

**Analysis of the most appropriate risk management option (RMOA)**

**Substance Name:** **Dibenzylbenzene, ar-methyl derivative**

**EC Number: 258-649-2**

**CAS Number: 53585-53-8**

**Substance Name:** **6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene**

**EC Number: 400-370-7**

**CAS Number:**

**Authority: Finland**

**Date: 24 February 2020**

**Cover Note**

The RMOA is part of a functional grouping approach for high temperature, non-pressurised heat transfer fluids, which might be used as substitutes for SVHC identified substance terphenyl, hydrogenated (EC 262-967-7). Terphenyl, hydrogenated was included in the Candidate list 2018 for being very persistent and very bioaccumulative (vPvB).

The potential substitution candidates in this RMOA – dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene – share also similar use as heat transfer fluid as terphenyl, hydrogenated, thus, they could be direct substitutes for terphenyl, hydrogenated in specific high temperature, non-pressurised heat transfer systems. Based on the screening level information these substances might have similar PBT/vPvB properties as terphenyl, hydrogenated, which is already in the Candidate List of substances of very high concern (SVHC) according to the procedure set out in REACH Article 59. To avoid regrettable substitution of terphenyl, hydrogenated, also PBT/vPvB properties of these alternative substances need to be clarified. This RMOA discusses different risk management options and further information needs for the assessment of PBT/vPvB properties of these potential alternative substances.

An initial functional grouping approach concept for high temperature, non-pressurised heat transfer fluids was presented at the RiME+ meeting in Oslo in February 2019. Consultation of the other Member States and Registrant(s) was arranged in December 2019 and January 2020, respectively. Comments were received from Registrant(s) and they were taken into consideration in the final RMOA.

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# identity of the substance

## Other identifiers of the substance

**Table 1:** **Other Substance identifiers**

|  |  |
| --- | --- |
| **EC name (public):** | dibenzylbenzene, ar-methyl derivative |
| **IUPAC name (public):** | dibenzylbenzene, ar-methyl derivative |
| **Index number in Annex VI of the CLP Regulation:** |  |
| **Molecular formula:** | C21H20 |
| **Molecular weight or molecular weight range:** | 272.38 g/mol |
| **Synonyms:** | *benzene, methylbis(phenylmethyl)-**dibenzyl toluene**MARLOTHERM SH**methylbis(phenylmethyl)benzene; dibenzyltoluene* |

**Type of substance** [ ]  Mono-constituent [ ]  Multi-constituent [x]  UVCB

**Structural formula:** UVCB substance

**Table 2: Other Substance identifiers**

|  |  |
| --- | --- |
| **EC name (public):** | 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene |
| **IUPAC name (public):** | 1,2,3,4,-tetrahydro-(1-phenylethyl)-naphthalene |
| **Index number in Annex VI of the CLP Regulation:** |  |
| **Molecular formula:** | C18H20 |
| **Molecular weight or molecular weight range:** | 236.36 g/mol |
| **Synonyms:** | *ACTREL 400**DOWTHERM\*RP HEAT TRANSFER FLUID**SYNTREL 350* |

**Type of substance** [ ]  Mono-constituent [x]  Multi-constituent [ ]  UVCB

**Structural formula:**



Structural formula is based on public name of the substance in the ECHA dissemination site (6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene). This structure is used as potential constituent of the registered multi-constituent substance.

**1.2 Similar substances/grouping possibilities**

**Functional grouping approach**

According to SVHC roadmap 2020 grouping of substances for RMO analysis based on the similarity of uses could be considered, if appropriate. In this RMOA, substances which might be used as substitutes for SVHC (vPvB) identified substance terphenyl, hydrogenated (EC 262-967-7) in its main use as a heat transfer fluid, are grouped based on the similarity of uses (heat transfer fluids). This approach has been further defined by eMSCA by limiting the scope to substances registered under REACH for uses that indicate that the substances may be considered as feasible alternatives for terphenyl, hydrogenated in the EU.

Heat transfer fluids (HTF) are used in situations where precise temperature control is needed, such as in the manufacture and processing of synthetic fibres, plastics, rubber and chemicals. Terphenyl, hydrogenated is specifically used as a heat transfer fluid in closed manufacturing systems, including those for polymers, waste heat recovery, oil and gas, petrochemicals and renewable energy[[1]](#footnote-2).

High temperature heat transfer fluids can be categorised by chemical structure into three groups; synthetic fluids, hot oils and silicone based fluids. According to Damiano (1998) synthetic fluids are aromatic compounds consisting of benzene-based structures with operating temperatures ranging from -55 to 400 °C. The hot oils are petroleum-based substances mostly consisting of paraffinic and/or napthenic hydrocarbons having a usual operating temperature ranging from -25 to 315 °C. Silicone-based and hybrid glycol fluids are used in specialised heat transfer applications and in the comparative temperature ranges of the synthetic fluids and hot oils they are unlikely choices for most process applications due to performance and cost factor disadvantages.

Heat transfer fluids can be used in non-pressurised or pressurised liquid phase systems. Non-pressurised liquid phase systems are generally simplest to design and operate. Heat transfer fluids can be used in this type of system as long as the operating temperature is below its boiling range. When the operating temperature of the HTF is above its boiling range a pressurised system is needed. A pressurised inert gas (nitrogen) is used to maintain HTF in liquid phase in these systems (Damiano 1998).

Terphenyl, hydrogenated can be used as a HTF with operating temperatures as high as 345 °C in non-pressurised liquid phase heat transfer systems (Therminol 2018). Substitutes need to have a similar high boiling point at standard atmospheric pressure (101.325 kPa) to be used without excessive thermal degradation in liquid phase non-pressurised systems at high temperature ranges of 300-350 °C. At temperatures above 350 °C heat transfer systems need to be pressurised (Wühr 2008). Synthetic heat transfer fluids generally have higher maximum bulk fluid temperatures than mineral oil based hot oils, which are not recommended to be used above the temperature of 315-320 °C (Damiano 1998, Teuvo et al. 1987).

In order to identify substances that might be used as substitutes for Terphenyl, hydrogenated in its main use, as a heat transfer fluid, a search for substances for which PC16 (“heat transfer fluids”) is indicated in the registration dossiers was conducted in the RMOA of Terphenyl, hydrogenated by ECHA from the database of REACH registered substances (19.6.2017). The search resulted in 71 industrial or professional uses mentioning “heat transfer fluid/agent/oil/system” in the use name. From those substances, inorganic and halogenated substances are excluded as there is no information available supporting their suitability for high temperature non-pressurised heat transfer fluid use. As a result, a list of 22 substances was obtained and shown in Table 3.

**Table 3. Organic substances used as Heat Transfer Fluids in addition to terphenyl hydrogenated.**

|  |  |  |  |
| --- | --- | --- | --- |
| EC | CAS | Substance name | Boiling point (°C) at (ca. 101 kPa)[[2]](#footnote-3). |
| 204-340-2 | 119-64-2 | 1,2,3,4-tetrahydronaphthalene | 207.57 |
| 211-443-6 | 645-45-4 | 3-phenylpropionyl chloride | 225 |
| 940-786-0 |   | Benzene, C15-16-alkyl derivs. | 306-365 |
| 271-802-8 | 68608-82-2 | Benzene, ethylated, by products from | 265-295 |
| 284-660-7 | 84961-70-6 | Benzene, mono-C10-13-alkyl derivs., distn. residues | 300.4-407.5 |
| 202-394-1 | 95-14-7 | benzotriazole | 204 |
| 248-654-8 | 27776-01-8 | benzyltoluene | 283-287 |
| 202-163-5 | 92-52-4 | biphenyl | 255.25 |
| 206-016-6 | 287-92-3 | cyclopentane | 50 |
| 258-649-2 | 53585-53-8 | dibenzylbenzene, ar-methyl derivative | 390.1 |
| 202-981-2 | 101-84-8 | diphenyl ether | 258 |
| 248-948-6 | 28299-41-4 | ditolyl ether | 283 |
| 200-578-6 | 64-17-5 | ethanol | 78 |
| 211-694-1 | 687-47-8 | ethyl (S)-2-hydroxypropionate | 154 |
| 203-492-7 | 107-46-0 | hexamethyldisiloxane | 100.5 |
| 249-596-6 | 29385-43-1 | methyl-1H-benzotriazole | < 195 |
| 203-497-4 | 107-51-7 | octamethyltrisiloxane | 154 |
| 273-066-3 | 68937-41-7 | Phenol, isopropylated, phosphate (3:1) | > 400 |
| 809-930-9 |  1330-78-5 | Tris(methylphenyl) phosphate | > 400 |
| 915-589-8 |   | Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl | 314 |
| 265-004-9 | 64665-57-2 | sodium 4(or 5)-methyl-1H-benzotriazolide | 230 |
| 216-699-2 | 1643-19-2 | tetrabutylammonium bromide | 144 |

There are only a limited number of substances in Table 3, in which the required upper operating temperature of 325-350 °C does not exceed the boiling point of the substance at atmospheric pressure. According to standard for heat transfer installations working with organic heat transfer fluids (DIN 4754-1), the upper operating temperature limit should be selected in such a way that the HTF remains in usable state for at least one year. A decomposition rate of a few percent of the HTF filling per year is considered acceptable for reasons of economy (Lanxess 2017).

