

## Justification for the selection of a substance for CoRAP inclusion

<b>Substance Name (Public Name):</b>	Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one
<b>Chemical Group:</b>	-
<b>EC Number:</b>	915-730-3
<b>CAS Number:</b>	-
<b>Submitted by:</b>	France
<b>Date:</b>	17/03/2015

### Note

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

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## 1 IDENTITY OF THE SUBSTANCE

### 1.1 Other identifiers of the substance

**Table 1: Substance identity**

<b>EC name:</b>	Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one
<b>IUPAC name:</b>	Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	C <sub>16</sub> H <sub>26</sub> O
<b>Molecular weight or molecular weight range:</b>	234.377
<b>Synonyms/Trade names:</b>	Iso E Super ® OTNE 2-acetoxy-2,3,8,8-tetramethyloctahydronaphthalene Amberonne Boisvelone Isocyclemone E Orbitone Iso Gamma Super®

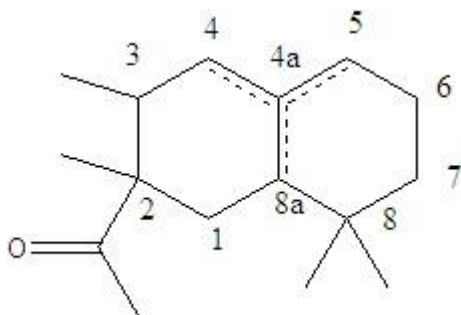
**Type of substance**

Mono-constituent

Multi-constituent

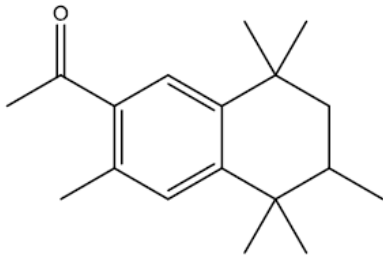
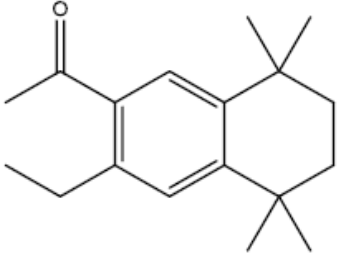
UVCB

**Structural formula:**



## 1.2 Similar substances/grouping possibilities

OTNE is a polycyclic synthetic musk. In particular, OTNE is considered structurally close to two of the other polycyclic synthetic musks presented in the table below:

Name	CAS	EC	Structural formula
AHTN 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one	1506-02-1 / 21145-77-7	216-133-4 / 244-240-6	
AETT 7-Acetyl-6-ethyl-1,1,4,4-tetramethyltetralin	88-29-9	201-817-7	

## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

OTNE has no harmonised classification.

### 2.2 Self classification

- In the registration :
  - Skin Irrit 2 – H 315
  - Skin Sens 1B – H317
  - Aquatic Chronic 1 – H410, M=1
- OTNE with EC number 915-730-3 is not found in the C&L Inventory. However, OTNE is a mixture of 3 isomers and, when looking for each isomer in the C&L inventory, the following hazard classes are in addition notified among the aggregated self classifications of the isomers in the C&L Inventory:

Constituent	EC	CAS	Additional/diverging classification compared to registration dossier of OTNE
1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	259-174-3	54464-57-2	Eye Dam 1- H318 Aquatic Chronic 2 – H411
1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	268-978-3	68155-66-8	Aquatic Chronic 2 – H411
1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	268-979-9	68155-67-9	Aquatic Chronic 2 – H411

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

None.

### 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input 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	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
OTNE is an odour agent. It is included in a wide range of products including detergents, maintenance products, cosmetic products, fragrances used by professionals and consumers.			

#### 4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	

#### 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

<b>Hazard based concerns</b>		
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 checked="" type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify below)
<b>Exposure/risk based concerns</b>		
<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)
<p><b><u>Potential endocrine disruptor:</u></b></p> <p>OTNE has structural analogy with other synthetic polycyclic musk for which in vitro and in vivo data on mammalian and non mammalian species show some indications of endocrine activity. As a consequence, the potential endocrine disruptor activity of OTNE must be clarified and justifies the inclusion in the CoRAP list of the substance with an initial concern of "suspected endocrine disruptor".</p> <p><b><u>Suspected PBT/vPvB:</u></b></p> <p>According to data provided in the disseminated dossier of the OTNE, the substance is not readily, nor inherently biodegradable. Therefore, this substance is considered as P/vP by screening approach. Considering that the potential degradation products must be taken into account in the PBT assessment, clarification is needed on the biodegradability of the OTNE and its potential degradation products.</p> <p>Moreover, data on potential of bioaccumulation of the OTNE are equivocal, and need to be clarified.</p> <p>Finally, it should be quoted that considering OTNE as a multiconstituent substance with a low water solubility, a moderate volatility, and a strong adsorption properties, this substance should be considered as a difficult substance according to the criteria of the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (2000). As a consequence, the ecotoxicity data should be checked, taking into account the adequacy of study protocol with the OTNE properties. Then data on ecotoxicity of the OTNE need to be clarified.</p> <p>To conclude, as Clarifications are needed on the biodegradability/persistence of the OTNE, its potential bioaccumulation, and its ecotoxicity, the PBT properties of the OTNE should be clarified and justified the inclusion in the CoRAP list of the substance with an initial concern of "suspected to be PBT or vPvB".</p> <p><b><u>Suspected Reproductive toxicant:</u></b></p> <p>Considering the ED potential of OTNE, toxicity to reproduction needs to be specifically investigated.</p>		

<sup>1</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

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

<input checked="" 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 checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
-	

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

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
To be further defined at later stages.			