Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**Benzaldehyde**
EC Number:	**202-860-4**
CAS Number:	**100-52-7**
Authority:	**FR MSCA**
Date:	**22/03/2016**

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Table of Contents

1 IDENTITY OF THE SUBSTANCE

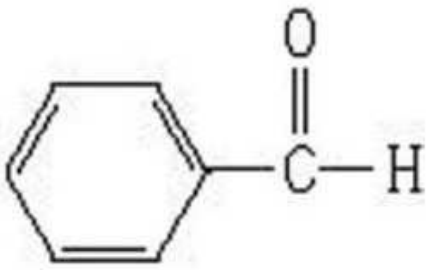
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	Benzaldehyde
IUPAC name (public):	Benzaldehyde
Index number in Annex VI of the CLP Regulation:	605-012-00-5
Molecular formula:	C_7H_6O
Molecular weight or molecular weight range:	106.1219 $g.mol^{-1}$
Synonyms:	*Benzoic aldehyde*

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

Structural formula:



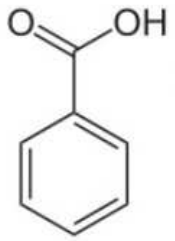
Other relevant information about substance composition

Degree of purity > 99.0 - 100.0 % (w/w)

1.2 Similar substances/grouping possibilities

EC number:	200-618-2
EC name (public):	Benzoic acid
CAS number:	65-85-0
CAS name (public):	Benzoic acid
IUPAC name (public):	Benzoic acid
Index number in Annex VI of the CLP Regulation:	607-705-00-8
Molecular formula:	$C_7H_6O_2$
Molecular weight or molecular weight range:	122.122 $g.mol^{-1}$

Structural formula:



EC number:	208-534-8
EC name (public):	Sodium benzoate
CAS number:	532-32-1
CAS name (public):	Sodium benzoate
IUPAC name (public):	Sodium benzoate
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_7H_5O_2Na$
Molecular weight or molecular weight range:	144.11 $g.mol^{-1}$
Synonyms:	

Structural formula:

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: 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)	

Further details	A decision on a compliance check was set in May, 2013, requiring information on benzaldehyde partition coefficient n-octanol/water (Annex VII, 7.8) and substance identity. These information were included in the 2014 CSR. Benzaldehyde has an harmonised classification for (Acute Tox.4 – H302), inserted in Annexe VI to CLP. According to the Cosmetics Regulation (EC) N) 1223/2009, benzaldehyde is used a a denaturant, masking agent and solvent in cosmetics.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table 3: 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)		
605-012-00-5	**benzaldehyde**	202-860-4	100-52-7	**Acute Tox. 4 ***	**H302**		

3.1.2 Self classification

- In the registration:

In addition to the harmonized classification in accordance with Annex VI of the CLP, the registrant self-classifies the substance as Acute Tox. 4; H332, Skin Irrit. 2; H315, Eye.Irrit 2; H319, STOT SE 3; H335, Aquatic Chronic 3; H412.

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

STOT SE1, H335 (respiratory tract)
Skin Sens. 1, H317, H319
Acute Tox. 1, H332
Acute Tox. 3, H331

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table 4: 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 5: Uses

Part 1:

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

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

Suspected Mutagenic properties:

Regarding the endpoint genotoxicity, *in vitro* Ames tests and gene mutation tests have been conducted according to OECD test guidelines for some of them. Results of these mutagenic tests were mainly negative, with or without metabolic activation. Results from chromosome aberration tests, sister chromatid exchange test and comet assay on human lymphocytes were contradictory. The registrant has concluded that, based on *in vitro* mutagenic assays, benzaldehyde has no mutagenic activity in bacterial systems but possible weak clastogenic effects .

On the other hand, *in* vivo clastogenicity tests have also been conducted that are judged poorly reliable. This conclusion is emphasized by the registrant Read-across approach with benzoic acid, supporting the same mutagenic profile.

No *further* genotoxic tests have been performed, especially *in vitro* micronucleus tests or *in vivo* assays. At the current state, no other *in vitro* nore *in vivo* clastogenicity assays have been published in the scientific literature. Furthermore, benzaldehyde has a wide dispersive use and is manufactured at high tonnage. Workers, as well as professional and consumers are expected to be exposed during the identified uses and others. These evidence raise concern that the substance is a potential mutagenic toxicant, which needs to be clarified.

Additionnaly the substance has a high aggregated tonnage, has wide dispersive uses and there is an exposure of the consumers.

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)
During the substance evaluation it should be verified, if others *in vitro* genotoxic assays are at disposal, whether by the registrant or in the scientific literature. Focus should be made on *in vitro* and *in vivo* clastogenicity tests.	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Potential follow-up actions for the substance depend on the outcome of this substance evaluation. Harmonised C&L on mutagenic properties may be considered.			