

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

<b>Substance Name (Public Name):</b>	pin-2(10)-ene
<b>Chemical Group:</b>	Terpenes
<b>EC Number:</b>	204-872-5
<b>CAS Number:</b>	127-91-3
<b>Submitted by:</b>	GREECE (HEL)
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### 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>	pin-2(10)-ene
<b>IUPAC name:</b>	(1S,5S)-6,6-dimethyl-2-methylenebicyclo[3.1.1]heptane
<b>Index number in Annex VI of the CLP Regulation</b>	none
<b>Molecular formula:</b>	C <sub>10</sub> H <sub>16</sub>
<b>Molecular weight or molecular weight range:</b>	136.23
<b>Synonyms/Trade names:</b>	β-Pinene, Beta Pinene 2(10)-pinene, nopinene, pseudopinene

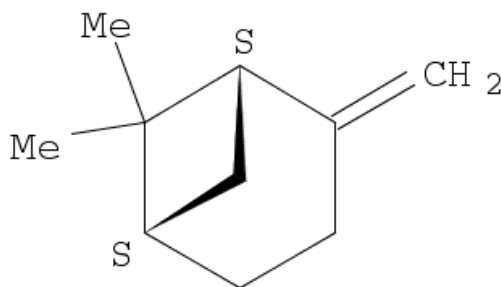
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



### 1.2 Similar substances/grouping possibilities

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## 2 CLASSIFICATION AND LABELLING

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

NONE

### 2.2 Self classification

In registration and C&L Inventory:

HAZARD CLASS	HAZARD STATEMENT CODE	REGISTRANT
Asp. Tox. 1	H304	√
Skin Sens. 1	H317	√ Skin Sens. 1B
Flam. Liq. 3	H226	√
Skin Irrit 2	H315	√
Aquatic Acute 1	H400	
Aquatic Chronic 1	H410	
Aquatic Chronic 2	H411	
Aquatic Chronic 4	H413	
Acute Tox. 4	H302	
Acute Tox. 4	H312	
Acute Tox. 4	H332	
Eye Irrit. 2	H319	

H226: Flammable liquid and vapour.

H304: May be fatal if swallowed and enters airways.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H302: Harmful if swallowed.

H312: Harmful in contact with skin.

H332: Harmful if inhaled.

H319: Causes serious eye irritation.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

H411: Toxic to aquatic life with long lasting effects.

H413: May cause long lasting harmful effects to aquatic life.

### 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

Industrial/Professional:

Manufacture of the substance  
 Formulation of mixtures  
 Formulation of Fragranced products  
 Use of Fragranced products  
 Use as laboratory agent

Consumers:

Use in products such as:  
 Adhesives, sealants  
 Air care products  
 Biocidal products (e.g. disinfectants, pest control) Coatings and paints, thinners, paint removes  
 Fillers, putties, plasters, modelling clay  
 Finger paints  
 Fuels  
 Ink and toners  
 Perfumes, fragrances  
 Polishes and wax blends  
 Textile dyes, finishing and impregnating products; including bleaches and other processing aids  
 Washing and cleaning products (including solvent based products)  
 Cosmetics, personal care products

### 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 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>In the registrants dossier, pin-2(10)-ene (<math>\beta</math>-Pinene) is described to be found in various commercial products, such as adhesives, air care products, coatings/ paints, fillers, finger paints, inks, perfumes/ cosmetics/ personal care products, textile dyes, washing and cleaning products, thus having a wide dispersive and consumers' use. Furthermore, workers of the relevant industry are also highly exposed to <math>\beta</math>-pinene through procedures such as transfer, mixing, blending, preparation and laboratory use. All the above in combination with the substance vapor pressure and boiling point, which point out that, if released to air, with a vapor pressure of 2.93 mm Hg at 25 °C, <math>\beta</math>-pinene will exist solely as a vapor in the atmosphere, are closely related to exposure to <math>\beta</math>-Pinene via inhalation</p> <p><a href="http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+5615">http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+5615</a>).</p> <p>The registrant provides toxicological data on <math>\beta</math>-pinene for most of the endpoints addressed, using read-across, but there is no reference to a study for the respiratory sensitization endpoint. Human data on skin sensitisation are provided through a read across study on turpentine oil. Regarding its physicochemical properties <math>\beta</math>-pinene is characterised as a Flam. Liq. 3 by waving since it is a liquid with a flash point between 23°C and 60°C (CLP).</p> <p>However, already published data on exposure to <math>\beta</math>-Pinene in occupational and indoor environment through inhalation (for example J Toxicol Environ Health A, 1999, 57(2): 89-114; Ann Ocup Hyg, 2012, 56(3):253-263; Ann Ocup Hyg, 2003, 47(4):287-295; Scand J Work Environ Health, 1997, 23(2):114-120 etc) have not been taken into account by the registrant in order to develop relevant exposure scenarios both for workers and consumers of relevant products.</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

Furthermore, there is primary and secondary toxicological data on  $\beta$ -Pinene (for example Contact Dermatitis, 1986, 14(4):205-208; J Occup Health, 2006, 48(6):480-486; J Toxicol Environ Health A, 1999; Arch Toxicol, 1998, 72(8):514-523; Inhal Toxicol, 2002, 14(7):663-684; Int Arch Occup Environ Health, 2006, 79(4):283-298; Fitoterapia, 2010, 81(6):649-655 etc) that should also be considered in order to evaluate any possible respiratory hazard risk for human health involved.

#### 4.4 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 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)	
<i>Please provide further details when relevant.</i>	

#### 4.5 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 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)

- A thorough evaluation of all recent literature data on respiratory data (respiratory sensitization, corrosion STOT) should be performed in order to have a clear opinion on possible risk(s)
- Exposure scenarios for consumer exposure via inhalation should be developed based on the products that consumers are exposed to (e.g. air fresheners, scented articles, potpourris etc).
- Risk Characterization Ratios (RCR) for respective uses by various groups of population should be determined based on DNELs derived from the recently processed data.

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

<input 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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$\beta$ -Pinene's application in certain uses or articles could be restricted (possible insertion of  $\beta$ -pinene in Annex XVII of REACH).