



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

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one

EC Number: 216-133-4 and 244-240-6

CAS Number: 1506-02-1 and 21145-77-7

Authority: DE MSCA

Date: 22/03/2016

Note

This document has been prepared by the evaluating Member State 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	8
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	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):	1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one
IUPAC name (public):	6-Acetyl-1,1,2,4,4,7-hexamethyltetraline
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C ₁₈ H ₂₆ O
Molecular weight or molecular weight range:	>258.41 g/mol
Synonyms:	1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one 6-Acetyl-1,1,2,4,4,7-hexamethyl-1,2,3,4-tetrahydronaphthalene 6-Acetyl-1,1,2,4,4,7-hexamethyltetraline 7-Acetyl-1,1,3,4,4,6-hexamethyl-1,2,3,4-tetrahydronaphthalene AHMT AHTN

Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



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 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 ¹
Harmful substances 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 checked="" 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)	

¹ Please specify the relevant entry.

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:
Acute Tox. 4 H302, Aquatic Acute 1 H400, Aquatic Chronic 1 H410 M-factor = 1
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
Aquatic Chronic 1 H410 M-factor = 1

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 USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site (accessed in April 2015)		
<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 checked="" type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input checked="" 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
2 Joint Submissions.		

4.2 Overview of uses

The uses of AHTN indicate that the release of relevant amounts of the substance into the environment is probable. There are wide dispersive professional and consumer uses, and also wide dispersive uses in article service life.

Table: Uses

Part 1:

<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
-------------------------------------------------	-------------------------------------------------	----------------------------------------------------	------------------------------------------------------	--------------------------------------------------	----------------------------------------------------------	----------------------------------------

Part 2:

	Use(s)
Formulation	Compounding AHTN in fragrance oils. Compounding AHTN in products (generic).
Uses at industrial sites	Industrial end-use of cleaning and maintenance products.
Uses by professional workers	Professional end-use of cleaning and maintenance products. Professional end-use of hand cleaners.
Consumer Uses	Consumer end-use of air care products. Consumer end-use of pest control products (biocidal product). Consumer end-use of cleaning

² Data taken from ECHA dissemination site (accessed in May 2015)

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

	products. Consumer use of cosmetic products.
Article service life	Service life stage of scented articles. AC 5: Fabrics, textiles and apparel AC 6: Leather articles AC 31: Scented clothes AC 32: Scented eraser AC 35: Scented paper articles AC 36: Scented CD

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 checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ³	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<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 type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

³ 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

ED-concern:

AHTN gives evidence for being an endocrine disruptor for the environment (estrogenic, anti-estrogenic and antagonistic on Estradiol in fish as well as anti-progesteronic) from reporter gene assays and in vivo gene expression analyses in the livers of male medaka (Mori et al., 2007; Schreurs et al., 2005; Yamauchi et al., 2008). The studies cited above provide evidence on an in vitro level for possible multiple modes of endocrine activity of AHTN. Most strikingly, in vitro anti-progesteronic effects were observed down to concentrations of 0.01 µM. On an in vivo level to our current knowledge there are no chronic fish and/or amphibian assays available (e.g. FSDT, LAGDA) to judge on adverse effects on an organismic in vivo level. We are aware of a risk assessment report (RAR) concerning PBT/vPvB compiled by the Netherlands from 2008 dealing with AHTN and concluding that there is no evidence for endocrine activity. However, since the studies by Mori et al., 2007; Schreurs et al., 2005 and Yamauchi et al., 2008 are not included in the RAR from 2008 and especially since the anti-progesteronic activity reported by Schreurs et al. is not discussed within the RAR, we think that a reevaluation of AHTN concerning its potential for endocrine activity in wildlife species should be performed in detail during a substance evaluation. Additionally, owing to the registered uses of the substance which point towards a wide dispersive use, significant environmental exposure has to be assumed for AHTN.

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 type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

It is necessary to examine the endocrine disrupting properties of AHTN and the effects on the environment. For this reason information from a non-standard ED-relevant test might be required as there is no adequate in vivo study available to conclude for the environment on the apical effects on organisms.
A fish sexual development test (OECD 234) or another test might be required to provide the required information.

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) (ED-concern)
-----------------------------------------	-------------------------------------------------	---------------------------------------------------	----------------------------------------------------------------------------------

If the initial concern is substantiated by the provided data an analysis of risk management options will be undertaken to identify the most adequate regulatory action. This analysis will include both Authorisation and Restriction.

References:

Mori, T., Iida, M., Ishibashi, H., Kohra, S., Takao, Y., Takemasa, T., Arizono, K., 2007. Hormonal activity of polycyclic musks evaluated by reporter gene assay. Environmental sciences : an international journal of environmental physiology and toxicology 14, 195-202.

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

Schreurs, R.H.M.M., Sonneveld, E., Jansen, J.H.J., Seinen, W., van der Burg, B., 2005. Interaction of Polycyclic Musks and UV Filters with the Estrogen Receptor (ER), Androgen Receptor (AR), and Progesterone Receptor (PR) in Reporter Gene Bioassays. *Toxicological science* 83, 264-272.

Umweltprobenbank: http://www.umweltprobenbank.de/de/documents/selected_results/13761;
access: 16.04.2015

Yamauchi, R., Ishibashi, H., Hirano, M., Mori, T., Kim, J.W., Arizono, K., 2008. Effects of synthetic polycyclic musks on estrogen receptor, vitellogenin, pregnane X receptor, and cytochrome P450 3A gene expression in the livers of male medaka (*Oryzias latipes*). *Aquat Toxicol* 90, 261-268.