Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Formaldehyde
Chemical Group:	
EC Number:	200-001-8
CAS Number:	50-00-0
Submitted by:	FRANCE
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

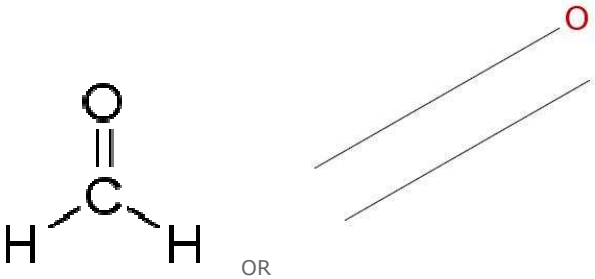
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Formaldehyde
EC number:	200-001-8
EC name:	Formaldehyde
CAS number (in the EC inventory):	50-00-0
CAS number:	50-00-0
CAS name:	
IUPAC name:	Formaldehyde
Index number in Annex VI of the CLP Regulation	605-001-00-5
Molecular formula:	CH2O
Molecular weight or molecular weight range:	30.0263
Synonyms:	

Type of substance: ☑ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



OR

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

According to CLP

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Carc. 2	H351: Suspected of causing cancer.
Acute Tox. 3 *	H331: Toxic if inhaled
Acute Tox. 3 *	H311: Toxic in contact with skin
Acute Tox. 3 *	H301: Toxic if swallowed
Skin Corr. 1B	H314: Causes severe skin burns and eye damage
Skin Sens. 1	H317: May cause an allergic skin reaction

Specific concentration limits

Specific Concentration Limits and M Factors	
Concentration	**Classification**
*	-
C ≥25 %	Skin Corr. 1B; H314
5 % ≤ C < 25 %	Skin Irrit. 2; H315
5 % ≤ C < 25 %	Eye Irrit. 2; H319
C ≥ 5 %	STOT SE 3; H335
C ≥ 0,2 %	Skin Sens. 1; H317

According to DSD

Classification	Risk phrases
Carc. Cat. 3; R40 T; R23/24/25 C; R34 R43	23/24/25: Toxic by inhalation, in contact with skin and if swallowed. 34: Causes burns. 40: Limited evidence of a carcinogenic effect. 43: May cause sensitisation by skin contact.

Specific concentration limits

Concentration Limits	
Concentration	**Classification**
C ≥25 %	T; R23/24/25
5 % ≤ C < 25 %	Xn; R20/21/22
C ≥25 %	C; R34
5 % ≤ C < 25 %	Xi; R36/37/38
C ≥ 0,2 %	R43

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

A French proposal for a harmonised classification in addition to the currant is under discussion in ECHA's Risk Assessment Committee (RAC). The proposal is to add the classifications:

Carc. Cat. 1A, H350: May cause cancer.

and

Muta. 2, H341: Suspected of causing genetic defects.

2.3 Self classification

The registration data includes the harmonised classification in Annex VI of the CLP and in addition the following self classification:

According to CLP criteria:

Eye Damage 1, H318: Causes serious eye damage.

In addition are the following classification(s) included in the Classification and Labelling Inventory:

Flam. Gas 1; H220: Extremely flammable gas.

Liq. Gas; H280: Contains gas under pressure; may explode if heated.

Met. Corr. 1; H290: May be corrosive to metals.

Eye Dam. 1, H318: Causes serious eye damage.

Eye Irrit. 2; H319: Causes serious eye irritation.

Resp. Sens. 1, H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

STOT SE 3, H335: May cause respiratory irritation.

Acute Tox. 2, H330: Fatal if inhaled.

STOT SE 1, H370: Causes damage to organs

STOT RE 1, H372: Causes damage to organs through prolonged or repeated exposure

Muta. 2, H341: Suspected of causing genetic defects.

Carc. 1A, H350: May cause cancer.

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

☒ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☒ Consumer use	☐ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive population	☒ Aggregated tonnage
☐ Suspected Endocrine disruptor	☒ Other (provide further detail below)	

It is not possible to come to definitive conclusions on the risks for consumers and workers because essential information is missing. The following information is needed to make a more in-depth risk assessment:

- Current measured workers exposure concentrations for all processes covering the whole life cycle.
- Measured indoor air exposure data for consumer in different European countries, taking into account worst-case scenario: newly built house with new kitchen, furniture, curtains and carpet. This may answer the question, if there is really a problem there.
- Data on how long high concentrations of formaldehyde in indoor air from new material (new kitchen, furniture, curtains and carpet) persist. Measured data is preferred, however modelling data based on several measurements is also acceptable.

DNELs for all exposure routes. As there are several proposals concerning NOAELs, it is not possible to estimate at present risk for worker and consumer.

3.3 Information on aggregated tonnage and uses

☐ 1 - 10 t	☐ 10 - 100 t	☑ 100 - 1000 t	☐ 1000 - 10,000 t	
☐ 10,000 - 100,000 t	☐ 100,000 - 1000,000 t	☑ > 1000,000 t	☐ Confidential	
1,000,000 + tonnes per annum				
☑ Industrial Use	☑ Professional Use	☑ Consumer Use	☐ Closed System	

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

☐ Compliance Check	☑ Annex VI (CLP)
☐ Testing Proposal(s)	☐ Annex XIV (Authorisation)
☐ Substance Identification Issues	☐ Annex XVII (Restriction)
☐ ESR Programme	☐ Other (provide further details below)
Ongoing harmonised classification based on French proposal (Carc. Cat. 1A, H350 – Muta. 2, H341), cf. 2.2.	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☑ Information on exposure
☐ Information on fate and behaviour	☑ Information on uses
☐ Information on ecotoxicological properties	☐ Other (provide further details below)
☐ Information on physico-chemical properties	
To be determined during the substance evaluation.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L
☐ Authorisation	☐ Other (provide further details below)
Depends on the outcome of substance evaluation.	