Risk Management Option Analysis Conclusion Document

1,3-dioxolane in consumer products

Substance Name: **1,3-dioxolane**
EC Number: **211-463-5**
CAS Number: **646-06-0**

Authority: DE CA (aMSCA)
Date: 15.12.2022

Version 2.1
October 2015

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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 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. 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.

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

In 2016, a SEv process for 1,3-dioxolane was initiated by the German Competent Authority (DE CA). Concerns included mutagenicity, reproductive toxicity, narcotic effects, skin irritation, serious eye damage, and consumer exposure. In 2022, the SEv of 1,3-dioxolane was concluded[1]; however, the concern regarding consumer exposure remained unsolved. As additional information particularly on specific consumer products was needed, this RMOA was initiated, which subsequently enabled the description of relevant exposure scenarios and estimates in particular for inhalation exposure of consumers.

1,3-dioxolane bears a harmonised classification for Flam. Liq. 2, H225 according to the CLP Regulation (table 3.1, Annex VI, Regulation (EC) 1272/2008). A further CLH proposal was submitted to ECHA by the industry in 2019 (proposal for Flam. Liq. 2, H225, Eye Irrit. 2, H319 and Repr. 1B, H360D), but the proposal was not resubmitted after ECHA's accordance check.

In 2021, ECHA initiated a screening assessment in a regulatory strategy of a group including 1,3-dioxolane (Group Name: Cyclic acetals from aldehydes)[2]. For 1,3-dioxolane, ECHA concluded as a first step a CCH and as follow-up next steps, if the hazards are confirmed, harmonised classification and labelling (CLH), restriction for professional uses, and SVHC identification.

Two dossier evaluations on 1,3-dioxolane were performed by ECHA. Following the first one, the registrants submitted an *in vitro* gene mutation study in bacteria (OECD TG 471) and a pre-natal developmental toxicity (PNDT) study in rabbits (OECD TG 414) in 2015 and 2017, respectively. The latest CCH (2021) requested an extended one-generation reproductive toxicity study (EOGRTS; OECD TG 443), which is currently being performed. Data are expected in April 2024.

2. CONCLUSION OF RMOA

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

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

The present RMOA addresses concerns regarding consumer exposure to 1,3-dioxolane, which could not be clarified during a preceding SEv process that was concluded in 2022.

1 https://echa.europa.eu/documents/10162/4d268951-ff95-e419-6d72-938035609afc (accessed 21. October 2022)
2 https://echa.europa.eu/documents/10162/de4510cd-f219-5476-6c89-10ddd82598d8 (accessed 21. October 2022)

During the course of this RMOA, it was analysed whether 1,3-dioxolane poses a realistic health risk to consumers after inhalation exposure, and whether and which further risk management measures would be necessary in order to protect consumers.

The aMSCA identified 26 consumer products on the EU market that contain 1,3-dioxolane with concentrations up to 100% according to safety data sheets (SDS). Most of the products are related to removing tasks (removal of paints, glues, sealants).

As RCRs above 1 were identified for most of the single and repeated uses of 1,3-dioxolane-containing consumer products, possible risk management measures are discussed.

3.1 Harmonised classification and labelling

In the course of the SEv of 1,3-dioxolane, it was concluded that the substance meets the criteria for classification as STOT SE 3, H336 (May cause drowsiness or dizziness) and Eye Dam. 1, H318 (Causes serious eye damage). Moreover, observed effects in foetuses of rats and rabbits after treatment with 1,3-dioxolane are indicative of the need for harmonised classification of the substance for developmental toxicity. However, data were not considered sufficient for an appropriate sub-categorisation (i.e. Repr. 1B, H360D vs. Repr. 2, H360d). Classification criteria of Category 2 appear to be fulfilled, whereas effects may be considered borderline for Category 1B. Results of an EOGRTS, which is currently being performed as requested by ECHA within a dossier evaluation (CCH)[3], have to be awaited for clarification of the hazard.
When the EOGRTS results are available, a proposal on a harmonised classification will be developed in order to generate an obligation for the labelling of mixtures containing 1,3-dioxolane (≥ 3% if Cat. 2 is warranted, or ≥ 0.3% if Cat. 1B is warranted). A harmonised classification of the substance as Repr. 1B would further lead to 1,3-dioxolane being restricted in mixtures for supply to the general public according to entry 30[4] of Annex XVII of REACH and would also restrict/limit potential cosmetic uses of the substance.

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

SVHC identification could become an option, if criteria for a harmonised classification of 1,3-dioxolane as Repr. 1B are fulfilled. This option may be analysed in more detail after conclusion of the CLH process.

3.3 Restriction under REACH

Following Entry 30[4] of Annex XVII a classification of 1,3-dioxolane as Repr. 1B would result in a ban on the sale of the substance as such and of mixtures containing concentrations of 1,3-dioxolane of 0.3% or more for supply to the general public.

However, if risks are identified at concentrations < 0.3% in consumer products in case of a Repr. 1B classification of the substance or if 1,3-dioxolane will be classified as Repr. 2, initiation of a restriction process is considered the most appropriate regulatory (follow-up) option. A restriction of 1,3-dioxolane in mixtures for supply to the general public may enable the regulation of the use of the substance in specific consumer products.

This option may be analysed in more detail after conclusion of the CLH process.

3 https://echa.europa.eu/documents/10162/7f5478d4-256b-22a7-2972-3250029a092c (accessed 21. October 2022)
4 https://echa.europa.eu/documents/10162/61845f2b-f319-ab2e-24aa-6fc4f8fc150f (accessed 21. October 2022)

4. 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
CLH	2024/2025	DE CA
Restriction	TBD (after CLH)	TBD
SVHC	TBD (after CLH)	TBD