Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis Conclusion Document

Benzyl alcohol in consumer products

Substance Name: Benzyl alcohol
EC Number: 202-859-9
CAS Number: 100-51-6

Authority: Germany
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Foreword

The purpose of a 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.

An 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 assess whether further regulatory management measures are needed.

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. Because 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.

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Benzyl alcohol was subject to a substance evaluation (SEv) by the German Competent Authority (DE CA) in 2016. A decision[1] was sent to the registrants of the substance in 2018. The SEv was concluded in 2021 indicating that numerous of the diverse uses of benzyl alcohol pose health risks for consumers, particularly with regards to dermal and inhalation exposure[2].

Currently, benzyl alcohol bears a harmonised classification (CLH) for acute toxicity only, which was set under Directive 67/548/EEC and translates into a minimum classification of Acute Tox. 4* (oral), H302: "Harmful if swallowed", and Acute Tox. 4* (inhalation), H332: "Harmful if inhaled". Minimum classification for a category is indicated by an asterisk.

A proposal for harmonised classification and labelling for benzyl alcohol (according to CLP art. 37(2)) was prepared by the DE CA with regards to the hazard classes acute toxicity, eye irritation and skin sensitisation. The proposal was submitted to ECHA in 2020, and the Committee for Risk Assessment (RAC) adopted its opinion to classify benzyl alcohol as Acute Tox. 4 (H302; ATE = 1230 mg/kg bw), Eye Irrit. 2 (H319) and Skin Sens. 1B (H317) in September 2021[3]. The inclusion of these classifications into Annex VI of CLP is currently pending.

According to the Cosmetic Products Regulation (EC) No 1223/2009 (EU, 2009b), benzyl alcohol has to be declared as an ingredient if its concentration exceeds 0.001 % in leave-on products and 0.01 % in rinse-off products, respectively. As a preservative, benzyl alcohol shall not exceed 1 % in the ready-for-use preparation.

Allergenic substances such as benzyl alcohol must be labelled on the packaging of detergents if added at concentrations exceeding 0.01 % (EU Regulation No 648/2004 on detergents) (EC, 2004).

Directive 2009/48/EC states that toys shall not contain benzyl alcohol because it is considered to be an allergenic fragrance (EU, 2009a). Exceptions are made for olfactory board games, cosmetic kits and gustative games under certain conditions.

Benzyl alcohol is regulated under the Biocides Product Regulation (BPR, Regulation (EU) 528/2012). It is listed in Annex I of Regulation (EU) 1451/2007 (EU, 2007) as an existing biocidal active substance. Currently, benzyl alcohol is in the biocidal active substance approval process for product type (PT) 6 (preservatives for products during storage).

Benzyl alcohol is classified by EFSA's Scientific Committee for Food (SCF-L) as a substance that is approved for the use of materials and articles intended to come into contact with food (List 1). The acceptable or tolerable daily intake (ADI/TDI) as set by this committee is 5 mg/kg bw (Council of Europe, 2002).

The addition of benzyl alcohol to some food items is further regulated in Regulation (EC) 1333/2008. The EFSA Panel on Contaminants in the Food Chain (CONTAM) recently re-evaluated the use of benzyl alcohol (E 1519) when used as food additive (EC, 2004; EMA, 2017; European Food Safety Authority, 2019) and established an ADI of 4 mg/kg bw per day. Overall it was concluded *"that the exposure to benzyl alcohol (E 1519) does not raise*

[1] https://echa.europa.eu/documents/10162/9b4cdcf2-9c23-7f17-87c6-390786e0cc06
[2] https://echa.europa.eu/documents/10162/f5bb38d2-5514-2999-8ae3-eae557021f08
[3] https://echa.europa.eu/documents/10162/c6a97dfc-3ff0-a9cf-fa11-e02328353d5a

a safety concern at the reported uses and use levels".