Some of the substances like benzene, C15-16-alkyl derivs (EC 940-786-0) and benzene, mono-C10-13-alkyl derivs., distn. residues (EC 284-660-7) are UVCB substances with varying boiling point ranges. However, for those substances it is expected that some constituents in the lower boiling point range would undergo significant thermal degradation at high temperatures in non-pressurised systems, thus they would not qualify as direct substitution candidates for terphenyl, hydrogenated in those specific conditions. Tris(methylphenyl) phosphate (EC 809-930-9) and Phenol, isopropylated, phosphate (3:1) (EC 273-066-3) have a boiling point over 400 °C, but they do not have industrial heat transfer fluid uses among the available public tradenames in ECHA registered substance factsheets. See more details in the confidential Annex I in this RMOA.

From the substances listed in Table 3, dibenzylbenzene, ar-methyl derivative (EC 258-649-2) screens as a possible substitute for terphenyl, hydrogenated. Dibenzylbenzene, ar-methyl derivative can be used up to 350 °C in pressureless heat transfer systems under a tradename Marlotherm SH (Sasol 2018). Separately from the search conducted by ECHA of the REACH registration database, one other potential substitute (with indication of heat transfer use) was notified to the Finnish Chemical Product Register under the tradename Dowtherm RP. This heat transfer fluid can be used up to 350 °C (DOW 1996). The substance is referred as 1,2,3,4,-tetrahydro-(1-phenylethyl)-napthalene in the publicly available SDS of Dowtherm RP. However, this substance is further referred to as 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene in this RMOA reflecting the public name on ECHA´s website.

Therefore, this RMOA refers to the 2 heat transfer fluids described above, as they could be applied reliably as substitutes for Terphenyl, hydrogenated at the whole high temperature range of 300-350 °C in non-pressurised heat transfer systems.

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#  OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table 4: Completed or ongoing processes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | dibenzylbenzene, ar-methyl erivative | 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene |
| RMOA |  | Risk Management Option Analysis (RMOA) other than this RMOA | [ ]  | [ ]  |
| REACH Processes | Evaluation | Compliance check, Final decision | [x]  Decision of 9 July 2018[[3]](#footnote-4): a request submitted according to Article 41 | [ ]  |
| Testing proposal | [ ]  | [ ]  |
| CoRAP and Substance Evaluation | [ ]  | [ ]  |
| Authorisation | Candidate List | [ ]  | [ ]  |
| Annex XIV  | [ ]  | [ ]  |
| Restri-ction | Annex XVII | [ ]  | [ ]  |
| Harmonised C&L  |  | Annex VI (CLP) (see section 3.1) | [ ]  | [ ]  |
| Processes under other EU legislation |  | Plant Protection Products RegulationRegulation (EC) No 1107/2009  | [ ]  | [ ]  |
|  | Biocidal Product RegulationRegulation (EU) 528/2012 and amendments  | [ ]  | [ ]  |
| Previous legislation |  |  Dangerous substances DirectiveDirective 67/548/EEC (NONS) | [ ]  | [x]  Substance is registered as NONS |
|  |  Existing Substances RegulationRegulation 793/93/EEC (RAR/RRS)  | [x] ECB PBT working group PBT assessment for dibenzyltoluene (EC: 248-097-0, CAS: 26898-17-9) with a outcome that dibenzyltoluene is not considered to be a PBT substance at that time. | [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| (UNEP) Stockholm convention (POPs Protocol) | Assessment  | ☐ | ☐ |
| In relevant Annex  | ☐ | ☐ |
| Other processes/ EU legislation | Other (provide further details below) | ☐ | ☐ |

# HAZARD INFORMATION (INCLUDING CLASSIFICATION)

## Classification

### Harmonised Classification in Annex VI of the CLP

No harmonised classifications.

### Self classification

* In the registration(s):

**Dibenzylbenzene, ar-methyl derivative**: Asp. Tox. 1 (H304), Aquatic Chronic 4 (H413).

**6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene:** Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410).

### Proposal for Harmonised Classification in Annex VI of the CLP

No proposals.

### CLP Notification Status

**Table 6: CLP Notifications**

|  |  |
| --- | --- |
|  | **CLP Notifications[[4]](#footnote-5)** |
|  | Dibenzylbenzene, ar-methyl derivative | 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene |
| Number of aggregated notifications | 1 | 3 |
| Total number of notifiers  | 34 | 95 |

## Additional hazard information

Hazard information for human health and the environment is briefly presented in the following sections 3.2.1 and 3.2.2 separately for dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. All hazard information in these sections are from the registration dossiers as presented in the public substance factsheets from the ECHA website. Confidential hazard information from the registration dossiers are included in to confidential Annex I of this RMOA.

For persistence, the PBT screening criteria (ECHA 2017a) are fulfilled for dibenzylbenzene, ar-methyl derivative indicating that at least some of its constituents are potentially P/vP according to the eMSCA. The substance may have B and T properties based on the information in the registration dossier. However, more information for human health and the environment are currently being requested under ECHA decision on a compliance check based on Article 41 of REACH Regulation (ECHA 2018). The requested information is relevant for PBT/vPvB assessment. Deadline for Registrant(s) to submit requested information in an updated registration dossier is 17th January 2022.

The screening criteria for PBT are met for persistence, bioaccumulation and aquatic toxicity for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene according to the eMSCA. However as there is no further information about which constituent(s) are tested or specific composition of the test substance, it is not possible for eMSCA to adequately assess the PBT properties of the substance.

In an Infocard[[5]](#footnote-6) of 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene, it is indicated that a majority of data submitters agree that this substance is Persistent, Bioaccumulative and Toxic. This comes from data submitted by industry to ECHA, and indicates that the data submitted is aligned with >= 50% of the data submitters have the same conclusion.

### Human health

**Dibenzylbenzene, ar-methyl derivative**

The substance does not have a harmonised classification and there are no existing self-classifications for CMR or STOT RE properties. The data pending a dossier evaluation decision on the substance are necessary to further inform the T assessment for human health endpoints. However, the currently available data from the dossier are summarised below for CMR and STOT RE properties.

**Carcinogenicity**

No data available.

**Mutagenicity**

There are 4 available in vitro gene mutation studies in bacteria, three of which are submitted only as supporting information. An in vitro gene mutation study in mammalian cells and an in vitro chromosome aberration study in mammalian cells are also available in the disseminated dossier.

The substance was negative in an Ames test applying 5 concentrations up to 5000 µg/plate in 5 strains of salmonella typhimurium with and without metabolic activation. Precipitation occurred at concentrations above 200 µg/plate. However, strains able to detect oxidizing mutagens, cross-linking agents and hydrazines (i.e. E. Coli WP2 uvrA or E. Coli WP2 uvrA (pKM101)) were not included in the tested strains.

In the supporting Ames tests, the test item (Marlotherm S) was negative in two studies up to concentrations of 5 mg/plate with precipitation in three and five concentrations tested. 5 strains of salmonella typhimurium were tested with and without metabolic activation, but tested strains did not include TA 102 or E. coli WP2. In the third supporting Ames test, dibenzylbenzene, ar-methyl derivative was tested at 4 concentrations up to 2 µl/plate with and without metabolic activation. The 5 salmonella strains used did not include TA 102 or E. coli WP2. The study was negative in the presence and absence of metabolic activation. Precipitation or cytotoxicity were not reported in this test.

The available bacterial reverse mutation studies have some deficiencies such as lack of appropriate strains used, lacking information on incubation times and temperatures, description of medium and reporting of cytotoxicity and precipitation.

