



## Justification Document for the Selection of a CoRAP Substance

<b>Substance Name (public name):</b>	6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene
<b>EC Number:</b>	400-370-7
<b>CAS Number:</b>	6196-98-1
<b>Authority:</b>	Finnish Safety and Chemicals Agency
<b>Date:</b>	18/03/2020

### Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update

## Table of Contents

<b>1</b>	<b>IDENTITY OF THE SUBSTANCE</b>	<b>3</b>
1.1	Other identifiers of the substance	3
1.2	Similar substances/grouping possibilities	3
<b>2</b>	<b>OVERVIEW OF OTHER PROCESSES / EU LEGISLATION</b>	<b>5</b>
<b>3</b>	<b>HAZARD INFORMATION (INCLUDING CLASSIFICATION)</b>	<b>6</b>
3.1	Classification	6
3.1.1	Harmonised Classification in Annex VI of the CLP	6
3.1.2	Self classification	6
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	6
<b>4</b>	<b>INFORMATION ON (AGGREGATED) TONNAGE AND USES</b>	<b>7</b>
4.1	Tonnage and registration status	7
4.2	Overview of uses	7
<b>5.</b>	<b>JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE</b>	<b>8</b>
5.1.	Legal basis for the proposal	8
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	8
5.3.	Initial grounds for concern to be clarified under Substance Evaluation	8
5.4.	Preliminary indication of information that may need to be requested to clarify the concern	10
5.5.	Potential follow-up and link to risk management	10

## 1 IDENTITY OF THE SUBSTANCE

### 1.1 Other identifiers of the substance

**Table: Other Substance identifiers**

<b>EC name (public):</b>	6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene
<b>IUPAC name (public):</b>	1,2,3,4,-tetrahydro-(1-phenylethyl)-naphthalene
<b>Index number in Annex VI of the CLP Regulation:</b>	Not included in Annex VI of CLP
<b>Molecular formula:</b>	C <sub>18</sub> H <sub>20</sub>
<b>Molecular weight or molecular weight range:</b>	236.36 g/mol
<b>Synonyms:</b>	<i>ACTREL 400</i> <i>DOWTHERM*RP Heat Transfer Fluid</i> <i>SYNTREL 350</i>

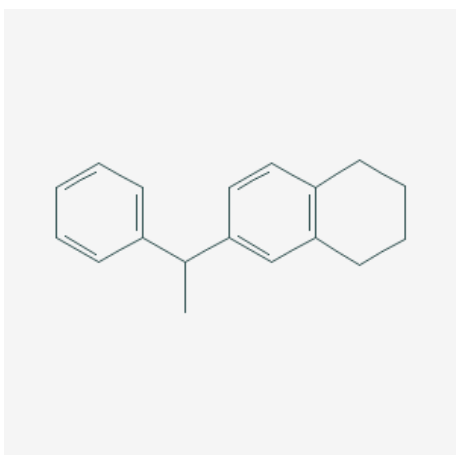
**Type of substance**

Mono-constituent

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.

Source for the structural formula: <https://pubchem.ncbi.nlm.nih.gov/compound/6-1-phenylethyl-1-2-3-4-tetrahydronaphthalene>

### 1.2 Similar substances/grouping possibilities

Structurally similar substances to 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene have not been considered at this stage of the

assessment. It is noted that there is a lot of information on other hydrocarbons in the REACH registration database and during substance evaluation the possibilities to employ e.g. read-across or grouping approaches can be explored. It is also noted that functional grouping is relevant for the case as described in Section 2.

## 2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table: Completed or ongoing processes**

RMOA	<input checked="" type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII <sup>1</sup>	
CLH	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input checked="" type="checkbox"/> Dangerous substances Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes/ EU legislation	<input type="checkbox"/> Other (provide further details below)	
Further details	The Finnish MSCA Tukes have submitted an RMOA intention for the substance based on bioaccumulation, persistence and other environmental toxicity concerns. 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 (vPvB) identified substance terphenyl, hydrogenated (EC 262-967-7). This RMOA intention covers two substances dibenzylbenzene, ar-methyl derivate (EC 258-649-2) & 1,2,3,4,-tetrahydro-(1-phenylethyl)-naphthalene (EC 400-370-7). The RMOA is currently under development and should be finished by	

<sup>1</sup> Please specify the relevant entry.

	the end of 2019. The anticipated conclusion of the RMOA will be to include the substance EC 400-370-7 to CoRAP 2020-2022.
--	---

### **3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)**

#### **3.1 Classification**

##### **3.1.1 Harmonised Classification in Annex VI of the CLP**

The substance does not have a harmonised classification in Annex VI of CLP Regulation (Regulation (EC) 1272/2008).

##### **3.1.2 Self classification**

In the registration: the substance has a self-classification as Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects, M=0) and Aquatic Acute 1 (H400: Very toxic to aquatic life).

There are no additional hazard classes notified among the aggregated self classifications in the C&L Inventory.

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

There are no past or present intentions or proposals for harmonised classification for the substance.

