

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name): Butanone oxime

Chemical Group:

EC Number: 202-496-6

CAS Number: 96-29-7

Submitted by: Germany

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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

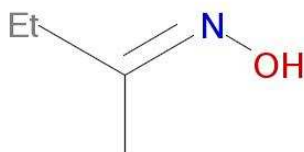
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Butanone oxime
EC number:	202-496-6
EC name:	Butanone oxime
CAS number (in the EC inventory):	96-29-7
CAS number:	96-29-7
CAS name:	2-Butanone, oxime
IUPAC name:	Butan-2-one oxime
Index number in Annex VI of the CLP Regulation	616-014-00-0
Molecular formula:	C ₄ H ₉ NO
Molecular weight or molecular weight range:	87.1204
Synonyms:	2-Butoxime Ethyl methyl ketone oxime Ethyl methyl ketoxime Methyl ethyl ketone oxime Methyl ethyl ketoxime, MEKO.

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Table 9: Classification according to part 3 of Annex VI, Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index number: 616-014-00-0				
Classification		Labelling		
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram Signal Word Code(s)	Pictogram Signal Word Code(s)	Suppl. Hazard statement code(s)
Carc. 2	H351	GHS08	H351	
Acute Tox. 4 *	H312	GHS05	H312	
Eye Dam. 1	H318	GHS07	H318	
Skin Sens. 1	H317	Dgr	H317	

Table 10: Classification according to part 3 of Annex VI, Table 3.2 (List of harmonised classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index number: 616-014-00-0			
Classification	Risk phrases	Safety phrases	Indication(s) of danger
Carc. Cat. 3; R40	21	2	Xn
Xn; R21	40	13	
Xi; R41	41	23	
R43	43	26	
		36/37/39	

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None.

2.3 Self classification

In addition to the harmonised classification in Annex VI (CLP) the following classifications are included in the notifications to the Classification and labelling inventory:

Flam. Liq. 3; H226: Flammable liquid and vapour.

Acute tox. 3; H311: Toxic in contact with skin.

Acute Tox. 3; H331: Toxic if inhaled

Acute Tox. 4; H302: Harmful if swallowed.

Skin Corr. 1B; H314: Causes sever skin burns and eye damage.

Aquatic Chronic 2; H411: toxic to aquatic life with long lasting effects.

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

- Article 44(1) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

3.2 Grounds for concern

<input checked="" type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

2-Butanone oxime shows wide dispersive use with high exposure for workers. The registrations identify a number of professional applications as identified uses with high total RCRs. 2-butanone oxime is predicted as toxic to reproduction by ECHA screening. Additionally, the substance is in discussion in Germany according to the carcinogenic properties. Besides, 2-butanone oxime is a skin sensitizer.

Substance evaluation shall clarify the classification and if risks especially for professional workers are adequately controlled.

3.3 Information on aggregated tonnage and uses

<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 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 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

Uses by workers in industrial settings:

- Use as intermediate
- Manufacturing liquid paints
- Industrial application of coatings
- Intermediate use of MEKO
- Formulation of liquid paints containing MEKO
- Industrial application of paints containing MEKO
- Professional application of paints containing MEKO
- Intermediate use of MEKO

Uses by professional workers

- Professional application of coatings (Indoor)
- Professional application of coatings (Outdoor)
- Professional application of paints containing MEKO

Uses by consumers

- Consumer application of coatings (Indoor)
- Consumer application of coatings (Outdoor)
- Consumer application of coatings

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check	<input checked="" type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input checked="" type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" 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
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
See 2.1 for entry in Annex VI (CLP).	

3.5 Information to be requested to clarify the suspected risk

<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"/> Other (provide further details below)	
Depending on the outcome of the substance evaluation the most effective Risk Management Option can be chosen. The necessity to write an Annex VI dossier for reclassification of 2-butanone oxime will be addressed.	
It may be decided to address unacceptable risks by initiating either an Annex XV Dossier for authorisation or for a restriction for the use of butanone oxime in certain products and/or applications.	

3.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
The substance evaluation shall clarify if a reclassification for the endpoint carcinogenicity of 2-butanone oxime is necessary. Depending on the exposure situation in real workplaces further risk management measures as authorisation requirement or a restriction will be proposed.			