In the available in vitro mammalian chromosome aberration test, Marlotherm S was tested in Chinese hamster ovarian cells at 3 concentrations up to 5000 µg/ml. No cytotoxicity was observed in the concentrations tested. Marlotherm S was negative in the study at both incubation concentrations of 12 and 20 hours with and without metabolic activation.

In the in vitro mammalian cell gene mutation test with Chinese hamster lung fibroblasts (V79), Marlotherm S did not affect mutation frequency at the 5 concentrations tested up to 5 mg/ml in the presence or absence of metabolic activation.

Five in vivo mammalian erythrocyte micronucleus tests are available; four with dibenzylbenzene, ar-methyl derivative and one with Marlotherm S. Two of the studies with dibenzylbenzene, ar-methyl derivative were performed as part of 4 month repeated dose toxicity studies employing doses of 500 mg/kg bw/day by oral gavage in rats. Both studies were negative for micronuclei however one of the tests used only male animals (4 in total). In two of the available studies with dibenzylbenzene, ar-methyl derivative 5 female and 5 male mice were treated with doses of 1000, 2000 and 4000 mg/kg bw/day by oral gavage for two days with a sampling time of 6 hours post-exposure. Both studies were negative for micronuclei. Finally, in a study with Marlotherm S, two doses of the test item were administered intraperitoneally using 1000, 2000 and 4000 mg/kg to 5 female and 5 male mice per group 24 hours apart and sampling conducted after 6 hours post-exposure. The test item was negative for micronucleus induction in this study.

An in vitro gene mutation study in bacteria as well as an in vitro gene mutation study in mammalian cells have been requested to be conducted with the registered substance in a compliance check decision by ECHA. Final conclusions on mutagenicity will be based also on these pending results.

**Reproductive toxicity**

A one generation reproduction toxicity study according to OECD TG 415 (version adopted 1983) conducted by oral gavage in rats with the test item Marlotherm S isavailable. Dose levels of 0, 20, 120 and 720 mg/kg bw/d were used based on a preliminary study and a 90-day repeated-dose toxicity study in rats. A NOAEL of 120 mg/kg bw/day for general toxicity in parental animals (males and females) was derived based on increased kidney, liver and prostate weights in males of the high dose group and on reduced body weight gain, reduced food consumption and increased liver and kidney weights in females of the high dose group. No effects on reproductive parameters were observed and a NOAEL of 720 mg/kg bw/day for reproduction was reported. The NOAEL reported for developmental toxicity in the F1 progeny was 720 mg/kg bw/day as effects on litter size, pup survival and organ weights (heart, kidney, brain, liver) were attributed to maternal toxicity of the test item and reduced pup weight.

Prenatal developmental toxicity was studied in rats (OECD TG 414) using Marlotherm S. Parental animals were treated from GD 6-15 with doses of 25, 150 and 1000 mg/kg bw/day by oral gavage based on a preliminary study. Several low dose animals mistakenly received larger doses than 25 mg/kg bw/day on day 6 or 7 of administration. Decreased body weight gain as well as slightly decreased corrected body weights were observed in the mid dose and high dose maternal females resulting in a maternal NOAEL of 150 mg/kg bw/day for general toxicity. Reduced fetal weights with an increased incidence of runts, increased early and late resorptions, diaphragmatic hernias in pups from one litter, increased incidence of dilated ureters as well as various skeletal abnormalities indicative of retarded ossification were observed in the high dose group. Hydrocephalus was observed in two animals of two different litters in the high dose group as well as kyphosis of the thoracic vertebral column in one fetus of the high dose group. The visceral findings were attributed to growth retardation. The resulting visceral and skeletal malformation index was 1.6% for high dose group pups. The frequency of skeletal anomalies was slightly increased also in the mid dose group. The frequency of early and late resorptions was increased in the high dose group was significant with a resorption index of 10.2% (compared to 4.4% in controls). A developmental NOAEL of 150 mg/kg bw/day was reported based on growth retardation and increased resorption rate at the highest dose tested. More detailed information on the individual animals and litters would be necessary for a detailed evaluation of the findings.

In a second prenatal developmental toxicity study similar to the OECD TG 414 also in rats with dibenzylbenzene, ar-methyl derivative of unknown purity was tested from days 7-17 of gestation at doses of 100, 300 and 1000 mg/kg bw/day by gavage. A maternal NOAEL of 300 mg/kg bw/day was derived based on a slightly decreased body weight gain in the high dose females. A decrease in the number of corpora lutea of high dose females was found but was not considered treatment related due to the commencement of dosing being subsequent to implantation. A slight decrease in pup body weight was reported in the high dose pups which was attributed to maternal toxicity. A developmental NOAEL of 1000 mg/kg bw/day was reported although no details were provided regarding visceral and skeletal findings.

In the available studies described, no effects on sexual function or fertility or on lactation were found. Effects on development were observed in the prenatal developmental toxicity study with Marlotherm S at 1000 mg/kg bw/day as well as in the one generation reproductive toxicity study at 720 mg/kg bw/day. The effects observed in both studies were reported to be attributed to maternal toxicity. No clear signs of toxicity were observed in the maternal animals with respect to clinical signs, mortality or morbidity orduring necropsy. However, a decreased weight gain during gestation days 6-15 of ~27% of the high dose dams compared to controls was observed in the prenatal developmental toxicity study. Decreased weight gain of 19.7% during weeks 0-2 (premating period) and 14.7% during gestation days 0-20 compared to controls in high dose dams was also observed in the one generation study. More detailed information on the individual animal and litter data would be necessary for further analysis of the findings.

A prenatal developmental toxicity study in a second species (rabbits) and an extended one generation reproductive toxicity study with an extension of cohort 1B to produce an F2 generation have been requested by ECHA under a compliance check decision. Final conclusions on the reproductive and developmental toxicity of the substance will be based on the available data together with the pending results of the new studies.

**Specific Target Organ Toxicity**

Two OECD TG 408 studies are available, one for Marlotherm S and one for the substance. Both conducted by gavage in rats using doses of 0-500 mg/kg bw/day. One in vivo and two in vitro studies on liver enzyme induction and peroxisome proliferation are available. In addition, a one generation reproductive toxicity study provides some evidence of systemic toxicity observed in parental animals.

In the first study administering 0, 5, 50 and 500 mg/kg bw/day, test item related effects were observed in clinical chemistry parameters, organ weights and histopathology. A NOAEL of 50 mg/kg bw/day was reported based on a LOAEL of 500 mg/kg bw/day. Changes in liver weights and histopathology as well as increased cholesterol levels were observed at this dose. Slight hepatocellular hypertrophy was observed in 2/10 males at 50 mg/kg bw/day.

In the second OECD TG 408 study doses of 0, 10, 100 and 500 mg/kg bw/day of Marlotherm S were used. Test item related effects were observed in haematology parameters, clinical chemistry, organ weights, gross pathology as well as histopathology. A NOEL of 10 mg/kg bw/day was reported based on dose-dependent increases in liver and kidney weights accompanied hepatocellular hypertrophy in the mid- and high dose groups. Liver and kidney weights were increased in mid- and high dose groups in a dose-dependent manner and livers were swollen upon gross examination. There were no treatment related findings reported in urinalysis parameters, gross pathology or histopathology of the kidneys.

CYP450 enzyme induction after repeated exposure was studied in a non-guideline in vivo study. 10 male and 10 female rats per group were dosed daily via gavage for a minimum of 120 days at 0, 5, 50 and 500 mg/kg bw/day. The livers were subsequently sampled and microsomal fractions prepared for enzyme activity determination as well as liver homogenate samples prepared for peroxisome proliferation assessment. CYP450 induction and slight hepatic peroxisome proliferation were observed at 500 mg/kg bw/day. These findings were consistent with observed centrilobular hepatocyte hypertrophy and increased liver weights and increased liver/body weight ratios observed in male and female animals. Hepatic enzyme induction and peroxisome proliferation potential of the substance have also been observed in vitro.

In a one generation reproductive toxicity study a NOAEL of 120 mg/kg bw/day for general toxicity in parental animals (males and females) was derived based on increased kidney, liver and prostate weights in males of the high dose group and on reduced body weight gain, reduced food consumption and increased liver and kidney weights in females of the high dose group.

