



Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): Butanone

EC Number: 201-159-0

CAS Number: 78-93-3

Authority: Swedish Chemicals Agency

Date: 21/03/2017

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: Other Substance identifiers

EC name (public):	Butanone
IUPAC name (public):	Butanone
Index number in Annex VI of the CLP Regulation:	606-002-00-3
Molecular formula:	C ₄ H ₈ O
Molecular weight or molecular weight range:	72.11 g/mol
Synonyms:	2-Butanone Methyl ethyl ketone (MEK) Methylethylketone

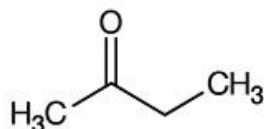
Type of substance

Mono-constituent

Multi-constituent

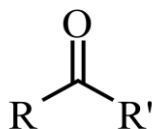
UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs) <small>Protocol</small>	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	

Further details	
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3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
606-002-00-3	Butanone Ethyl methyl ketone	201-159-0	78-93-3	Eye Irrit. 2	H319		
				STOT SE 3	H336		
				Flam Liq. 2	H225		

3.1.2 Self classification

- In the registration:
 - Flam. Liq. 2 H225
 - Eye Irrit. 2 H319
 - STOT SE 3 H336

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - STOT SE 3 H335

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input checked="" type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input 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 checked="" 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>This substance has 19 active registrations under REACH, 1 Joint Submission and 1 Individual Submission.</i>		

4.2 Overview of uses

Table: Uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

	Use(s)
Uses as intermediate	Industrial use resulting in manufacture of another substance
Formulation	Laboratories Water treatment Transfer and packing of substances and mixtures
Uses at industrial sites	Laboratories Lubricants Functional fluids

¹ The dissemination site was accessed 31 May 2016.

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	Coatings Cleaning
Uses by professional workers	Agrochemicals Coatings Paints Laboratoriesroad and construction applications Cleaning agents
Consumer Uses	Cleaning agents Lubricants Adhesives/sealants Anti-freez products
Article service life	-

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 disruptor
- 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 checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<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 checked="" type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² 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

No reproductive toxicity study is available for butanone. The study is waived by read-across to a two-generation reproductive toxicity study with 2-Butanol, which shows some reproductive effects (decreased pup viability and decreased foetal body weights). In this study the endocrine parameters (oestrous cyclicity, sperm parameters and uterine weights) were not examined.

Prenatal developmental toxicity studies in mouse and rat are available, which indicate possible teratogenic effects of butanone. Moreover, butanone is a neurotoxicant in humans and in a subchronic inhalation study it is shown to depress brain weights. This raises a concern for developmental neurotoxicity.

In the subchronic inhalation toxicity study, butanone caused formation of cysts in the ovaries, supporting a potential ED concern.

The substance has wide dispersive and widespread uses. There are no chronic toxicity information available for butanone and therefore there is a risk for humans who are repeatedly exposed to relatively high levels of the substance.

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 checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
Proper justification for read-across to a study with 2-butanol for the reproductive toxicity may be requested. However, as the study lacks examination of several relevant hormonal/reproductive parameters, further information on reproductive toxicity may be requested. More detailed information on environmental exposure may be requested.	

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)
Harmonised classification for reproductive/developmental toxicity.			