# Justification for the selection of a candidate CoRAP substance

| | |
|---|---|
| **Substance Name (Public Name):** | 4-hydroxybenzoic acid |
| **Chemical Group:** | Organic acid |
| **EC Number:** | 202-804-9 |
| **CAS Number:** | 99-96-7 |
| **Submitted by:** | Ministry of Environment, Czech Republic |
| **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

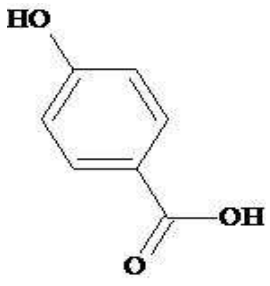
## 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

| | |
|---|---|
| **Public Name:** | 4-hydroxybenzoic acid |
| **EC number:** | 202-804-9 |
| **EC name:** | 4-hydroxybenzoic acid |
| **CAS number (in the EC inventory):** | |
| **CAS number:** | 99-96-7 |
| **CAS name:** | Benzoic acid, 4-hydroxy- |
| **IUPAC name:** | 4-hydroxybenzoic acid |
| **Index number in Annex VI of the CLP Regulation** | - |
| **Molecular formula:** | C7H6O3 |
| **Molecular weight or molecular weight range:** | 138.1207 |
| **Synonyms:** | p-Hydroxybenzoesäure<br>para-hydroxybenzoic acid<br>PHBA<br>p-HBA<br>4-hydroxybenzoic acid<br>PHBS<br>p-Salicylsäure<br>4-Carboxyphenol<br>p-salicylic acid<br>p-Hydroxybenzoic acid<br>4-Hydroxybenzoesäure<br>para-Hydroxybenzoesäure<br>p-HBS |

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

**Structural formula:**



# 2 CLASSIFICATION AND LABELLING

## 2.1 Harmonised Classification in Annex VI of the CLP

Not applicable

## 2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

## 2.3 Self classification

The follwing self classification is given in the registrations:

**CLP**:

- Eye Damage 1 - H318: Causes serious eye damage.
- STOT SE 3 - H335: May cause respiratory irritation.

  Route of exposure: Oral for extremely high dosages.

  Route of exposure: Inhalation. Depending on the physical state, the risk of inhalation can vary.

**DSD**: Xi; R37 Irritating to respiratory system

Xi; R41 Risk of serious damage to eyes.

**The Classification and Labelling Inventory:**

In addition to the self classification given above, are the following notified:

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

Skin Irrit. 2; H315: Causes skin irritation.

Acute Tox. 4; H302: Harmful if swallowed

# 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) | |

***Information from databases:***

| | |
|---|---|
| **EC Endocrine Substances Database** | Conclusion: Clear Evidenc of ED effects<br>Human Health: CAT1 Wildlife CAT3b |
| **QSAR toolbox profiler ERBA** | YES Weak Potential for ER Binding |
| **Predicted ERBA TIMES** | |
| **FDA Endocrine Screening Database** | Non Potential Endocrine Disrupter via ER<br>Gene/Species:/Structure:/Assay: ER Gene (Reporter Gene Assay) |

The technical function of the substance is reported as intermediate. Potential uses as preservative in cosmetics identified from publicly available information. SPIN DB also indicates narrow uses. Read across from acetylsalicilic acid and methylparaben in reproductive section is claimed. RCRs for workers are well below 1. Some in vitro studies on ER binding are included in the registration data. It is recommended to be considered with other structurally similar substances, to investigate potential for exposure during the life cycle and to assess the information from the EC Database. (Note: to be considered together with other parabens and acetylsaliciic acid).

Repeated dose toxicity: longest duration 42 days, males only.

Reproductive toxicity: poorly reported screening study with conflicting results. NOEL parental systemic toxicity 40 mg/kg/day (body weight) and reproductive and developmental NOEL at 1000 mg/kg, dose spacing in appropriate. Old developmental toxicity studies in multiple species, read-across from metylparaben. No two generation study.

Specific investigation uterothrophic assay in mice no effect on uterine weight.

## 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 tpa | ☐ <1 . . . . . >+ tpa |
| ☐ Confidential | | |

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

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

| | |
|---|---|
| ☐ Compliance check | ☐ 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) | |

## 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) | |

Investigation of potential for endocrine disruption and more detailed information on repeated dose toxicity and reproductive toxicity are needed.

## 3.6 Potential follow-up and link to risk management

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

Depending on the outcome of the evaluation it could be appropriate to consider SVHC identification.