The substance induced effects on the liver and kidney at doses of 100 mg/kg bw/day and greater. The findings in the liver are complemented by the data from in vitro and in vivo enzyme induction and peroxisome proliferation studies. The morphological as well as functional changes observed in the liver are considered test item related and may be adaptive. However, peroxisome proliferation following exposure to the substance is not considered relevant for adversity in humans (ECHA 2017b). Furthermore, the nature and severity of the findings do not fulfil the classification criteria for specific target organ toxicity, repeated exposure.

**6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene**

The substance is not self-classified for CMR or STOT RE properties and does not have a harmonised classification. There are no experimental data publicly available for the T assessment of this substance. Confidential data are briefly summarized in the confidential Annex to this document.

**Carcinogenicity**

No data available

**Mutagenicity**

No data publicly available

**Reproductive toxicity**

No data publicly available

**Specific Target Organ Toxicity**

No data publicly available

### Environment

**Dibenzylbenzene, ar-methyl derivative**

**Persistence**

Simulation testing is currently being requested under ECHA decision on a compliance check (ECHA 2018).

Three ready biodegradability studies are available for dibenzylbenzene, ar-methyl derivative in the registration dossier. In a modified Sturm-test (OECD TG 301B) with 16.2 mg/L test substance described as Marlotherm S (97.3 % (v/v) Dibenzyltoluene, 2.0 % (v/v) Tribenzyltoluene), 1 % degradation (CO2 evolution) after 29 d was observed. Test temperature was 20.7 – 33.4 °C.

In another OECD TG 301B study 2.3 % degradation (CO2 evolution) after 28 d was observed with 10 mg/L of test substance (Marlotherm S) at 22.9 ± 1.5 °C. The test was prolonged to 43 days with the second test substance concentration of 20 mg/L as a plateau was not reached after 28 days. Observed degradation after 43 days was 28.5 %.

In third ready biodegradability OECD TG 301D study with 2 mg/L Marlotherm S as test substance 0.5 % degradation (O2 consumption) at 20 ± 1 °C was observed after 5 d and 0 % degradation after 15 d.

One inherent biodegradability study (OECD TG 302C) with 100 mg/l test substance as Marlotherm S showed 0.2 % degradation (O2 consumption) after 28 d.

One non-standard study with mention of conditions similar to a ready biodegradability test was conducted with 10 mg/L of dibenzyltoluene (EC: 248-097-0, CAS: 26898-17-9) as test substance in 20 °C and showed 65 % primary degradation after 62 d and 94 % after 149 d. Furthermore, after 149 days 67 % of aromatic rings have been degraded. Based on this study the ECB working group concluded in 2008 that substance dibenzyltoluene does not meet the P/vP criterion based on screening data. However, in the the CCH decision for dibenzylbenzene, ar-methyl derivative ECHA came to the following conclusion:

 *“Based on the current REACH legislation and the available ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapters R.11., PBT/vPvB assessment, ECHA comes to a different conclusion than the ECB PBT working group. Especially the experimental data (as explained above) do not support a conclusion that the substance is “not P/not vP”.”*

The half-life for photodegradation in air is estimated to be 4.736 h (12 h day, 1.5 x 106 OH/cm³) using AOPWIN v1.92 for dibenzylbenzene, ar-methyl derivative.

**Bioaccumulation**

Experimental n-octanol/water partition coefficient for test substance dibenzylbenzene, ar-methyl derivative is > 6 log Pow at 22 °C as determined according to OECD TG 117, HPLC method. The retention times of all peaks of the test substance were reported to be above the range of reference substance and out of range of the method.

Based on the study above experimental log Kow 6.38 was used for QSAR estimation for bioaccumulation potential of dibenzylbenzene, ar-methyl derivative in the substance factsheet. The estimated fish BCF (BCFBAF v3.00 from EpiWin 4.00) is 7525 L/kg wet-wt with regression-based model.

One experimental OECD TG 305 bioaccumulation study for fish common carp (*Cyprinus carpio*) is available in the substance factsheet with Marlotherm S as test substance (70% various isomers of dibenzyltoluene and benzylphenylmethyltoluene with ca. 30% isomers of tetratoluene as impurities. Derived whole body fish BCF at steady state after 8 weeks was 6300 (wet weight) for test substance concentration of 200 µg/L and BCF 2000 (wet weight) for the concentration of 20 µg/L.

In Japanese CHEmicals Collaborative Knowledge database (J-CHECK) one experimental 60 day fish bioaccumulation study (OECD TG 305) is available for dibenzyltoluene. Steady state BCF for *Cyprinus carpio* was 8300 at the concentration of 10 µg/L and 5900 for 1 µg/L.

**Aquatic toxicity**

Further long-term aquatic toxicity studies are currently being requested under ECHA decision on a compliance check (ECHA 2018).

From the ECHA dissemination site 7 acute toxicity studies for fish are available and cited below:

*In a semi-static study, Scholz, 1995, didn't observed mortality of Danio rerio at a reported concentration of 0.32 mg/L. Exposure concentration was estimated by TLC, solutions were WAF. Few experimental details, as well as an exposure well above water solubility leads to conclude that this study is probably unreliable, but nevertheless that Dibenzylbenzene, ar-methyl derivativeis probably not acutely toxic to fish.*

*Another study, on rainbow trout (Knacker et al, 1990), although being a GLP one, must be disregarded as it is made use of a surfactant, in varying concentrations, that is not recommended by OECD. Concentrations as high as 1 mg/L were tested (50 times higher than water solubility limit). 20% mortality was observed in 96 hours at that concentration.*

*A third study (Scholz, 1990c) on Golden Orfe has been carried out under flow-through conditions with the help of a vehicle whose identity is not available. Concentrations as high as 3.2 mg/L were tested; no mortality was observed.*

*Two other studies were reported (Lepailleur, 1981, 1983) regarding the prolonged acute toxicity (14 days) of Dibenzylbenzene, ar-methyl derivative to Danio rerio. The studies used high concentrations of acetone and the 14 day EC50 of 2.3 mg/L is not considered reliable for the same reasons as mentioned above.*

*An additional prolonged acute toxicity study was conducted under flow-through conditions with Golden Orfe (Scholz, 1990b). At none of the concentrations were there signs of toxicity or abnormal behavior that were attributable to dibenzyltoluene. The 14 day LC50 was >0.46 mg/L (measured concentration). As a surfactant was used to solubilize the Dibenzylbenzene, ar-methyl derivative, the resulting value is well above the level of water solubility.*

*Finally, the Companies in the consortium decided to commission a new study: using the OECD 203 protocol under semi-static conditions and under GLP conditions, it has been confirmed (Knight, 2010) that, at the highest exposure achievable with a Water Accommodated Fraction (yet lower than the analytical limit of quantification, 50 µg/L), there is no acute toxicity towards Danio rerio. The 96 h LC50 of dibenzyltoluene to zebra fish is concluded to be greater than the maximum solubility of Dibenzylbenzene, ar-methyl derivative in water, under the conditions of the test. The no observed effect concentration (NOEC) is concluded to be the maximum solubility of Dibenzylbenzene, ar-methyl derivative in test water.*

Four acute toxicity studies are available for aquatic invertebrates in fresh water and two in sea water and cited below:

*Three Daphnia magna studies (Scholz 1990 & 1994, Knacker 1990) are considered as not reliable as they make use of a surfactant to expose the animals at concentrations well above solubility limit. In addition the surfactant concentration varies with the test substance concentration which does not allow to separate effects of the two. In the fourth Daphnia test (Thiébaud, 1996), no immobilization was observed after 48h exposure at the highest soluble (measured) concentration, 29 µg/L.*

*In the first Acartia test (Rogaland 1996) a LC50 -48h has been determined as being 87 µg/L (nominal), using acetone as solvent.In the second Acartia test (Inveresk, 1997) LC50 was not attained at the highest soluble concentration of 20.6 µg/L.*

*It can be concluded that in normal conditions (not trespassing water solubility limit) there is no significant acute toxicity towards fresh- or seawater invertebrates.*

One other aquatic toxicity study is also available, conducted according to OECD TG 204 for fish (*Leuciscus idus melanotus*), with Marlotherm S. Observed 14 d NOEC was >0.46 mg/L (measured concentration) according to the ECHA dissemination site.

One long-term toxicity study (OECD TG 202) is available for aquatic invertebrates (*Daphnia magna*) with a 21 d NOEC value of 0.03 mg/L and a LOEC value of 0.1 mg/L based on nominal concentrations (ECHA dissemination site). However, test substance (Marlotherm S) concentrations were not stable during the course of the study. The test substance seemed to be adsorptive to surfaces (glass, algae) increasing the uncertainty of the test results.