According to Regulation (EU) 10/2011 on Plastic Materials and Articles Intended to Come into Contact with Food (EU, 2011), the use as additive or polymer production aid is not allowed.

In 2017, the European Medicines Agency (EMA) concluded that benzyl alcohol must not be used as excipient in the treatment of pre-term and full-term neonates (EC, 2004; EMA, 2017). EMA accordingly recommended revising and implementing information on this exemption in the package leaflet of medicinal products. The conclusion was based on data showing that *"benzyl alcohol administered intravenously has led to 'gasping syndrome' in several pre-term neonates with metabolic acidosis involving deterioration of the neurological state, cardio-vascular failure and haematological anomalies. The majority of poisonings were fatal. This syndrome was associated with the accumulation of benzyl alcohol and its metabolite, benzoic acid."*

Table 1: Overview of other processes/EU Legislations that address benzyl alcohol

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
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 (for details see text above in section 1)

2. CONCLUSION OF RMOA

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

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Not applicable.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Not applicable.

5. NO ACTION NEEDED AT THIS TIME

It is noted that, if adopted by COM, benzyl alcohol will be classified for Skin Sens. 1B, H317. Therefore, the substance will be considered in the planned restriction proposal for skin sensitising substances in consumer mixtures[4]. In the course of this activity, appropriate restricting measures will be evaluated to control risks arising from harmonised classified skin sensitisers (including benzyl alcohol) that are used in mixtures available to consumers. A Call for Evidence on skin sensitisers in consumer mixtures recently took place until 31/10/2022[5] in order to obtain information on the presence of skin sensitising substances in mixtures with consumer uses, including information on known safe uses. In

[4] https://ec.europa.eu/docsroom/documents/49734
[5] https://echa.europa.eu/de/previous-calls-for-comments-and-evidence/-/substance-rev/70301/del/50/col/synonymDynamicField_1495/type/desc/pre/1/view

addition, epidemiological data on allergic contact dermatitis and information on health costs are requested. Moreover, the Call for Evidence is issued to assess (i) whether there are risks that are adequately controlled under specific conditions, and (ii) what impact additional regulatory risk management would have on society.

Thus, to avoid duplication, the present RMOA is concluded without assessing potential risks for the diverse uses of benzyl alcohol and without designating potential follow-up regulatory management measures (RMM). The aMSCA, however, will monitor the restriction processes closely until specific regulatory action has been decided on. The aMSCA will subsequently assess whether the restrictions of benzyl alcohol (among other skin sensitisers) will be sufficient to control consumer health risks of benzyl alcohol that were identified during the SEv process. This may be evaluated in an additional follow-up RMOA by the aMSCA.

6. 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.

Follow-up action	Date for follow-up	Actor
Follow-up assessment (e.g. in the frame of another RMOA)	TBD	DE CA

7. REFERENCES

Council of Europe (2002): List of FCMs for Paper and Board (Tech Doc No. 1), Resolution AP (2002)1 on Paper and Board Materials and Articles Intended to Come into Contact with Foodstuffs

EC (2004): Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (Text with EEA relevance). The European Parliament and the Council of the European Union. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0648 (last accessed on 26.11.2020)

EMA (2017): Questions and answers on benzyl alcohol used as an excipient in medicinal products for human us. European Medicines Agency (EMA) / Committee for Human Medicinal Products (CHMP)

(2007): Commission Regulation (EC) No 1451/2007 of 4 December 2007 [Biocides], Annex I, Active substances identified as existing. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32007R1451

(2009a): Directive 2009/48/EC Of The European Parliament And Of The Council of 18 June 2009 on the safety of toys. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20140721&from=EN

(2009b): Regulation (Ec) No 1223/2009 Of The European Parliament And Of The Council of 30 November 2009 on cosmetic products. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&from=EN

(2011): Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0010

European Food Safety Authority (2019): Re-evaluation of benzyl alcohol (E 1519) as food additive. EFSA Journal 17 (10), 5876. DOI: 10.2903/j.efsa.2019.5876