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

Risk Management Option Analysis Conclusion Document

n-Hexane in consumer products

Substance Name: *n*-hexane
EC Number: 203-777-6
CAS Number: 110-54-3

Authority: German CA
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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 2012, a Substance Evaluation (SEv) for *n*-hexane was carried out by German CA and concluded in 2017.

The substance *n*-hexane is currently classified as Flam. Liq. 2, Skin Irrit. 2, Asp. Tox. 1, STOT SE 3, STOT RE 2*, Aquatic Chronic 2 and Repr. 2 according to Annex VI of Regulation (EC) No 1272/2008 (CLP).

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information.

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	x
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 substance *n*-hexane is of general health concern mainly due to its neurotoxicity and suspected reproductive toxicity after repeated inhalation exposure. For neurotoxic effects, a potential uncontrolled risk (RCR > 1) was identified for infrequent use of *n*-hexane containing consumer products indoors. The identified and discussed uncertainties do not allow to exclude realistic unacceptable health risks for consumers and therefore further (regulatory) action is needed. Several RMM options have been assessed.

3.1 Harmonised classification and labelling

The following harmonised classification currently applies for *n*-hexane: Flam. Liq. 2, Asp. Tox. 1, Skin Irrit. 2, STOT SE 3, Repr. 2, STOT RE 2 *, Aquatic Chronic 2a. (Table 3). Additionally, in 2021 the German CA submitted a proposal to modify the STOT RE classification to STOT RE 1, H372 (nervous system). According to its opinion adopted in 2022, RAC agrees with this proposal. The implementation of this modification in Annex VI of the CLP Regulation is still pending[1]. A further proposal for harmonised classification of *n*-hexane is not considered appropriate

[1] https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18166df77

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

The requirements laid down in Article 57 a) - e) are not fulfilled for *n*-hexane. With regards to the severe neurotoxicity of *n*-hexane, there may be sufficient scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern (ELOC) to substances listed in Article 57 a) - e) and hence may meet the criteria for being identified as SVHC (Article 57 f). For this reason, an inclusion in the candidate list and subsequently in Annex XIV may be considered a suitable RMM option. However, *n*-hexane in imported articles would not be covered by a duty for authorisation.

3.3 Restriction under REACH

For the EU market, the German CA identified several consumer products that contain *n*-hexane as constituent or impurity of other registered substances. According to safety data sheets (SDS), the *n*-hexane concentration in these products ranges from 0.1 % to 3 %; in some products also up to 5 %. All the products are rather infrequently used by consumers indoors and often for DIY activities. In the exposure assessment, the German CA assessed a sentinel consumer product that represents various *n*-hexane containing products (adhesives, lacquers and isolating primer products) with consumer use patterns, which are realistic, but sufficiently conservative regarding their exposure parameters (frequency, indoor use and product amounts).

The available information leads to an RCR above 1 (neurotoxic effects), hence clearly demonstrates an unacceptable health risk for consumers for the considered consumer products in the sentinel exposure scenarios. Calculated RCRs are based on exposure estimates and specific DNELs. Both are associated with uncertainties; however, the described uncertainties do not allow to exclude a potential for a realistic unacceptable risk for certain uses by consumers.

Therefore, it is concluded that a restriction may be an appropriate risk management option to ensure that human health risks for consumers are minimised, while taking into account the availability of possible alternatives and socioeconomic impacts. The restriction entry would cover *n*-hexane as a substance, constituent or impurity in other substances and mixtures in specific consumer uses up to a certain threshold.

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
Annex XV dossier for restrictions of specific uses	TBD	German CA
Annex XV SVHC dossier	TBD	TBD