For algae toxicity 4 out of the 5 studies available are considered unreliable in the substance factsheet based on uncertainty on exposure concentrations and/or use of a surfactant. In the key study marine diatom *Skeletonema costatum* was tested according to protocol described in ISO 10253 standard (Water quality – Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum). No EC50 or NOEC could be determined as no inhibition of growth was observed at the highest soluble concentration (16 µg/L). Robust study summaries are currently being asked for algae toxicity studies in the CCH decision by ECHA.

From studies indicated as disregarded in the ECHA dissemination site, following results are available:

| Method | Species | Test material | Results |
| --- | --- | --- | --- |
| OECD TG 201 | Desmodesmus subspicatus | dibenzyltoluene | biomass inhibition (nominal conc.): EC10 = 0.02 mg/L (1st test)EC50 = 0.21 mg/L (1st test)NOEC = 0.003 mg/L (1st test)EC10 = 0.10 mg/L (2nd test)EC50 = 0.53 mg/ (2nd test)NOEC = 0.07 mg(2nd test)growth rate inhibition (nominal conc.)EC10 = 0.36 mg/ (1st test)EC50 = 2.7 mg/L (1st test)NOEC = 0.22 mg/L (1st test)EC10 = 0.28 mg/L (2nd test)EC50 = 1.2 mg/L (2nd test)NOEC = 0.20 mg/(2nd test) |
| OECD TG 201 | Desmodesmus subspicatus | dibenzyltoluene | biomass inhibition (geom. mean): EC50 = 0.019 mg/LEC10 = 0.035 mg/Lgrowth rate inhibition (geom. mean): EC50 = 0.046 mg/LEC10 = 0.0079 mg/L |
| OECD TG 201 | Desmodesmus subspicatus | Marlotherm S | biomass inhibition: EC50 = 0.015 mg/LEC10 = 0.003 mg/Lgrowth rate inhibition : EC50 = 0.019 mg/LEC10 = 0.006 mg/LNOEC < 0.004 mg/L |
| Draft ISO 10253 standard | Skeletonema costatum | dibenzyltoluene | growth rate inhibition:EC50 = 0.007 mg/L EC10 = 0.001 mg/LNOEC = 0.002 mg/L |

**6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene**

**Persistence**

Information from the registration dossier is discussed in the confidential Annex I.

Biodegradability QSAR estimations for the public name of the substance on ECHA dissemination site 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (SMILES: CC(c1cc2c(cc1)CCCC2)c3ccccc3) using BIOWIN v4.10 and BioHCwin v1.01 are presented in Table 7. The registered substance is a multi-constituent substance and further information on the composition is confidential. Thus, all QSAR estimations for this substance are based on the potential constituent under public name 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (CAS: 6196-98-1). For Biowin 3 the number of the fragment ‘alkyl substituent on aromatic ring’ (3) exceeds the maximum number of fragment counts in the training set (max 2 for this fragment). No further analysis of the applicability of the model is done at this stage of the PBT assessment by the eMSCA.

**Table 7: QSAR estimation done by eMSCA for constituent 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene**.

|  |  |  |
| --- | --- | --- |
| Model | Results | Prediction |
| Biowin 1 (Linear) | 0.9271 | biodegrades fast |
| Biowin 2 (Non-Linear) | 0.9602 | biodegrades fast |
| Biowin 3 (Ultimate) | 2.4743 | weeks-months |
| Biowin 4 (Primary) | 3.3060 | days-weeks |
| Biowin 5 (MITI Linear) | -0.0066 | not readily degradable |
| Biowin 6 (MITI Non-Linear) | 0.0557 | not readily degradable |
| Biowin 7 (Anaerobic Linear)  | -0.3537 | does not biodegrade fast |
| BioHCwin (v1.01) | 5.7254 | half-life (days) |

According to Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.11, version 3.0), based on the combination of Biowin 2 and Biowin 3, the substance does not screen as P or vP. On the contrary, based on the combination of Biowin 3 and Biowin 6 the substance screens as potentially P or vP. However, substances screened as potentially P or vP based on the combination of Biowin 3 and Biowin 6 but for which Biowin 3 indicates a value between 2.25 and 2.75 (2.4743), more degradation relevant information is generally warranted according to the guidance.

The primary degradation half-life estimated by BioHCwin was 5.7 days. It is noted that because the model is partly based on data from experiments where several hydrocarbons have been available in the test system, it is considered that the BioHCwin half-lives may overestimate the rate of degradation (ECHA guidance R.7b, ECHA 2017a). Therefore, the results of BioHCwin should not be used to indicate that the substance is not P/vP. It should also be noted, however, that care must be taken for branched compounds as their environmental half-lives may be overestimated by BioHCwin (Rorije et al. 2012) (ECHA guidance R.7b, ECHA 2017a).

PBT prioritisazation scheme in OECD QSAR toolbox v4.0 predicts 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene to be persistent (P).

No experimental data is available for abiotic degradation for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. However, hydrolysis is not expected to be a relevant degradation pathway for the substance based on the lack of hydrolysable functional groups. Indirect photochemical degradation in the atmosphere was estimated using AOPWIN v1.92 (12 h day, 1.5 x 106 OH/cm3). Half-life was estimated to be 4.963 h with overall OH rate constant of 25.8612 E-12 cm3/molecule-sec.

The environmental distribution of 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene was estimated using Level III Fugacity Model in EPISuite v4.11 under default emission scenarios. Under these conditions, the environmental distribution between different compartments was 0.354 % to air, 5.38 % to water, 54.5 % to soil and 39.8 % to sediment. This indicates that 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene is mainly distributed to soil and sediment compartment in the environment. Additional emission scenarios corresponding to 100 % emission to air, water or soil are represented below:

|  |  |
| --- | --- |
|  | Mass Distribution (Percent %) |
| Emission pattern | Air | Water | Soil | Sediment |
| Equal emission | 0.4 | 5.4 | 54.5 | 39.8 |
| 100% to air | 60.6 | 2.4 | 19.2 | 17.8 |
| 100% to water | 0.2 | 11.9 | 0.1 | 87.9 |
| 100% to soil | <0.1 | <0.1 | 100 | <0.1 |

**Bioaccumulation**

No experimental bioaccumulation data is available for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. Octanol-water partition coefficient (log Pow) provided in the substance factsheet is 3.94. However, QSAR estimated log Kow is 6.11 (KOWWIN v1.68). Estimated bioaccumulation with BCFBAF v3.01 using the log Kow of 6.11 is BCF 5026 L/kg from regression-based method and BCF 1697 L/Kg from Arnot-Gobas method (upper trophic) including biotransformation estimates. From Arnot-Gobas method (upper trophic) also BAF value of 4618 can be estimated. If the log Pow of 3.94 from the substance factsheet is used, the estimated BCF is 184.8 L/kg from regression based model and 322.9 using Arnot-Gobas method (upper trophic) including biotransformation rate estimates.

PBT prioritisazation scheme in OECD QSAR toolbox v4.0 predicts 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene to be very bioaccumulative (vB). Log Pow of 3.94 from the substance factsheet does not fulfil the screening criteria of > 4.5 for bioaccumulation assessment. However, no information is available on how the Log Pow value is derived in the substance factsheet. The estimated Log Kow value of 6.11 clearly indicates a potential for bioaccumulation and thus the screening criterion for bioaccumulation is fulfilled.

**Aquatic toxicity**

Information from the registration dossier is discussed in the confidential Annex I.

QSAR estimations using Ecosar v1.11 with estimated water solubility of 0.1688 mg/l (WSKowwin v1.43) and estimated log Kow of 6.114 for aquatic toxicity predict chronic toxicity values of 0.006 mg/L for fish, 0.009 for daphnid and 0.071 for green algae suggesting high chronic toxicity for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. Estimated Acute toxicity values with same parameters are 96 h LC50 0.039 mg/L for fish, 48 h LC50 0.033 mg/L for daphnid and 96 h EC50 0.177 mg/L for green algae.

QSAR estimations indicate that the T criterion might be fulfilled for a potential constituent 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene based on ecotoxicity.

