

**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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Cover 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

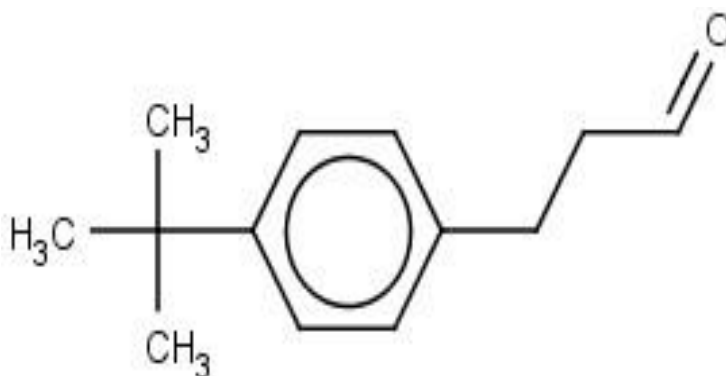
1.1 Other identifiers of the substance

Table 1: Substance identity

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>

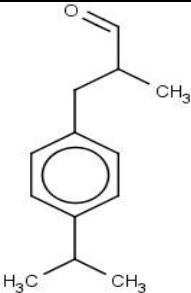
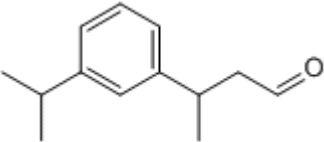
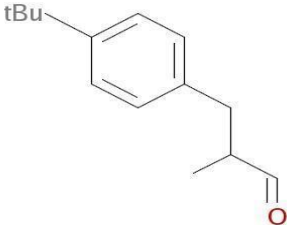
Type of substance Mono-constituent Multi-constituent UVCB

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)benzenepropanal (<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
 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 USES¹

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	
<p>*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</p>			
<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.			

¹ The dissemination site was accessed August 2018.

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 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)	
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.	

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

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<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 type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>For reproductive toxicity endpoint, 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 study on sexually mature rats, the Registrant has self-classified bourgeonal for fertility effects under Repr. 2 category. By read-across to cyclamal a NOAEL of 25 mg/kg bw/day observed in onegeneration study (OECD 415) is used for risk assessment of bourgeonal. In addition to adverse fertility effects a significant reduction in the anogenital distance of male pups was observed for cyclamal.</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>			