SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

4-hydroxybenzoic acid

EC No 202-804-9

CAS No 99-96-7

Evaluating Member State(s): Czech Republic

Dated: 26th May 2016

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2014

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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1. CONCERN(S) SUBJECT TO EVALUATION

4-hydroxybenzoic acid was originally selected for substance evaluation in order to clarify initial grounds for concern:

- suspected endocrine disruptor

- consumer use

- high (aggregated) tonnage

During the evaluation also other concerns were identified. The additional concerns were:

reproductive toxicity, developmental and repeated dose toxicity

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	
Need for other Community-wide measures	
No need for regulatory follow-up action	X

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

Not applicable.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

3.1.3. Need for restrictions

Not applicable.

3.1.4. Proposal for other Community-wide regulatory risk management measures

Not applicable.

3.2. NO FOLLOW-UP ACTION NEEDED

At the moment there is no follow up action needed under REACH Article 48.

The concern could be removed because	**Tick box**
Hazard and /or exposure was verified to be not relevant and/or	
Hazard and /or exposure was verified to be under appropriate control and/or	X
The registrant modified the applied risk management measures.	

Based on unpublished and published available information it can be concluded that for the evaluated substance concerns about the endocrine activity are unjustified. The inclusion of 4-HBA in the Priority list (database of substances with ED potential) can be attributed to precautionary criteria and unavailability of the unpublished study with negative results already available at the time of the inclusion.

The estrogenic activity of 4-HBA is insignificant considering that the positive result from first UT assay from Priority list is isolated.

This is concluded with regard to later results from UT assays together with negative results in binding assay on ERRγ (unlike parabens in the same assay). This is also supported e.g. by no activity (comparing to parabens) in toxicity study by yolk protein induction addressing hazard towards environment. All available data suggested that 4-HBA as such is inactive in connection with the endocrine activity in contrast to alkyl parabens in general. The concern in relation with endocrine disruption as main concern was not confirmed within this evaluation and 4-HBA is not regarded as having estrogenic activity.

It should be also noted, that the identified use presented currently in the registration dossiers is only intermediate (transported, isolated) for industry sectors. Information about uses and relevant amounts used in EU confirm that there is no consumer or professional use. It became clear that uses, which might lead to additional concerns on the basis of tonnage and exposure to general population, are not relevant for the evaluated substance.