# Information on (aggregated) Tonnage and uses[[6]](#footnote-7)

**Dibenzylbenzene, ar-methyl derivative**:

2 registrants (ARKEMA FRANCE and Eastman Chemical HTF GmbH)

**6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene**:

1 registrant (DOW BENELUX B.V)

## Tonnage and registration status

**Table 8: Tonnage and registration status of Di****benzylbenzene, ar-methyl derivative**

|  |
| --- |
| **From ECHA dissemination site**  |
| Registrations | [x]  Full registration(s)(Art. 10)[ ]  Intermediate registration(s)(Art. 17 and/or 18) |
| Total tonnage band for substance (excluding volume registered under Art 17 or Art 18, or directly exported)  | 1,000-10,000 tpa |

**Table 9: Tonnage and registration status of 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene**

|  |
| --- |
| **From ECHA dissemination site** |
| Registrations | [ ]  Full registration(s)(Art. 10)[ ]  Intermediate registration(s)(Art. 17 and/or 18)[x]  NONS (Directive 67/548/EEC) |
| Total tonnage band for substance (excluding volume registered under Art 17 or Art 18, or directly exported)  | Confidential |

## Overview of uses

Overview of registered uses of Dibenzylbenzene, ar-methyl derivative from the substance factsheet in the ECHA website are presented below. There is no publicly available information of the REACH registered uses of the NONS registered substance 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene*.* This substance has been registered under the tradename DOWTHERM RP Heat Transfer Fluid. DOWTHERM RP Heat transfer fluid is used as industrial closed system heat transfer fluid. Also, in the ECHA infocard of 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene, there is a mention of pre-registration as plasticizer under the tradename Actrel 400.

**Table 10: Uses of Dibenzylbenzene, ar-methyl derivative**

|  |  |
| --- | --- |
|  | **Use(s)** |
| **Uses as intermediate** |  |
| **Formulation** | Use of plasticiser in the production of rubber products: ERC 3, PROC 5, 8b, 9, 10, 13, 14, 21.Formulation of plasticiser: ERC 2, PROC 2, 3, 4, 8a, 8b, 9, 15. |
| **Uses at industrial sites** | Manufacture: ERC 1, PROC 1, 2, 4, 8b, 9.Use of heat transfer fluids: ERC 7, PROC 2, 4, 8a, 8b, 9, Industrial Use of dielectric fluids: ERC 7, PROC 2, 3, 4, 8b, 9, 13, 19, Use in the production of cables: ERC 5, PROC 5, 14, Recycling of heat transfer fluids: ERC 7, PROC 3, 4. For all industrial uses total tonnage >= 10 tonnes/year per registrant. |
| **Uses by professional workers** | Use of heat transfer fluids: ERC 7, PROC 20, Use of dielectric fluids: ERC 7, PROC 5, 19. |
| **Consumer Uses** | ERC 8c, PC 0: Other: dental paste.  |
| **Article service life** | Use of plasticiser in production of rubber products: AC 10, ERC 3, PROC 14, 21, Use of rubber articles: AC 1, 10, ERC 10a, 11a. |

Product categories (PROC) as reported in Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12, Version 3.0, December 2015:

* PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
* PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.
* PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.
* PROC 4: Chemical production where opportunity for exposure arises.
* PROC 5: Mixing or blending in batch processes.
* PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities.
* PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities.
* PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing).
* PROC 10: Roller application or brushing.
* PROC 13: Treatment of articles by dipping and pouring.
* PROC 14: Tabletting, compression, extrusion, pelletisation, granulation.
* PROC 15: Use as laboratory reagent.
* PROC 19: Manual activities involving hand contact.
* PROC 20: Use of functional fluids in small devices
* PROC 21: Low energy manipulation and handling of substances bound in/on materials or articles.

Environmental release categories (ERC):

* ERC 1: Manufacture of the substance.
* ERC 2: Formulation into mixture.
* ERC 3: Formulation into solid matrix.
* ERC 5: Use of reactive processing aid at industrial site (no inclusion into or onto article).
* ERC 7: Use of functional fluid at industrial site.
* ERC 8c: Widespread use leading to inclusion into/onto article (indoor).
* ERC 10a: Widespread use of articles with low release (outdoor).
* ERC 11a: Widespread use of articles with low release (indoor)

Article categories (AC):

* AC 1: Vehicles.
* AC 10: Rubber articles.

## Additional information

**Finnish Chemical Product Register**

More information about notifications to the Finnish Chemical Product register of dibenzylbenzene (previous substance identity of dibenzylbenzene, ar-methyl derivative) and 1,2,3,4,-tetrahydro-(1-phenylethyl)-naphthalene is provided in the confidential Annex.

**Nordic Product Register (SPIN register)**

Substances in preparations in Nordic countries database (SPIN) is based on data from the Product Registries of Norway, Sweden, Denmark and Finland. The total tonnage and number of preparations of dibenzyltoluene is shown in Figure 1.



Figure 1. Total amount of dibenzyltoluene in preparations and total number of preparations in the Nordic countries.

# Justification for the risk management option

## Need for (further) risk management

**Table 11: SVHC Roadmap 2020 criteria for Dibenzylbenzene, ar-methyl derivative and 1,2,3,4,-tetrahydro-(1-phenylethyl)-naphthalene**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| a) Art 57 criteria fulfilled? | x\* |  |
| b) Registrations in accordance with Article 10? | x |  |
| c) Registrations include uses within scope of authorisation? | x |  |
| d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution? | x |  |

\* Based on PBT/vPvB screening criteria only.

Dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene share similar use as heat transfer fluids as terphenyl, hydrogenated. These substances could be direct substitutes for terphenyl, hydrogenatedat specific high temperature, non-pressurised heat transfer systems. Based on the screening level information these alternative substances might have similar PBT/vPvB properties as terphenyl, hydrogenated, which is already on the Candidate List of SVHC according to the procedure set in REACH Article 59. To avoid regrettable substitution of terphenyl, hydrogenated, PBT/vPvB properties of the alternative substances should be assessed.

Dibenzylbenzene, ar-methyl derivative is currently not treated as PBT/vPvB substances in their registration dossiers. The available information does not allow to conclude whether the Annex XIII criteria are fulfilled or not. Further information for the PBT/vPvB assessment is needed to be able to make a well informed analysis of appropriate RMMs.

Currently, more information for human health and environment are being requested for dibenzylbenzene, ar-methyl derivative under ECHA decision on a compliance check (CCH) based on Article 41 of REACH Regulation (ECHA 2018). The requested information is relevant for PBT/vPvB assessment. The need for further information e.g. under the Substance Evaluation (SEv) will be assessed when the information requested under CCH is available. The deadline for Registrant(s) to submit the information requested under CCH in an updated registration dossier is 17th January 2022.

For 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene more information on environmental hazard properties are needed to conclude the fulfilment of Annex XIII criteria. Compliance check under dossier evaluation for previously notified substance (NONS) is not applicable, if no relevant new information has been submitted in a registration dossier under REACH on top of information required under the Dangerous Substances Directive 67/548/EC. Thus, it is proposed to add this substance to CoRAP 2020-2022 by Finland and the applicability of CCH could be reviewed during the substance evaluation. The main concerns for the CoRAP listing are the potential for PBT/vPvB properties, the potential for environmental exposure and the potential to be a substitution candidate for the already identified SVHC substance terphenyl, hydrogenated (vPvB). Evaluation by Finland under CoRAP is proposed to take place in 2021 for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene.

For regulatory consistency reasons, if these alternative heat transfer fluids in this RMOA are considered as PBT/vPvB substances, SVHC identification would be the first RRM option to be considered, with authorisation or restriction as a potential follow-up measure. In order to prevent regrettable substitution, future risk management should, as far as possible, be carried out jointly for the functional group as a whole. This RMOA document will be updated when the PBT/vPvB properties of these substances are further clarified. A preliminary identification and assessment of all risk management options are presented in the following section 5.2.

## Identification and assessment of risk management options

The following legislative instruments and other initiatives have the potential to influence emissions to the environment.

1. **REACH**

**Registration**

Dibenzylbenzene, ar-methyl derivative is currently not identified as a PBT/vPvB in the substance factsheet. 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene is considered as PBT substance according to the ECHA infocard of the substance.

Based on the preliminary assessment by eMSCA Dibenzylbenzene, ar-methyl derivative might potentially fulfil the Annex XIII criteria. As it is currently not treated as a PBT/vPvB substance, the recommended RMM in the Chemical Safety Report (CSR) do not actively seek to minimise emissions. Thus, it is unclear if the recommended RMMs are adequate for the substance. If the Annex XIII criteria are fulfilled for the substance, its emission to the environment should be reduced to a minimum.

