

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** Isobutyl 4-hydroxybenzoate

**EC Number:** 224-208-8

**CAS Number:** 4247-02-3

**Authority:** Denmark

**Date:** 23 June 2022

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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[[1]](#footnote-1).

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

In an opinion from 2013, the scientific committee of consumer safety (SCCS) concluded that data was lacking to ensure safe use of isobutylparaben (IBP) in cosmetic products. As a consequence, the substance was removed from Annex V (the list of preservatives allowed in cosmetic products) of the cosmetic regulation and listed in Annex II of prohibited substances (Commission regulation (EU) No 358/2014).

In 2017, the Danish Centre on Endocrine Disruptors (CeHoS) published a report evaluating IBP among 13 substances according to the WHO definition of an endocrine disruptor or a potential endocrine disruptor[[2]](#footnote-2). The report concluded that, despite of a significant data gap, there is some evidence of *in vitro* and *in vivo* estrogenic activity and adverse effects on sperm motility and sperm numbers in male pups, and effects on sexual dimorphic behaviour.

In 2020, the structurally related substance butylparaben (BP) was identified as an endocrine disruptor in humans according to REACH Article 57(f). Based on a thorough read-across analysis to this substance, it is considered that there is substantial data suggesting that IBP is an endocrine disruptor.

In Q2 of 2022, the discussion of the hazard properties of IBP in the Endocrine Disruptor Expert Group (ED-EG) was running in parallel with the present RMOA. Several comments were received from the members of the expert group, supporting the conclusion that IBP is an endocrine disrupter.

### CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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| --- | --- |
| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level: | X |
| *Harmonised classification and labelling* |  |
| *Identification as SVHC (authorisation)* | X |
| *Restriction under REACH* |  |
| *Other EU-wide regulatory measures* |  |
| Need for action other than EU regulatory action |  |
| No action needed at this time |  |

### Need for follow-up regulatory action at EU level

IBP is considered to fulfil the criteria for an SVHC according to REACH Article 57f based on evidence on the substance itself supported with read-across to the endocrine disrupting substance BP.

According to the registration dossier, IBP is used in the production of consumer products such as various Do-It-Your-Self products and modelling clay. This underlines the need for further risk management of the substance to encourage substitution and to avoid potential regrettable substation from BP to IBP.

It is very likely that feasible, easily accessible alternatives to IBP are available. Examples could be other preservatives that are approved for use in cosmetic products, listed in Annex V of the cosmetic regulation (Regulation (EC) No 1223/2009).

### Identification as a substance of very high concern, SVHC (first step towards authorisation)

SVHC identification is the only mean of identifying substances as endocrine disruptors. IBP is considered to fulfil the criteria for identification as a substance of very high concern in accordance with REACH Article 57f.

As it is currently not possible to classify substances for endocrine disrupting properties under CLP, identification of IBP as an SVHC would be the only available possibility to achieve an EU-wide agreement on the endocrine disrupting properties of this substance. Furthermore, identification of IBP as SVHC would be a strong signal to enterprises manufacturing, importing and using IBP to substitute this substance, in addition, to avoid using IBP as a substitution for BP as a consequence of the SVHC identification of BP.

Following an SVHC identification of IBP, subsequent inclusion in Annex XIV could be a possible next regulatory risk management step. Those substances that are identified according to Article 57(f) owing to their endocrine disrupting properties will most likely be treated as non-threshold substances. As long as the registrant cannot demonstrate a safe threshold, it is very likely that IBP would fall under the socio-economic route to authorisation.

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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| **Follow-up action** | **Date for follow-up**  | **Actor** |
| Submission of SVHC proposal in accordance with REACH Art. 57(f) | August / 2022  | Member State - DK |

1. For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation> [↑](#footnote-ref-1)
2. <https://backend.orbit.dtu.dk/ws/files/162337566/DK_ED_list_final_2018.pdf> [↑](#footnote-ref-2)