

Justification for the selection of a substance for CoRAP inclusion

– UPDATE –

Substance Name (Public Name): 3-(4-tert-butylphenyl)propionaldehyde
Chemical Group:

EC Number: 242-016-2

CAS Number: 18127-01-0

Submitted by: Swedish Chemicals Agency

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19/03/2019 (1. update)
18/03/2020 (2. update)

Note

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

Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
1.2	Similar substances/grouping possibilities	4
2	CLASSIFICATION AND LABELLING	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Self classification	4
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
3	INFORMATION ON AGGREGATED TONNAGE AND USES	5
4	OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION	5
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	6
5.1	Legal basis for the proposal	6
5.2	Selection criteria met (why the substance qualifies for being in CoRAP)	6
5.3	Initial grounds for concern to be clarified under Substance Evaluation	6
5.4	Preliminary indication of information that may need to be requested to clarify the concern	7
5.5	Potential follow-up and link to risk management	7

1 IDENTITY OF THE SUBSTANCE

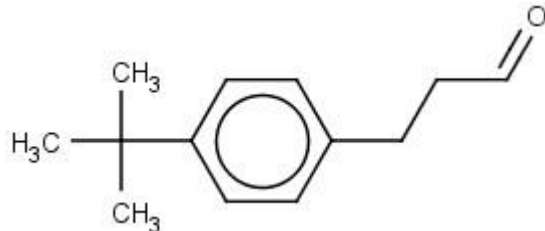
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	3-(4-tert-butylphenyl)propionaldehyde
IUPAC name:	3-(4-tert-butylphenyl)propanal
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	C ₁₃ H ₁₈ O
Molecular weight or molecular weight range:	190.2814
Synonyms/Trade names:	<i>Benzenepropanal, 4-(1,1-dimethylethyl)- Bourgeonal</i>

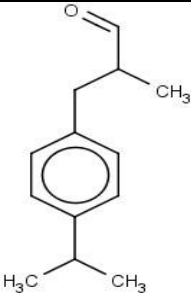
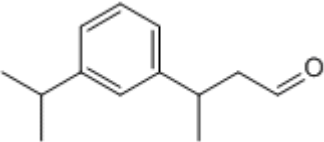
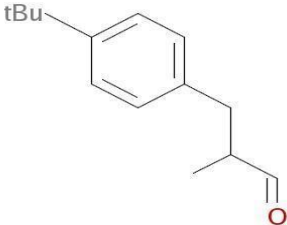
Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Table 2: Identity of similar substances

Public name (<i>Synonym</i>)	EC no	Index number in Annex VI to the CLP	Molecular formula	Molecular weight	Structural formula
3-pcumenyl-2methylpropionaldehyde (<i>Cyclamal</i>)	203-161-7	NA	C ₁₃ H ₁₈ O	190.2814	
β-methyl-3-(1methylethyl)benzenepropional (<i>Florhydral</i>)	412-050-4	605028-002	C ₁₃ H ₁₈ O	190.28	
2-(4-tertbutylbenzyl)propionaldehyde (<i>Lysmeral</i>)	201-289-8	NA	C ₁₄ H ₂₀ O	204.308	

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

NA

2.2 Self classification

- In the registration

Skin Irrit. 2

H315: Causes skin irritation

Skin Sens. 1B

H317: May cause an allergic skin reaction

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

Repr. 2 H361: Suspected of damaging fertility or the unborn child
 STOT RE H373: May cause damage to organs through prolonged or repeated exposure

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

Acute Tox. 3 H301: Toxic if swallowed
 Skin Sens. 1 H317: May cause an allergic skin reaction
 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 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
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Bourgeonal is a fragrant and the fragranced end-products are used at industrial sites, by professional workers and by consumers.			

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

<input checked="" type="checkbox"/> Compliance check, ECHA 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)	
<p>CCH was performed in 2017: In vitro genotoxicity studies and a reproductive toxicity screening test (OECD 422) was requested with DL April 2018. The Reg informed ECHA in 2018 that the reproductive toxicity screening test is delayed and a final report is expected in Feb 2019. In August 2019 the test results are still not provided (according to the registration information on ECHA website).</p> <p>The SE CA proposes to postpone the evaluation year to 2022 to also consider the outcome of the ongoing evaluations for the structurally similar substances lysmeral (EC 201-298-8, SE Follow-up ongoing) and cyclamal (EC 203-161-7, ECHA decision).</p>	

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

- Article 44(2)
 Article 45(5)

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 checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<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

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>Relevant for the reproductive toxicity, only one study carried out with bourgeonal is reported in the registration dossier. Based on testicular and epididymal toxicity observed in the 5 day oral (gavage) study on sexually mature rats, the Registrant has self-classified bourgeonal for fertility effects under Repr. 2 category.</p> <p>By read-across from cyclamal (source) a NOAEL of 25 mg/kg bw/day, observed in a one-generation study (OECD 415) with cyclamal is used for risk assessment of bourgeonal for the reproductive toxicity endpoint (until the ongoing study with bourgeonal is available). In addition to adverse fertility effects a significant reduction in the anogenital distance of male pups was observed for cyclamal in this study.</p>		

- ¹ 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 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 type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Appropriate study to investigate developmental toxicity of bourgeonal and further information to discern the severity of fertility effects may be needed.</p>	

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Depending on the outcome of the evaluation, harmonised classification and labelling proposal could be a potential follow-up.</p>			