For 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene there is no CSR available in the registration dossier. CSR is not required, for example, if there are no changes in tonnage band for the notified substance under previous legislation (Directive 67/548/EEC). Therefore, safe use and emissions of the substance can not be currently assessed adequately. In this case, without the adequate chemical safety assessment in the registration dossier, the environmental exposure cannot be excluded even though there are no other registered uses for the substance than industrial closed system use as a heat transfer fluid. However, a CSR has to be provided if the updated notification is above 10 t/a and covers new identified uses, or new knowledge arises with regard to the risks of the substance to human health and/or the environment which would lead to changes in the SDS (ECHA 2018: How to prepare registration and PPORD dossiers version 6.0).

**Safety data sheets (SDSs)**

There are publicly available Safety Data Sheets for heat transfer fluids Dowtherm RP and Marlotherm SH[[7]](#footnote-8). In SDS for Marlotherm SH, it is concluded that the substance (dibenzylbenzene, ar-methyl derivative) is not considered as PBT/vPvB and for Dowtherm RP it is stated that the substance (6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene) has not been assessed for persistence, bioaccumulation and toxicity (PBT). This is a contradiction to the ECHA dissemination site where the majority of data submitters have considered 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene PBT. If these substances would be identified as PBT/vPvB substances in the registration dossier, there would be an obligation to reflect this in the SDSs according to REACH. This could improve the risk management of these substances. Currently the information available is inconclusive with respect to PBT/vPvB properties of 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene.

**Candidate listing**

Based on the screening of PBT/vPvB properties for substances in this RMOA, they might both fulfil the Annex XIII criteria similarly to terphenyl, hydrogenated. An inclusion in Candidate List would clearly establish that these alternative heat transfer fluids have similar PBT/vPvB properties and thus regrettable substitution of terphenyl, hydrogenated by other substances with similar properties might be avoided. Candidate listing would also, in and of itself, carry additional risk management benefits. IT would e.g. trigger notification and communication obligations in accordance with REACH Articles 7 and 33, respectively. In addition, the confirmation of their PBT/vPvB status could potentially improve risk management due to acknowledgement of their PBT/vPvB properties. It is also worth noting that Candidate listing of these alternative HTFs is the only way to confirm PBT/vPvB properties of these substances and by that ensure that the users are aware of these hazardous properties.

For dibenzylbenzene, ar-methyl derivative, there are also other registered uses than heat transfer. For these uses adding the substance to Candidate List could promote substitution by less hazardous substances where possible.

**Authorisation**

Both of these alternative heat transfer fluids to terphenyl, hydrogenated in this RMOA seems to fulfil the SVHC roadmap 2020 criteria (Table 11) for being a relevant SVHC candidate for inclusion in Annex XIV. Dibenzylbenzene, ar-methyl derivative is manufactured in high tonnages (1000 – 10 000 tpa). The total tonnage band for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene is presented in the confidential Annex I. The known uses in the registrations are within the scope of authorisation in REACH. Both substances are expected to score high based on General Approach for prioritisation similar to terphenyl, hydrogenated (13-15 if identified as PBT and/or vPvB, 3-12 for volume, 5-15 for WDU).[[8]](#footnote-9)

Although the main use as a heat transfer fluid takes place in closed loop manufacturing system with limited discharges, exposure to the environment cannot be overruled. For any substance, for which it is not possible to establish a safe level of exposure, especially PBT/vPvB substances in this case, risk management measures should always be taken to minimise exposure and emissions, as far as technically and practically possible (REACH recital 70). Exposure and emissions are possible during loading operations, renewal and disposal phase of heat transfer fluids. In addition, dibenzylbenzene, ar-methyl derivative has also other industrial, professional and consumer uses (Table 10).

Inclusion in Annex XIV would indicate to registrant(s) a need to substitute the substances in uses where safer alternatives are available, and/or to demonstrate that there are no risk from their uses. For the specific use as a high temperature, non-pressurised heat transfer fluid, the registrant(s) of these substances can apply for authorisation to continue HTF use. Authorisation is typically granted if the risks from uses are adequately controlled, or it is shown that socio-economic benefits outweigh the risks and no suitable alternatives are available (e.g., if the potential alternatives would also fulfil the Annex XIII criteria). It is understood however that the investment cycles for heat transfer fluids on industrial sites may extend beyond the typical authorisation review periods granted under REACH.

It is worth noting that according to REACH Article 59, all substances in the candidate list are eventually to be included in Annex XIV. Only substances for which all uses have been prohibited shall not be included in Annex XIV or shall be removed from it according to Article 58(7). In the case of high-temperature non-pressurised HTFs used in closed systems for periods that often extend beyond 20 years, however, it is important to note that, according to feedback received from the registrants, typical authorisation review periods may be challenging to implement in practice.

**Restriction**

Restriction can be introduced when there is an unacceptable risk to human health and/or the environment, arising from the manufacture, placing on the market (including imports) or use of the substances, which needs to be addressed on a Community-wide basis. A restriction may apply to any substance on its own, in a mixture or in an article. Restriction procedure also takes into account the socioeconomic impact of the restriction, including the availability of alternatives. If it can be demonstrated that there is a Community-wide risk, which is not adequately controlled for certain uses of substances, a restriction process according to REACH Articles 69(1) and 69(4) should be started.

Heat transfer use in closed system would probably not warrant a restriction as such. However, exposure and emissions to the environment may still be possible, for example, during transport, refilling and disposal of HTFs. A potential restriction could e.g. define mandatory containment measures that industrial sites should implement to prevent environmental emissions from HTF systems. For other current or potential industrial, professional or consumer uses of these alternative heat transfer fluids as well as for terphenyl, hydrogenated itself, further work would be necessary in order to demonstrate whether there is a Community-wide risk as no measured data on discharges or monitoring data for environmental concentrations are currently available. It should be noted, however, given that PBTs/vPvBs are treated as non-threshold substances for the purpose of risk management under REACH, even small levels of environmental emissions could be sufficient to demonstrate a risk.

A restriction as a risk management measure has the advantage that it can be targeted at the uses posing a risk. In case it is shown that other uses than HTF cause risk, the uses giving rise to risks could be restricted. In the case of authorisation this is not that straightforward; in practice it is possible to exempt from authorisation only uses where the risk is properly controlled based on specific union-wide legislation imposing minimum requirements to the protection of human health or the environment. Therefore, if 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene and/or dibenzylbenzene, ar-methyl derivative is included in Annex XIV to REACH, also users who have only closed system uses and minimal risks from their uses of these substance, would have to apply for authorisation. However, as substances discussed in this RMOA are either identified or suspected PBT/vPvB substances, exemption of any uses from potential restriction would only be acceptable if it can be demonstrated that there is limited exposure to the environment from the full lifecycle of these substances for these specific uses.

1. **Classification and labelling (CLP-regulation)**

Dibenzylbenzene, ar-methyl derivative is currently classified as Asp. Tox. 1 (H304) and Aquatic Chronic 4 (H413) and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) in the substance factsheets. When the information requested in the CCH decision is available for dibenzylbenzene, ar-methyl derivative, the need to update the classification will have to be assessed. However, for the risk management purposes, for example, even a self classification of Aquatic Chronic 4 would result in a substance to be classified as hazardous waste under the Waste Framework Directive (see also point 5).

1. **Water Framework Directive (WFD) (2000/60/EC)**

WFD provides a framework for the protection of inland surface waters, transitional waters, coastal water and groundwater. It places duties on Member States to regulate the release of discharges into the aquatic environment when environmental quality objectives set by the Directive are not met. Environmental Quality Standards are set for substances that are identified as Priority Substances (PS) and Priority Hazardous Substances (PHS)[[9]](#footnote-10). The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment would be controlled by national measures including environmental permits. Neither of the substances in this RMOA are Priority Substances or Priority Hazardous Substances. Based on their hazardous properties they could be considered as Priority Hazardous Substances under WFD. The prioritisation of substances under WFD is, however, a risk based process based usually on monitoring data in the water environments. Therefore, it is not likely that these substances would be prioritised as there are no environmental monitoring data available. In any case, the procedure under WFD would trigger no direct RMM.

