



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

- Update -

Substance Name (public name):	Tetradecahydro-7-isopropyl-1,4a-dimethylphenanthren-1-methanol
EC Number:	236-476-3
CAS Number:	13393-93-6
Authority:	DE MSCA
Date:	22/03/2016 21/03/2017 (Updated version)

Note

This document has been prepared by the evaluating Member State(s) given in the CoRAP update.

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	4
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	5
3.1	Classification	5
3.1.1	Harmonised Classification in Annex VI of the CLP	5
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	6
4.1	Tonnage and registration status	6
4.2	Overview of uses	6
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	7
5.1.	Legal basis for the proposal	7
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	7
5.3	Initial grounds for concern to be clarified under Substance Evaluation	7
5.4	Preliminary indication of information that may need to be requested to clarify the concern	9
5.5	Potential follow-up and link to risk management	9

1 IDENTITY OF THE SUBSTANCE

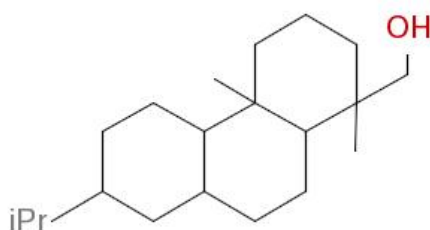
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Tetradecahydro-7-isopropyl-1,4a-dimethylphenanthren-1-methanol
IUPAC name (public):	(7-isopropyl-1,4a-dimethyl-1,2,3,4,4a,4b,5,6,10,10a-decahydrophenanthren-1-yl)methanol
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C ₂₀ H ₃₆ O
Molecular weight or molecular weight range:	292.49 g·mol ⁻¹
Synonyms:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula: This structural formula represents one of the possible structures.



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input checked="" 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
Harmonised C&L	<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 type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation 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)	

There has been testing proposals for bioaccumulation aquatic/sediment, oral sub-chronic toxicity (90-d) and prenatal development toxicity.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available.

3.1.2 Self classification

- In the registration:

Aquatic Chronic 4 H413

Skin Sens. 1 H317

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Aquatic Chronic 2 H411

Skin Sens. 1B H317

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site*		
<input checked="" 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 checked="" 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 type="checkbox"/> Confidential
Joined submission. The disseminated tonnage is lower than overall tonnage. The relevance of this is under verification.		

**the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):*

https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

The substance is used as a binding agent in coatings, inks, adhesives and sealants. The uses include professional and consumer uses.

Table: Uses

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

¹ Data taken from ECHA dissemination site (accessed in 1 February 2017).

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
 Article 45(5) (Member State priority)

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 ¹ <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 ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" 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 checked="" type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² 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

The substance is fulfilling the screening criteria for PBT/vPvB as defined in Annex XIII, i.e.

P/vP criterion

The substance is not readily biodegradable. However, the available simulation test on degradation in surface water indicates that the substance is degraded with a half-life of 4.5 days. Therefore, the substance itself is not considered to be persistent. Two major metabolites were found in the simulation test and the registrant announces a follow-up study to identify these metabolites. As the PBT/vPvB assessment shall include the PBT/vPvB properties of metabolites, the identity and the properties of these metabolites have to be assessed further.

Regarding the result of the test on ready biodegradability, it is possible that in analogy to the simulation test the two metabolites were formed and that actually these are not readily biodegradable.

Therefore, the metabolites of the substance are considered as potentially persistent. Further information is required to draw a conclusion on the persistency of the degradation products.

B/vB criterion

The substance has a $\log Pow > 4.5$. No measured data on bioconcentration in fish are available. The substance is therefore considered to be potentially bioaccumulative. A fish bioaccumulation study is planned by the registrant.

No data are available for the two degradation products. Therefore a conclusion on bioaccumulation cannot be drawn.

T criterion

Data on short-term ecotoxicology on aquatic organisms are available and show low ecotoxicity. No long-term studies for ecotoxicology on aquatic organisms are available. No data on aquatic ecotoxicology are available for the two unknown metabolites. Therefore a definitive conclusion on toxicity could not be drawn. However, it is likely that the parent substance does not fulfill the T criterion.

Use and Exposure

The substance has wide dispersive uses for professionals and consumers. Based on the uses of this substance it can be assumed that it may be released to the environment.

The assumptions in the environmental exposure scenarios are partly insufficient. This relates to the use of spERCs and to the assessment of the life cycle steps. There is no justification showing the applicability of the spERCs used based on e.g. operational conditions. An assessment of article service life and waste life cycle stage is not provided. However, there is no conclusive justification why these life cycle steps should not be relevant.

The risk characterization ratios for secondary poisoning, especially for fish-eating birds and mammals (fresh water) and for marine top predators are already close to 1 for several exposure scenarios. An assessment of aggregated exposure is not provided. Therefore, unacceptable risks arising from combined releases from multiple uses cannot be excluded.

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 checked="" 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)

Further information on the biodegradation of the two transformation products of tetradecahydro-7-isopropyl-1,4a-dimethylphenanthren-1-methanol is required to clarify whether they are persistent or very persistent. Further information on bioaccumulation is required to clarify whether the substance and transformation products are bioaccumulative or very bioaccumulative. Further information on toxicity may be required to clarify the toxic potential of both tetradecahydro-7-isopropyl-1,4a-dimethylphenanthren-1-methanol and its metabolites. For the assessment of environmental exposure further information on operational conditions and emissions are required. More information is needed on the life cycle steps of the substance. An assessment of aggregated Exposure is required to assess risks arising from multiple uses. Depending on the outcome a refinement of the exposure assessment may be necessary.

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 checked="" type="checkbox"/> Other (provide further details)
---	---	---	---

If the substance is identified as a PBT/vPvB substance, an analysis of risk management options will be provided, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List, Authorisation, or Restriction.