Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**CYCLOHEXANONE**
EC Number:	**203-631-1**
CAS Number:	**108-94-1**
Authority:	**Bureau for Chemical Substances, Poland**
Date:	**22/03/2016**

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

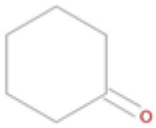
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	cyclohexanone
IUPAC name (public):	cyclohexanone
Index number in Annex VI of the CLP Regulation:	606-010-00-7
Molecular formula:	$C_6H_{10}O$
Molecular weight or molecular weight range:	98.143
Synonyms:	Cyclohexanone, anone, cyclohexyl ketone, hexanon, ketohexamethylene, nadone, pimelic ketone, pimelin ketone, sexton

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

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

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)		
606-010-00-7	cyclohexanone	203-631-1	108-94-1	Flam. Liq. 3 Acute Tox. 4*	H226 H332	-	-

3.1.2 Self classification

- In the registration: the self classification includes additional classification than mentioned as harmonized classification.

Acute Tox. 4 H302
Acute Tox. 4 H312
Skin Irrit. 2 H315
Eye Damage 1 H318

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

Self classification notifications for cyclohexanone (EC Number: 203-631-1) are available in the C&L Inventory (http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/427). In the following table an overview (dating of April 2015) of notifications for cyclohexanone in addition to the ones above is given.

STOT SE 3, H335 (Respiratory sys...) (Inhalation).
Eye Irrit. 2 H315, H319

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

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4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☒ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint submission		

4.2 Overview of uses

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses at industrial sites	Cyclohexanone is used in organic synthesis, particularly in the production of adipic acid and caprolactam , polyvinyl chloride and its copolymers, and methacrylate ester polymers (OECD SIDS).
Uses by professional workers	Additional uses include wood stains, paint and varnish removers, spot remover, degreasing of metals, polishes, levelling agents, dyeing and delustering silk, lubricating oil additives, solvent for herbicides, cellulosics, natural and synthetic resins, waxes, fats (OECD SIDS).

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 ☐ C ☐ M ☐ R	Suspected CMR[1] ☒ C ☒ M ☒ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☒ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☒ High (aggregated) tonnage	☐ Other (please specify below)

[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

Cyclohexanone can exhibit mutagenic, genotoxic and reprotoxic potential. Cyclohexanone was positive in the forward mutation assay using Bacillus subtilis and the reverse mutation assay using Salmonella typhimurium. In a two-generation reproduction study, decreased fertility was observed in rats exposed via inhalation at 1400 ppm but not at 500 ppm; however, the effect was found to be reversible following a post-exposure recovery period. There is unclear evidence for the carcinogenicity of cyclohexanone. According to ACGIH cyclohexanone is an animal carcinogen with unknown relevance to humans. Cyclohexanone could exert harmful effects on mammalian chromosomes and affect reproductive functions. Cyclohexanone is irritant to the skin, eyes and respiratory tract. Cyclohexanone has wide dispersive use and high workers exposure. American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, OH, 22, 2008, IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans, Vol. 47: 157-69, 1989, http://toxnet.nlm.nih.gov.

5.4. Preliminary indication of information that may need to be requested to clarify the concern

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)
Detailed evaluation of the available data may lead to further information requirements.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Depending on the results of the evaluation.			