1. **Industrial Emissions Directive (2010/75/EU)**

Industrial Emissions Directive (IED) aims to achieve a high level of protection of human health and the environment by reducing the harmful industrial emissions across the EU, in particular through better application of Best available Techniques (BAT)[[10]](#footnote-11). Around 50,000 installations undertaking the industrial activities listed in Annex I of the IED are required to operate in accordance with a permit (granted by the authorities in the Member States). This permit should contain conditions set under the principles and provisions of the IED.

The manufacture of these heat transfer fluids is covered by the IED. However, as no Best Available Technique (BAT) reference documents related to the use of heat transfer fluids are available, the IED is considered, for the time being, of limited applicability for the risk management of the substances referred to in this RMOA.

1. **Waste Framework Directive (2008/98/EC)**

As the heat transfer fluid use takes place in closed industrial system, discharges to the environment are considered potentially significant mainly from the waste disposal phase. Therefore, RMMs related to waste management and disposal of used heat transfer fluids and equipment are considered important.

Waste Framework Directive (2008/98/EC) provides a general framework of waste management requirements and sets the basic waste management definitions for the EU[[11]](#footnote-12). The Directive requires that waste (including waste oils) is managed without endangering human health and harming the environment, and in particular without risk to water, air, soil, plants or animals. Costs are borne by the waste producer or waste holder. Hazardous wastes pose a greater risk to the environment and human health than non hazardous wastes and thus require a stricter control regime as laid down in particular in Articles 17 to 20 of the Directive. It provides additional labelling, record keeping, monitoring and control obligations from the "cradle to the grave", i.e., from the waste producer to the final disposal or recovery. The classification into hazardous and non hazardous waste is based on the system for the classification and labelling of hazardous substances and mixtures (CLP Regulation 1272/2008), which ensures the application of similar principles over their whole life cycle. The properties which render waste hazardous are laid down in Annex III of Directive 2008/98/EC.

The criteria for waste, which presents or may present immediate or delayed risks for the environment (HP 14 “Ecotoxic”) is defined in Annex III of Directive 2008/98/EC. Even with a current self-classification of Aquatic Chronic 4, dibenzylbenzene, ar-methyl derivative (≥ 25 %) would be classified as hazardous waste. 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene has even more stringent environmental self-classification of Aquatic Acute 1 and Aquatic Chronic 1. Thus, both substances in this RMOA are subject to be classified as hazardous waste and subject to RMM required under the Waste Framework Directive. Directive 2008/98/EC requires a sound management of waste but would not directly prevent the emissions arising eg. from disposal, refilling phase or cleaning of equipment of heat transfer fluids.

1. **Voluntary Product Stewardship**

No information on voluntary actions is available for the substances in this RMOA. There is an indication of identification of 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene as PBT/vPvB in the substance factsheet. However, the substance is not considered as a PBT/vPvB substance in the SDS of Dowtherm RP. In case the registrant(s) would identify the substance as PBT/vPvB substance this might improve the recommended risk management measures as well as SDSs, waste management etc.

## Consequences of taking regulatory risk management action

Preliminary socio-economic considerations of the RMM options are discussed based on the ECHA document “How RMOA can reflect the consequences of taking RRM action” presented at RiME-3, 2017. “Factors checklist” from that ECHA document is annexed to this RMOA (Annex II, confidential).

**Quantities**

High tonnage (>1000 tpa) for dibenzylbenzene, ar-methyl derivative reflects the potential of high consequences of RRM action(s). The total tonnage band for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene is confidential information. Further information on manufactured and/or imported quantities of these substances is available in the confidential annex I.

**Number of actors**

There are few REACH registrations for dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene indicating that only a limited number of companies are manufacturing or importing these substances (section 4). The registrants represent large companies (The Dow Chemical Company, Arkema S.A. and Eastman Chemical Company) which might have different sites in the EU increasing the potential consequences of RRM actions. There are no downstream user (DU) reports or PPORDs for these substances either. However, there are high numbers (>45) of C&L notifications (CLP Article 40) for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene and medium number (15-45) for dibenzylbenzene, ar-methyl derivative. The number of C&L notifiers indicates that there are medium to high number of people dealing with these substances. Depending on the RRM, the consequences could be between medium to high.

**Diversity of uses**

The diversity of uses is low for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene as there is only closed system industrial HTF use under the tradename Dowtherm RP. However, for dibenzylbenzene ar-methyl derivative, the actors using the substance seems to be very diverse as there are indications of a high number of lifecycle stages for uses in the substance factsheet (manufacture, formulation, uses at industrial sites, uses by professional workers, consumer uses and article service life). There is an indication that the consequences of RRM could be high for dibenzylbenzene, ar-methyl derivative. However, the diversity of uses does not take into account the total volumes of substances in different uses.

**Complexity of the supply chain**

Similarly to the diversity of uses the supply chain might be complex for dibenzylbenzene, ar-methyl derivative based on the information on the substance factsheet. There is an indication of high diversity of uses linked to many sectors, products, and articles where the substance is used. The complexity of the supply chain might increase the consequences of RRM for dibenzylbenzene, ar-methyl derivative.

**Alternatives**

Substances in this RMOA are potential alternatives for terphenyl, hydrogenated in its main use as heat transfer fluid in high temperature, non-pressurised heat transfer systems. There is no information on other potential alternatives to HTF use for terphenyl, hydrogenated. However, it could be possible that there are other alternatives or they are not currently used in the EU and thus not registered in REACH. In that case, they would be outside the scope of this RMOA. A search for alternatives for other uses than HTF of dibenzylbenzene, ar-methyl derivative is not conducted in this RMOA. Availability of alternatives for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene in its only known use as HTF is similar to terphenyl, hydrogenated as discussed above.

Terphenyl, hydrogenated can be used as a HTF with operating temperatures as high as 345 °C in non-pressurised liquid phase heat transfer systems (Therminol 2018). Substitutes need to have a similar high boiling point at standard atmospheric pressure (101.325 kPa) to be used without excessive thermal degradation in liquid phase non-pressurised systems at high temperature ranges of 300-350 °C. As high thermal stability is needed for the HTFs, they are likely to have a stable chemical structure. Thus, available alternatives might have similar persistency as well. Alternatives might also have shorter service life than currently used HTFs, which either are PBT/vPvB substances (terphenyl, hydrogenated) or are potentially PBT/vPvB (6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene and dibenzylbenzene, ar-methyl derivative). According to the factors checklist by ECHA, the consequences of RRM can be expected to be high if no alternatives are available or the price of alternatives is high.

**Benefits for the environment**

6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene and dibenzylbenzene, ar-methyl derivative may have PBT/vPvB properties. Exposure and emission of PBT/vPvB substances should always be minimised as far as technically and practically possible.

## Conclusions on the most appropriate (combination of) risk management options

Dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene share similar use as heat transfer fluids as terphenyl, hydrogenated at specific high temperature, non-pressurised heat transfer systems. Based on the screening level information these alternative substances might have similar PBT/vPvB properties as terphenyl, hydrogenated, which is already included on the Candidate list. To avoid regrettable substitution of terphenyl, hydrogenated, PBT/vPvB properties of the alternative substances should be assessed.

The available information does not allow to conclude whether the Annex XIII criteria are fulfilled or not for dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. Further information for the PBT/vPvB assessment is needed to be able to make a well informed analysis of appropriate RMMs.

Currently, more information for human health and environment are being requested for dibenzylbenzene, ar-methyl derivative under ECHA decision on a compliance check based on Article 41 of REACH Regulation (ECHA 2018). The requested information is relevant for PBT/vPvB assessment. The need for further information e.g. under the Substance Evaluation (SEv) will be assessed when the information requested under CCH is available. The deadline for Registrant(s) to submit the information requested under CCH in an updated registration dossier is 17th January 2022.

For 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene more information on environmental hazard properties are needed. It is proposed to add this substance to CoRAP 2020-2022 by Finland. The main concerns for the proposed CoRAP listing are the potential for PBT/vPvB properties, the potential for environmental exposure and the potential to be a substitution candidate for the already identified SVHC substance terphenyl, hydrogenated (vPvB). Evaluation by Finland under CoRAP is proposed to take place in 2021 for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene.

For regulatory consistency reasons, if these alternative heat transfer fluids in this RMOA are considered as PBT/vPvB substances, SVHC identification would be the first RRM option to be considered, with authorisation or restriction as a potential follow-up measure. In order to prevent regrettable substitution, future risk management should, as far as possible, be carried out jointly for the functional group as a whole. This RMOA document will be updated when the PBT/vPvB properties of dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene are further clarified.

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