

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** 2-(4-tert-butylbenzyl)propionaldehyde

**EC Number:** 201-289-8

**CAS Number:** 80-54-6

**Authority: Swedish Chemicals Agency**

**Date: 2019-06-25**

**DISCLAIMER**

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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

**Completed or ongoing processes**

|  |  |  |
| --- | --- | --- |
| RMOA |  | Risk Management Option Analysis (RMOA) other than this RMOA |
| REACH Processes | Evaluation | Compliance check, Final decision |
| Testing proposal |
| CoRAP and Substance Evaluation |
| Authorisation | Candidate List |
| Annex XIV |
| Restri-ction | Annex XVII[[2]](#footnote-2) |
| Harmonised C&L |  | Annex VI (CLP) (see section 3.1) |
| Processes under other EU legislation |  | Plant Protection Products Regulation  Regulation (EC) No 1107/2009 |
|  | Biocidal Product Regulation  Regulation (EU) 528/2012 and amendments |
| Previous legislation |  | Dangerous substances Directive  Directive 67/548/EEC (NONS) |
|  | Existing Substances Regulation  Regulation 793/93/EEC (RAR/RRS) |
| (UNEP) Stockholm convention (POPs Protocol) |  | Assessment |
|  | In relevant Annex |
| Other processes/ EU legislation |  | Other (provide further details below) |

The possible PBT/vPvB-properties of the substance was discussed in the PBT expert group at ECHA in 2016 and the conclusion was that 2-(4-tert-butylbenzyl)propionaldehyde was not considered to meet the PBT/vPvB criteria of REACH Annex XIII.

The possible ED-properties of the substance was discussed in November 2017 by the advisory ED expert group at ECHA, but no conclusion was reached as data were considered inconclusive.

The Scientific Committee on Consumer Safety (SCCS) concluded in their opinion from 2017 on the safety of the substance in cosmetic products that they could not conclude on the safety and that the evaluation by scientific bodies (under REACH) will also need to be taken into consideration for any future assessment of the substance (SCCS, 2017). The reason for this was that genotoxicity of butylphenyl methylpropional could not be excluded.

### 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: |  |
| *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

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

In the Committee for Risk Assessment (RAC) opinion, adopted 28 January 2019, the resulting Annex VI entry, if agreed by the COM, is Repr. 1B, H360Fd[[3]](#footnote-3).

2-(4-tert-butylbenzyl)propionaldehyde is thus considered to fulfil the criteria for classification as toxic for reproduction in category 1B and therefore fulfils the criteria as SVHC according to Article 57 (c) of REACH. The Swedish Chemicals Agency proposes to identify 2-(4-tert-butylbenzyl)propionaldehyde as an SVHC for inclusion in the Candidate List, with the primary aim to provide pressure on industry to substitute the substance with less hazardous fragrance materials.

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

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| **Follow-up action** | **Date for follow-up** | **Actor** |
| Submission of REACH Annex XV dossier for SVHC | February/2020 | Sweden |

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. Please specify the relevant entry. [↑](#footnote-ref-2)
3. https://www.echa.europa.eu/documents/10162/9b07d500-5c11-4e47-9c30-57a203f9f644 [↑](#footnote-ref-3)