MINISTERIUM FÜR EIN LEBENSWERTES ÖSTERREICH

RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Nitrobenzene

EC No 202-716-0

CAS No 98-95-3

Member State(s): [Austria]

Dated: 3rd July 2015

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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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].

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 other Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Nitrobenzene is covered by index number 609-003-00-7 in Annex VI, Table 3.1 of Regulation (EC) No 1272/2008 amended by Regulation (EC) No 944/2013 (5th ATP)[2]. Its harmonised classification covers the following endpoints: Acute Tox. 3; Carc. 2; Repr. 1B; STOT RE1; Aquatic Chronic 3.

An EU wide indicative occupational exposure limit (OEL) value has been set[3] and other measures to protect workers from risks related to exposure to nitrobenzene are in place[4,5].

The OEL for eight hours is 0,2 ppm (1 mg/m^3) based on the recommendation from the scientific committee on occupational exposure limits (SCOEL) (SCOEL, 2002). SCOEL recommends also to classify nitrobenzene as a skin penetrating compound ("skin notation") based on its rather high skin absorption rate. No short term exposure levels (STEL) are provided.

This indicative OEL has been taken over by AT, BE, FIN, FR, DE, HU, IT, LV, PL, ES, NL and UK. However, DK and SE have set a higher limit value of 1 ppm (5 mg/m^3). Additional short term exposure levels have been set by AT, DK, FIN, DE, and SE[6].

In the frame of the Existing Substances Regulation (ESR) (EEC) No 793/93 a detailed risk assessment has been carried out (RAR, 2007) by the German CA.[7]

2. 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.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	x
Harmonised classification and labelling	
Identification as SVHC (authorisation)	x
Restrictions	
Other EU-wide measures	x
No need for regulatory follow-up action	

[2] Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

[3] Commission Directive 2006/15/EC of 7 February 2006 establishing the second list of indicative occupational limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

[4] Council Directive of June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC).

[5] Council Directive 98/24/EC of April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/291/EEC).

[6] Source: BIA GESTIS International limit values: http://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx

[7] http://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation?search_criteria_name=Nitrobenzene&search_criteria_ecnumber=202-716-0&search_criteria=Nitrobenzene

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

Nitrobenzene exhibits repeated dose toxicity, carcinogenicity and reproductive toxicity and has a harmonised classification as STOT RE 1, Carc. 2 and Repr 1B.

There is concern for the substance nitrobenzene due to its hazardous properties and the potential for exposure at the workplace. While there is prima facie no evidence that the use of nitrobenzene possesses an unacceptable risk which needs to be addressed by a ban on a Union-wide basis, there is concern for workers' health based on the available data, and thus measures should be taken to minimize exposure to workers.

Only few uses amounting to low tonnages of nitrobenzene are presently non-intermediate uses. Concerning the workplace, mainly dermal and inhalation exposure may occur during these uses. The RCRs calculated in the full registration dossier are generally below but for some uses very close to 1. Most of the uses registered for nitrobenzene are considered as intermediate uses which are applied under strictly controlled conditions (SCC). It should be noted, however, that it is not guaranteed that SCC as communicated by the registrants, ensure that the exposure of workers to nitrobenzene is - in view of the relatively low DNEL value derived by the registrant for nitrobenzene (DNEL inhal., longterm, systemic of 0.07 mg/m^3) – actually at safe levels for all of these uses.

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

According to REACH intermediate uses (on-site isolated intermediates and transported isolated intermediates) are exempted from Authorisation (Article 2(8)(b) of REACH). Therefore, the identification of nitrobenzene as an SVHC substance would be related to its non-intermediate uses only. For nitrobenzene the following non-intermediate exposure scenarios have been identified:

- Industrial manufacture of laboratory chemicals and intermediates,
- Industrial use of a laboratory chemical as a processing aid,
- Industrial formulation using laboratory chemicals,
- Industrial use in the manufacture of pharmaceuticals,
- Professional use of laboratory chemicals,
- Professional use in the manufacture of pharmaceuticals.

There is a concern regarding worker exposure and therefore SVHC identification in order to substitute the substance on a long term perspective is desirable. Identification of nitrobenzene as a SVHC and subsequent authorisation would increase pressure to industry to substitute the remaining uses by alternatives. For specific uses for which this might not be possible within a short time, authorisation would allow for continued use and, at the same time, ensure that for these uses workers are well protected.

In the frame of the SVHC Roadmap 2020 different criteria have been defined for selecting substances that are relevant for identification as SVHC. These criteria are clearly fulfilled for nitrobenzene:

	Yes	No
a) Art 57 criteria fulfilled?	x	
b) Registrations in accordance with Article 10?	x	
c) Registrations include uses within scope of authorization?	x	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	x	

3.1.2 Other Union-wide regulatory risk management measures – revision of iOEL

The major volume of nitrobenzene is presently used as an intermediate. As described above, for this use concerns may exist for workers manipulating the substance in industrial and professional uses.

The currently applicable EU indicative occupational exposure limit (TWA) of 1mg/m3 (SCOEL, 2002) should ensure protection of workers. However, the OEL value is 14-fold higher than the DNEL derived by the registrants on the basis of REACH for inhalative exposure.

Therefore it is proposed that the two responsible scientific committees for workers´ protection and for REACH, SCOEL and RAC respectively, should discuss and clarify the existing discrepancies. If appropriate, the OEL or the DNEL or both could be revised accordingly, thus establishing a sufficient protection of workers from potential exposure to nitrobenzene during intermediate use.

3.1.3 Other actions

The verification of the application of the strictly controlled conditions in the use of nitrobenzene as an intermediate is part of the enforcement activities by Member States. Additional or more specific enforcement measures at EU level may be discussed in the Forum of ECHA.

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 intention	Actor
Annex XV SVHC dossier for authorisation	August 2015	MS Austria