BUREAU FOR CHEMICAL SUBSTANCES

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**3-methylbutan-1-ol**
EC Number:	**204-633-5**
CAS Number:	**123-51-3**
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.

CONTENTS

1 IDENTITY OF THE SUBSTANCE

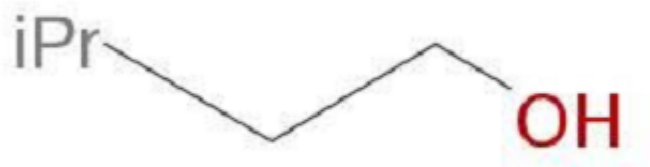
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	3-methylbutan-1-ol
IUPAC name (public):	3-methylbutan-1-ol
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$C_5H_{12}O$
Molecular weight or molecular weight range:	88.1482
Synonyms:	

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

Structural formula:



1.2 Similar substances/grouping possibilities

Eight structural isomers with molecular formula $C_5H_{12}O$ and all alcohols are know belongs to the group of primary amyl alcohols.
The registrant has also proposed to use data generated on primary amyl acetate.

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
	Restri -ction	☐ 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)[1]

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)		
-	-	-	-	-	-	-	-

3.1.2 Self classification

In the registration:

International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement code(s)		
3-methylbutan-1-ol	204-633-5	123-51-3	Flam. Liquid 3	H226: Flammable liquid and vapour.		
			Acute Tox. 4	H332: Harmful if inhaled.		
			Skin Irrit. 2	H315: Causes skin irritation.		
			Eye Irrit. 2A	H319: Causes serious eye irritation.		
			STOT Single Exp. 3 Affected organs: respiratory tract Route of exposure: Inhalation	H335: May cause respiratory irritation.		
			EUH066	Repeated exposure may cause skin dryness or cracking.		

- Additional notified classification and labelling according to CLP criteria (beside of self classification of registrant). Taken from:

[1] *The ECHA dissemination site was accessed 20.03.2016.*

http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/24439:

Muta. 2, H341

Carc. 2, H351

Acute Tox. 4 H302

Eye Irrit. 2 H318

STOT SE 3 H336

Eye Irrit. 2A H319

Skin Irrit. 2 H314

STOT SE 1 H370

Flam. Liq. 4 H226

Eye Dam. 1 H318

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

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
☒ 100+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
There are three registrations.		

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 as intermediate	Use as Process Chemical
Formulation	Formulation & (re)packing of substances and mixtures, distribution of the substance
Uses at industrial sites	Use in Coatings, Use in Cleaning Agents, Lubricants, Use as binders and release agents, Use in laboratories, Polymer processing
Uses by professional workers	Use in Coatings, Use in Cleaning Agents, Lubricants, Use as binders and release agents, Use in laboratories, Polymer processing
Consumer Uses	Use in Coatings, Use in Cleaning Agents, Lubricants, Personal Care Products
Article service life	-

[2] *The ECHA dissemination site was accessed 20.03.2016.*

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[3] ☒ C ☐ M ☒ R	☐ Potential endocrine disruptor
☐ Sensitiser	☒ Suspected Sensitiser[3]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[3]	☐ 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

[3] 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

☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

Suspected sensitiser:

3-methylbutan-1-ol is not classified for skin sensitisation. There are no studies on skin sensitisation available for 3-methylbutan-1-ol. Registrant presented only outcome from the studies performed on structural analog reaction mass of 2-methylbutyl acetate and pentyl acetate. Presented study outcomes for the skin sensitising endpoint (guinea pig maximization test) give conflicting results (negative and ambiguous). Additionally ambiguous results for other structural annalogs (primary amyl alcohols) are available.

The registrant declares that no information regarding the respiratory sensitisation properties is available. Taking into account that substance is classified as Acute toxicity (inhaled) and STOT SE 3 (respiratory system) it would be good to obtain more data on sensitisation by inhalation. Data provided in dossier on exposure related observations in humans is not sufficient.

Within the SEV process it should be further evaluated whether the substance might have sensitising properties to the respiratory tract and skin.

Suspected CMR:

Registered substance activates DART (DART profiler in the QSAR Toolbox) alerts for developmental/reproductive toxicity (known precedent reproductive and developmental toxic potential) as implemented in the QSAR Toolbox v3.3. After running a chemical through the decision tree, the results indicated that the chemical of interest is associated with chemical structures known to have DART.

The carcinogenicity of 3-methylbutan-1-ol was evaluated in a studies (disregarded by registrant) which were described in two publications (Gibel et al. 1974, 1975). Postmortal examination after the average life time of 527 days included blood analysis as well as histopathological analysis of the organs, spinal segments and femurs. As result, severe chronic-toxic effects were reported, as liver cirrhosis, myocard necrosis and effects on pancreas and haematopoietic organs as well as tumours distributed over a variety of different organs. There are no additional experimental studies on registered substance, the effects seen in the carcinogenicity test raise concern that the substance is a carcinogen, which needs to be clarified.

Exposure/risk based concerns:

The identified uses in the registration data indicate potential dermal and inhalation exposure to both workers and consumers. Further assessment of the exposure assessment and risk characterisation is required in order to confirm that risks are adequately controlled.

5.4 Preliminary indication of information that may need to be requested t 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)

Depending upon the outcomes of the evaluation.

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Harmonised C&L might follow , further action and risk management measures will depend upon the outcome of the evaluation.			