of terphenyl, hydrogenated for PPORD** from authorisation.

## 4. References

Annex XV SVHC report (2018): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Terphenyl, hydrogenated. Submitted by Finland, February 2018.

<https://echa.europa.eu/documents/10162/3c36efa2-f86b-5065-1fbe-eb60459b4806>

ComRef (2021): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 5/03/2020 – 5/06/2020 on ECHA's proposal to include terphenyl, hydrogenated in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

[https://echa.europa.eu/documents/10162/13640/10th\\_recom\\_comref\\_terphenyl\\_hydrogenated\\_en.rtf](https://echa.europa.eu/documents/10162/13640/10th_recom_comref_terphenyl_hydrogenated_en.rtf)

ECHA (2020): Terphenyl, hydrogenated. ECHA's dissemination website on registered substances. Accessed on 5 June 2020.

<https://echa.europa.eu/search-for-chemicals>

RCOM (2018): "Responses to comments" document. Document compiled by Finland from the commenting period 8/03/2018 - 23/04/2018 on the proposal to identify Terphenyl, hydrogenated as a Substance of Very High Concern.

<https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e18250183f>

RCOM (2021): "Responses to comments" document. Document compiling the responses to comments from commenting period 5/03/2020 – 5/06/2020 on ECHA's proposal to include terphenyl, hydrogenated in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

[https://echa.europa.eu/documents/10162/13640/10th\\_recom\\_respdoc\\_terphenyl\\_hydrogenated\\_en.pdf](https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_terphenyl_hydrogenated_en.pdf)

## Annex I: Further information on uses

### 1. Information on uses

Registered uses of terphenyl, hydrogenated include formulation and uses at industrial sites, uses by professional workers, and uses in articles.

Consumer uses (as additive is 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, 2020). Some registrants report the consumer uses in coatings, inks, adhesives and sealants as uses advised against.

During the SVHC consultation (RCOM, 2018) and the Recommendation consultation (ComRef, 2021), comment submitters have provided some additional information on uses (see below). No comments on the uses in coatings, inks and paints have been received.

- **Use as Heat transfer fluid**

One of the major registrants indicated that terphenyl, hydrogenated is a significant commercial product in Europe, manufactured by the company under the name Therminol™ 66 and used predominantly as a heat transfer fluid (HTF) in high temperature, non-pressurised closed manufacturing systems, including those for polymers, waste heat recovery, oil and gas, petrochemicals, and renewable energy (RCOM, 2018). The comment submitter further noted that as an ingredient in heat transfer fluids, terphenyl, hydrogenated is critical to many industrial processes, including, among others, the manufacture of polyethylene terephthalate (PET) and the conversion of biomass to energy. The same registrants commenting during the consultation on the draft recommendation further specified that 96% of the total EU volumes of Therminol 66 is for use as a high-temperature non-pressurised heat transfer fluid (HTF) in closed systems on industrial sites (ComRef, 2021).

The company itself is a direct user of the substance in two of its plants where petrochemicals, basic chemicals, or resins products are produced.

A number of individual companies from various further sectors (e.g. food and pharmaceutical, polymers, power production<sup>11</sup>, aluminium, activated-carbon and textile sectors) also commented on the use of terphenyl, hydrogenated for its properties as heat transfer fluid (RCOM, 2018; ComRef, 2021).

Some comment submitters provided estimations on the number of installations where the substance is used. One company indicated that to its knowledge there are more than 400 systems installed in Germany and Austria, relying on terphenyl, hydrogenated in thermal oil products. Another commenter estimated the number of users in Italy to be above 400 (RCOM, 2018).

One distributor indicated supplying hydrogenated, terphenyl for industrial and professional uses as heat transfer agent to a wide range of users spanning between large industrial installations (such as large chemical manufacturing installations) to typical SME's (all using the HTF in dedicated closed installations) (ComRef, 2021).

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<sup>11</sup> The substance is used in various district-heating systems.

- **Plasticizer in plastics, adhesives and sealants applications**

One of the major registrants indicated that the substance is used as a plasticiser in high-voltage underground cables, aircraft sealants and other plasticiser applications.

Downstream sectors (Gifas<sup>12</sup> and the Aerospace Industries Association) confirmed the use of the substance in their sectors in sealants. The Aerospace Industries Association further specified that the substance is found in most polysulfide sealants. It is used as a high viscosity plasticizer to prevent phase separation of heavy constituents from settling out during storage, often found in accelerators. Polysulfide sealants are broadly used in the aerospace and defence industry because they provide flexible and chemically resistant sealing with low moisture permeability. Other uses of the substance in polysulfides includes specialty aerospace sealants for fuel tanks, window installations, sealing sandwich assemblies, self-levelling compounds, hole filling, low density, fast cure sealants, temperature-resistance, fuel, pressure and weather resistance, and pressure and environmental sealants. They are also used in potting compounds for potting of electrical connectors and potting inserts in sandwich panels.

The Aerospace Industries Association indicated that the substance can also be used in structural adhesives (terphenyl, hydrogenated is used in the catalyst component of general purpose epoxy adhesives used to bond metals, printed circuit boards, electronic components, glass and plastics) and in other processes (hydrogenated terphenyls are also found in tapes, electrical insulating coating compounds, epoxies, polyurethane potting and moulding compounds, and electric cables).

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.

- **Use as use as solvent/process medium at industrial sites**

The substance is registered for use as solvent/process medium at industrial sites.

