

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): bis(pentane-2,4-dionato)calcium
Chemical Group:
EC Number: 243-001-3
CAS Number: 19372-44-2
Submitted by: Germany
Date: 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

EC name:	bis(pentane-2,4-dionato)calcium
IUPAC name:	calcium bis[(2Z)-4-oxopent-2-en-2-olate]
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	C ₁₀ H ₁₄ CaO ₄
Molecular weight or molecular weight range:	238.30 g·mol ⁻¹
Synonyms/Trade names:	Calcium acetylacetonate Calcium 2,4-pentanedionate Bis(pentane-2,4-dionato)calcium

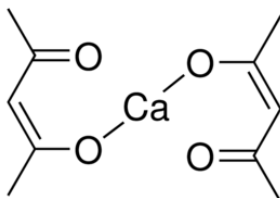
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI of the CLP regulation.

2.2 Self classification

- In the registration:
 - Acute Tox. 4 H302: Harmful if swallowed
 - Acute Tox. 3 H311: Toxic in contact with skin
 - Acute Tox. 3 H331: Toxic if inhaled
 - Skin Sens. 1A H317: May cause an allergic skin reaction
 - Eye Dam. 1 H318: Causes serious eye damage
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Acute Tox. 4 H332: Harmful if inhaled
 - Acute Tox. 4 H312: Harmful in contact with skin
 - Skin Irrit. 2 H315: Causes skin irritation
 - Eye Irrit. 2 H319: Causes serious eye irritation
 - Skin Sens. 1 H317: May cause an allergic skin reaction
 - STOT SE 3 H335: May cause respiratory irritation
 - Repr. 2. H361(d): Suspected of damaging fertility or unborn child

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

There is currently no proposal for harmonised classification registered or under consideration for this substance.

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 type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Closed System
<p>Besides manufacture and formulation the only registered use of calcium acetylacetonate is as an additive (stabilizing agent) in polymer industry (e.g. rubber and plastic). Although relatively controlled conditions might be expected at industrial sites there are some open applications listed which potentially might lead to high exposures of workers. No uses by professional workers are registered.</p>			

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) (MemberState 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 checked="" type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input checked="" 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 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>Calcium acetylacetonate can be used as a substitute for lead stabilizers in PVC. Therefore, it is important to assess the complete toxicological profile of the substance. Calcium acetylacetonate is self-classified as Skin Sens. 1A. Additional studies might be needed in order to analyze the potential for reproductive toxicity and to check the reported classification as Repr. 2 in the C&L inventory.</p> <p>In view of the expected increasing importance of the substance as a substitute, worker exposure needs to be evaluated.</p>		

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 checked="" 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>Calcium acetylacetonate can be used as a substitute for lead stabilizers in PVC. Application of the read-across approach seems unclear. An initial review of the registration dossier indicates that additional studies for the end point reproductive toxicity might be needed.</p> <p>If the Substance Evaluation indicates that risks for workers arise further information on exposure might be necessary.</p>	

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
<p>It is unclear whether there is a risk for workers and further risk management measures need to be implemented.</p>			

¹CMR/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