Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Butan-1-ol
EC Number:	200-751-6
CAS Number:	71-36-3
Authority:	National Public Health Center – National Directorate of Chemical Safety, Hungary
Date:	21/03/2017

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

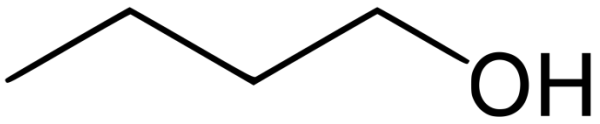
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Butan-1-ol
IUPAC name (public):	butan-1-ol
Index number in Annex VI of the CLP Regulation:	603-004-00-6
Molecular formula:	$C_4H_{10}O$
Molecular weight or molecular weight range:	74.12 g/mol
Synonyms:	*n-Butanol* *Butanol* *butyl alcohol* *1-Butanol* *Hemostyp* *Methylolpropane* *Nacol 4* *Propylcarbinol*

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

Structural formula:



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, Final decison
		☐ 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)

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)		
603-004-00-6	**butan-1-ol n-butanol**	200-751-6	71-36-3	Flam. Liq. 3 Acute Tox. 4* Skin Irrit. 2 Eye Dam. 1 STOT SE 3 STOT SE 3	H226 H302 H315 H318 H335 H336		

Signal Words	Pictograms
Danger	 Exclamation mark  Flame  Corrosion

Precautanory statements

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233: Keep container tightly closed.
P240: Ground/bond container and receiving equipment.
P241: Use explosion-proof electrical/ventilating/lighting/.../ equipment.
P242: Use only non-sparking tools.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P370+P378: In case of fire: Use... to extinguish.
P403+P235: Store in a well-ventilated place. Keep cool.
P501: Dispose of contents/container to ...

3.1.2 Self classification

- In the registration:

  Compared to Annex VI of CLP Regulation the substance has the same classification in the registration.

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

  Acute Tox. 4

  STOT SE 3 (respiratory tract)

  STOT SE 3 (lung) (oral)

  STOT SE 3 (lung) (Inhalation)

  STOT SE 3 (stomach)

  STOT SE 3 (brain) (Inhalation)

  STOT SE 3 (CNS, Respiratory tract)

  STOT SE 3 (Dermal)

  STOT SE 3 (mouth, pharynx,...)

  STOT SE 3 (central nervous system) (Inhalation)

  Asp. Tox. 1

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

HU MSCA has no information about any proposal for harmonised classification regarding this substance.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

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
There is a joint submission with more than 30 active registrants. There is also an individual subsmission (intermediate use) with only one registrant.		

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	Used in closed batch process and used as laboratory reagent
Formulation	Formulation, (re)packing and distribution of substances and mixtures
Uses at industrial sites	Used in cleaning agents, coatings, lubricants, in polymer production and in metal work oils
Uses by professional workers	Used in cleaning agents, coatings, lubricants, metal work oils and in laboratories

[1] *Dissemination site was accessed 7 March 2017.*

Consumer Uses	Used in cleaning agents, coatings, lubricants and in costumer care products
Article service life	-

Part 3: There is high potential for exposure of

☐ Humans	☐ Environment

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[2]	
☐ 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)

[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

In a teratogenicity study performed with n-butanol (Nelson et al. 1989), skeletal malformations (mainly rudimentary cervical ribs) were observed at the highest tested concentration of 8000 ppm. The authors of the study concluded that the results suggest a possible selective developmental effect that maternal toxicity per se was not responsible for, although they did not consider this as a strongly selective effect. Occasional visceral malformations and variations (e.g. enlarged brain ventricles) were also observed, although these effects did not reach statistical significance.

A study by Ema et al. (2005) gave negative results, however, in another study by Sitarek et al. (1994) developmental anomalies were observed, including central nervous system and rib defects, at doses with no maternal toxicity. The authors of this study concluded that even maintaining workplace concentrations below maternally acceptable levels may prove insufficient in protecting the progeny.

The accessible information are contradictory, and therefore do not warrants further clarification. The reliability and relevance of the available studies should be addressed in a full evaluation of the substance. The relevance of the concern should also be examined considering potential human exposure levels.

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 on ED potential	☐ Other (provide further details below)
In order to clarify concerns identified, further information on developmental toxicity properties of the substance may be necessary.	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Depending on the outcome of the substance evaluation a proposal for harmonized classification and labelling is a possible risk management measure. As a follow-up of a potential CLH further assessment is needed whether a restriction proposal or authorization will be proposed as an appropriate risk management measure.			