One company commenting during the consultation on the draft recommendation (ComRef, 2021) indicated using terphenyl, hydrogenated in a reaction of isomerisation of an epoxide in aldehyde as a non-reactive processing aid, to solubilise the catalyst.

No further information is available on that use.

## 2. Market trend and possible alternatives

Information on the market trend of terphenyl, hydrogenated is not available in registration dossiers and has not been provided in the SVHC consultation nor in the consultation on the draft recommendation.

Two substances having structural similarities and common uses with terphenyl, hydrogenated have been scrutinised by the Finnish Competent Authority in the context of an RMOA<sup>13</sup>. The RMOA activity covers two substances (dibenzylbenzene, ar-methyl derivate (EC 258-649-2) and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (EC 400-370-7)) and was motivated by a

<sup>12</sup> Groupement des industries françaises aéronautiques et spatiales

<sup>13</sup> Regulatory Management Option Analysis: <https://echa.europa.eu/understanding-rmoa>



functional grouping approach for high temperature, non-pressurised heat transfer fluids that might be used as substitutes for terphenyl, hydrogenated<sup>14, 15</sup>.

Comments received during the consultation on the draft recommendation confirmed that the above identified substances are considered as alternatives to terphenyl, hydrogenated by several industry actors (ComRef, 2021). The substance 258-649-2 is currently under compliance check (deadline for registrants to submit requested information: 17/01/2022)<sup>16</sup>. The substance 400-370-7 is under substance evaluation<sup>17</sup>.

One comment submitter listed another substance (EC 202-163-5 (biphenyl; diphenyl) as a substance known to be used in synthetic heat transfer fluid systems (HTF). This substance was evaluated under Substance Evaluation by Portugal<sup>18</sup> who concluded that the substance does not have PBT/vPvB properties (ComRef, 2021).

Several comment submitters emphasised that in order to meet their functionality requirements, high-temperature non-pressurised HTFs must possess physical properties that also make them likely to meet REACH Annex XIII criteria for persistence and bioaccumulation. Properties considered as critical for meeting technical requirements for such application include high thermal and oxidation stability (to provide long fluid life), low vapour pressure and high boiling point (in order to avoid pressurized systems) (ComRef, 2021).

In addition, low viscosity over the operating range (to ensure proper heat transfer), low pour point (to enable easy start-up at ambient temperatures) and absence of process safety concerns (should the substance get into contact with the other chemicals used in the plants) have been commented to be important criteria by some companies (ComRef, 2021).

### 3. Structure and complexity of supply chains

The following information is available on the structure and complexity of supply. The information has been used to allocate the substance to a specific LAD slot in the final recommendation.

Terphenyl, hydrogenated is manufactured and/or imported by a limited number of registrants. No precise information is available on the total number of industrial sites where the substances is currently used. However, this number has been confirmed by comment submitters during consultation to be well above 100 (RCOM, 2018; RCOM, 2021).

The supply chain can be characterised<sup>19</sup> by the following actors: formulators, users at industrial sites (including articles producers), professional workers and users of articles (relevant life cycle stages: F, IS, PW, SL).

<sup>14</sup> Further information on this RMOA can be found at <https://echa.europa.eu/rmoa/-/dislist/details/0b0236e1834a0ed6>

<sup>15</sup> The Italian Competent Authority is carrying out a further RMOA on terphenyl, hydrogenated. However, ECHA is not aware that the work would have identified further alternative substances. To follow the status of this RMOA see PACT: <https://echa.europa.eu/pact>

<sup>16</sup> See <https://echa.europa.eu/documents/10162/142079ba-ed44-66e4-e9ee-ab31045282cf>

<sup>17</sup> See CoRAP List: [https://echa.europa.eu/documents/10162/9801478/corap\\_update\\_2021-2023\\_en.pdf/fdb46fb0-21a2-1ab7-3ce2-74dbe509a60f](https://echa.europa.eu/documents/10162/9801478/corap_update_2021-2023_en.pdf/fdb46fb0-21a2-1ab7-3ce2-74dbe509a60f)

<sup>18</sup> See <https://echa.europa.eu/documents/10162/5795770e-ba49-26d6-2ae4-57fbe2408459>

<sup>19</sup> Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: [https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r12\\_en.pdf](https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf)

Terphenyl, hydrogenated seems to be used in the following product types: adhesives, sealants, coatings, inks, paints, heat transfer fluids, polymer preparations and process medium products (Relevant product categories: PC1, PC9a, PC9b, PC16, PC32, PC0/PC20)<sup>20</sup>.

Various sectors are relying on the substance in some of their uses including: manufacturers of fine chemicals, bulk/large scale chemicals, plastic, metal, textile and food products, electrical equipment, transport equipment as well as the construction and electricity/steam/gas/water supply sectors (relevant sector of use categories: SU4, SU5, SU8, SU9, SU12, SU15, SU16, SU17, SU19, SU23).

Uses of terphenyl, hydrogenated in the scope of authorisation seem to be relevant for the production of a number of article types such as plastic articles and electrical/electronic articles (e.g. thermostats) (relevant article categories: AC2, AC13).

Some of the categories mentioned above are not reported as such in registrations but could be derived from other information on uses available in registration dossiers, from information from substance in article notifications and from information submitted during consultation (RCOM, 2018; ComRef, 2021).

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<sup>20</sup> The substance is also reported for use as laboratory chemical (PC21). This use/product type is not reflected here as it might fall outside the scope of authorisation and therefore not contribute to the workload at AfA stage.