Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Resorcinol
Chemical Group:	
EC Number:	203-585-2
CAS Number:	108-46-3
Submitted by:	Finnish Safety and Chemicals Agency, Tukes, Finland
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

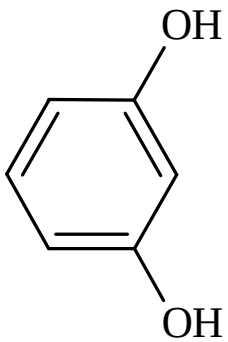
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Resorcinol
EC number:	203-585-2
EC name:	Resorcinol
CAS number (in the EC inventory):	108-46-3
CAS number:	108-46-3
CAS name:	1,3-Benzenediol
IUPAC name:	Benzene-1,3-diol
Index number in Annex VI of the CLP Regulation	604-010-00-1
Molecular formula:	$C_6H_6O_2$
Molecular weight or molecular weight range:	110.11
Synonyms:	1,3-Benzenediol, 1,3-Dihydroxybenzene, 3-Hydroxyphenol, Dihydroxybenzol, Resorcin, Resorcinol

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index number: 604-010-00-1

CLP:

Hazard Class and Category Codes	Hazard Statement Codes	Hazard Statements	Pictogram Signal Word Codes	Hazard State-ment Codes	Specific Concentration Limits and M-Factors
Acute tox. 4 * Skin Irrit. 2 Eye Irrit. 2 Aquatic acute 1	H302 H315 H319 H400	H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. H400: Very toxic to aquatic life.	GHS07 GHS09 Wng	H302 H315 H319 H400	-

DSD:

Classifi-cation	Risk Phrase Codes	Risk Phrases	Safety Phrases	Indications of danger	Concen-tration Limits
Xn Xi N	R22 R36/38 R50	R22: Harmful if swallowed. R36/38: Irritating to eyes and skin. R50: Very toxic to aquatic organisms.	S2 S26 S61	Xn N	Xn; R22: C ≥ 10 %

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classification by the lead registrant is consistent with harmonised classification.

In addition to the harmonised classification, are the following classifications for other endpoints notified to the Classification and Labelling Inventory:

Hazard Class and Category Codes	Hazard Statement Codes	Hazard Statements
Eye Dam. 1	H318	Causes serious eye damage.
Skin Sens. 1	H317	May cause an allergic skin reaction.
STOT RE 1	H372	Causes damage to organs through prolonged or repeated exposure.
STOT SE 1	H370	Causes damage to organs.
STOT SE 2	H371	May cause damage to organs.

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 populations	☒ Aggregated tonnage
☒ Suspected endocrine disruptor	☐ Other (provide further details below)	

Used by consumers in hair dyes. Many industrial uses identified. There are multiple repeated dose toxicity studies, the lowest no adverse effect level (NOAEL) associated with a reproducible effect (body weight changes) is 80 mg/kg bw/day. No carcinogenic effects were observed. CNS effects of acute nature only. Further clarification is needed about exposure of consumers and workers.

The two generation study indicates no effects on fertility parameters according to the registration data.

In the registration data it is concluded that there is no concern for developmental toxicity. However, there was a significant increase in the incidence of fetuses with an incompletely ossified interparietal at 40 and 80 mg/kg/day, when compared to controls (p0.05 and p0.01, respectively). The incidence of incompletely ossified parietals was also significantly greater at 80 mg/kg/day, when compared to controls (p0.05). In the absence of any effects at 250 mg/kg/day, these observations were not considered to be treatment-related.

Under specific investigations the registrant discusses thyroid toxicity putting together human and animal data; inconclusive according to registration data. Thyroid hormones regulate a number of biological processes in the body being essential for growth, development and differentiation, especially for developing brain. There is a need to clarify if the effects of resorcinol on the thyroid gland in animals, particularly rats, are relevant in humans. Adverse thyroid gland effects of resorcinol have been reported in clinical case histories. The two generation study indicates no concern according to registration data. There is self-classification as STOT SE1 H370 (CNS and blood effects). Further clarification is needed about effects on development, especially for brain.

Resorcinol is included in the EC endocrine substances list based on conclusion for evidence of endocrine disrupting properties and high concern of exposure. The human health relevant endocrine disruption data were evaluated as category 1 and the wildlife relevant endocrine disruption data as category 3. It was considered that there is clear evidence of interference with T3 and T4 metabolism in rat and epidemiological studies suggesting a goitrogenic activity in humans.

Danish Centre on Endocrine Disrupters (CEHOS) has evaluated resorcinol according the basis of the Danish proposal for criteria for endocrine disrupters and according to the Joint British-German Position Paper: Regulatory Definition of an Endocrine Disrupter in relation to Potential Threat to Human Health that is based on potency cut-off criteria. Mainly based on human studies resorcinol was placed in Category 1 Endocrine disrupter according the Danish criteria. According to the DE-UK criteria, it was unclear whether resorcinol can be considered as an endocrine disrupter of very high regulatory concern. (Evaluation of 22 SIN List 2.0 substances according to the Danish proposal on criteria for endocrine disrupters, Danish Centre on Endocrine Disrupters, May 2012).

3.3 Information on aggregated tonnage and uses

☐ 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 tpa	
☒ 10,000 + tpa	☐ Confidential	

Note: In addition to the above ticked tonnage band there is confidential tonnage band.

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Numerous uses, including rubber and resins, in cosmetics, pharmaceuticals and hair dye.

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

☐ Compliance check final decision	☒ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☒ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

Harmonised classification in Annex VI of the CLP and in Dangerous substances Directive (see section 2.1).

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	

Information about effects on thyroid hormone system. The available and the requested information are evaluated on the basis of the criteria for ED chemicals.

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☐ Authorisation	☒ Other (provide further details)

If possible, elaborate on the possible follow-up regulatory action(s), in case the suspected risk is confirmed after receiving further information and finalization of the evaluation.

Depending on the outcome of the evaluation, Annex XV dossier for SVHC (article 57(f)).