## 4 INFORMATION ON (AGGREGATED) TONNAGE AND USES<sup>2</sup>

### 4.1 Tonnage and registration status

**Table: Tonnage and registration status**

<b>From ECHA dissemination site *</b>		
<input type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential
This substance is registered as NONS. The tonnage data in the ECHA dissemination site are marked confidential. There is currently one active registration (individual submission) for the substance.		

### 4.2 Overview of uses

There is no publicly available information of the REACH registered uses of the substance. The substance has been registered under the trade name DOWTHERM RP Heat Transfer Fluid. DOWTHERM RP Heat transfer fluid is used as industrial closed system heat transfer fluid.

**Part 1:**

<input type="checkbox"/> Manufacture	<input type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input checked="" type="checkbox"/> Closed system
--------------------------------------	--------------------------------------	--	---	---------------------------------------	---	---

<sup>2</sup> The dissemination site was accessed July 2019.

## 5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 5.1. Legal basis for the proposal

- Article 44(2)  
 Article 45(5)

### 5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR  
 Fulfils criteria as Sensitiser/ Suspected sensitiser  
 Fulfils criteria as potential endocrine disrupter  
 Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB  
 Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)  
 Fulfils exposure criteria  
 Fulfils MS's (national) priorities

### 5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR <sup>1</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>3</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

<sup>3</sup> CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)  
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)  
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic



Although the use of the substance as a heat transfer fluid takes place in an industrial closed system, exposure to the environment cannot be overruled. Information about other possible uses are not available in ECHA dissemination site for this NONS registered substance. Exposure and emissions to the environment are possible, for example, during loading operations, renewal and disposal phase of heat transfer fluids. Thus, there is a concern for potential exposure of the environment combined with the suspected PBT/vPvB properties of the substance. No chemical safety assessment is available for the substance to further assess exposure potential of the substance.

The substance shares also similar use as heat transfer fluid as terphenyl, hydrogenated, thus, it could be a direct substitute for terphenyl, hydrogenated in specific high temperature, non-pressurised heat transfer systems. Based on the screening level information the substance might have similar PBT/vPvB properties as terphenyl, hydrogenated, which is already in the Candidate List of SVHC for authorisation. To avoid regrettable substitution of terphenyl, hydrogenated, also PBT/vPvB properties of the alternative substance need to be clarified.

#### Suspected PBT/vPvB

The substance is a multi-constituent substance registered as NONS. Information in the registration dossier indicates that the substance is not readily biodegradable or inherently biodegradable. However, there is limited information available indicating that the substance is actually tested in the biodegradation studies (primary or ultimate degradation) and, if tests have been conducted, what has been the specific composition of the test substance. Therefore, it is not possible to adequately assess the biodegradation studies or the PBT properties of the substance.

Biodegradability QSAR estimations are calculated for the public name and potential constituent 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. The combination of Biowin 2 (0.9602) and Biowin 3 (2.4743) do not screen as P or vP. On the contrary, the combination of Biowin 3 (2.4743) and Biowin 6 (0.0557) screens as potential P or vP. However, substances fulfilling screening criteria 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 ECHA guidance R.7b v4.0.

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

No experimental bioaccumulation data is available for 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. Octanol-water partition coefficient (log Pow) provided in the registration dossier 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 a regression-based method and BCF 1697 L/Kg from a Arnot-Gobas method (upper trophic) including biotransformation estimates. From the Arnot-Gobas method (upper trophic) also BAF value of 4618 can be estimated. If log Pow of 3.94 from the registration dossier is used, the estimated BCF is 184.8 L/kg from the regression based model and 322.9 using the Arnot-Gobas method (upper trophic) including biotransformation rate estimates. However, no information is available to assess the reliability of the log Pow value in the registration dossier.

PBT prioritisation scheme in OECD QSAR toolbox v4.0 predicts 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene to be very bioaccumulative (vB).

For long-term toxicity a 28d NOEC value of 0.023 mg/L for fish (*Oncorhynchus mykiss*), 21d NOEC value of <0.002 mg/L for aquatic invertebrates and 72h NOEC

value of <0.076 mg/L are publicly available in the ECHA dissemination site for the substance.

In an ECHA Infocard of the substance, it is also 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 providing the same concern.

Based on the available experimental and QSAR estimated data of the substance, the screening criteria for PBT are met for persistence, bioaccumulation and aquatic toxicity.

#### 5.4. Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p><u>Suspected PBT/vPvB</u>                  To clarify the PBT/vPvB concern of the substance or one or more of its constituents, further assessment is needed. Due to the data gaps, it is likely that experimental data (ready biodegradability/ simulation testing) is needed to substantiate the persistence. If the substance fulfils the P or vP criterion, then further information on bioaccumulation (e.g., BCF test in aquatic species) and/or toxicity (e.g., long-term aquatic toxicity testing) potential of the substance may be needed.</p>	

#### 5.5. Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>If the substance is identified as PBT/vPvB, it may be listed as SVHC, with authorisation or restriction as potential follow up. The further risk management measures will be considered together with other substitution candidates of terphenyl, hydrogenated.</p>			