

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

<b>Substance Name (Public Name):</b>	citronellal
<b>Chemical Group:</b>	Aldehydes
<b>EC Number:</b>	203-376-6
<b>CAS Number:</b>	106-23-0
<b>Submitted by:</b>	Sweden
<b>Published:</b>	26/03/2014

### 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>	citronellal
<b>IUPAC name:</b>	3,7-dimethyloct-6-enal
<b>Index number in Annex VI of the CLP Regulation</b>	Not registered in Annex VI of the CLP Regulation
<b>Molecular formula:</b>	C <sub>10</sub> H <sub>18</sub> O
<b>Molecular weight or molecular weight range:</b>	154.2493
<b>Synonyms/Trade names:</b>	Rhodinal 2,3-Dihydrocitral beta-citronellal 6-Octenal, 3,7-dimethyl-

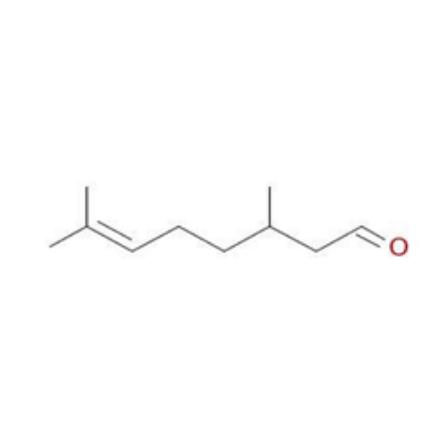
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**



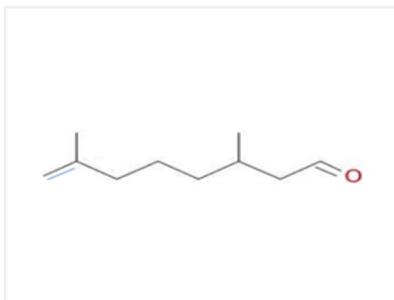
### 1.2 Similar substances/grouping possibilities

**Chemical group:** aldehydes

**Table 1.2.1. Similar substance identity**

<b>EC name:</b>	3,7-dimethyloct-7-enal
<b>IUPAC name:</b>	3,7-dimethyloct-7-enal
<b>EC number</b>	205-474-4
<b>CAS number</b>	141-26-4
<b>Index number in Annex VI of the CLP Regulation</b>	
<b>Molecular formula:</b>	C <sub>10</sub> H <sub>18</sub> O
<b>Molecular weight or molecular weight range:</b>	154.2493
<b>Synonyms/Trade names:</b>	7-Octenal, 3,7-dimethyl-

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

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

*No harmonized classification adopted*

### 2.2 Self classification

- In the registration:
  - Skin Irrit. 2, H315: Causes skin irritation.
  - Skin Sensit. 1, H317: May cause an allergic skin reaction.
  - Eye Irrit 2, H319: Causes serious eye irritation
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - STOT SE 3, H335: May cause respiratory irritation.
  - Aquatic Chronic 2, H411: Toxic to aquatic life with long lasting effects.

## 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	
<i>Please provide further details if appropriate</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Closed System
Citronellal is used in cosmetics, personal care products, cleaning agents, detergents, home care products, air fresheners and perfumes mainly as a fragrance agent. Also used in biocidal products (e.g. disinfectants, pest control), Coatings and paints, thinners, paint removes, Fillers, putties, plasters, modelling clay, Finger paints, Ink and toners.			

## 4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 4.1 Legal basis for the proposal

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

### 4.2 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

### 4.3 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 checked="" type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" 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)
<p>Citronellal is a suspected sensitiser and the scientific studies provided by the registrants are reliable (1 without restrictions or 2 with restrictions) and lead to self-classification as Skin Sensit. 1, H317.</p> <p>Exposure to citronellal is documented both for workers/ professionals and consumers, although the RCRs calculated in the CSR are below 0.1 for consumers and &lt; 1 for workers (PROC 8d, short-term/ long term exposure, local, dermal). Nevertheless, RCRs for consumers' exposure through uses other than cleaning products (i.e. air fresheners, home care products) should also be calculated. In addition, the low RCRs presented by the registrant in the CSR are due to low content of commercial products in citronellal, which is not due to legal requirements but rather a matter of common practice, as reported through feedback from the downstream users without any further documentation. Therefore, products with higher concentrations of citronellal could be out in the market thus increasing the consumer exposures to the substance.</p>		

### 4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input checked="" 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 checked="" 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)	
<p>Citronellal appears in Annex I of Reg. (EU) 528/2012 (eligible for simplified authorization procedure for use as an active substance in biocidal products).</p> <p>CCH final decision available (18-09-2013), expected update of registration dossier is 18-09-2014.</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

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

Detailed and structured information on the following should be provided:

- Types of commercial products that carry citronellal and connection with sensitive types of population (e.g. scented toys used by children)
- Concentration range of citronellal in commercial products
- Exposure scenarios from routes of exposure, like dermal, oral and through air

Case reports on humans dealing with adverse effects due to citronellal use

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

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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- Citronellal is a suspected sensitiser and the scientific studies provided by the registrants are reliable (1 without restrictions or 2 with restrictions) and lead to self-classification as Skin Sensit. 1, H317. Additionally, 1041 notifiers have chosen Skin Sensit. 1, H317 as self-classification and another 93 notifiers have chosen Skin Sensit. 1B, H317.
- Based on the information on exposure and uses of citronellal (section 3, 4.5) and on its classification as a sensitizer, a restriction according to Annex XVII on the use of citronellal in certain products could be decided.