5 September 2018

Draft background document for 2-methoxyethanol

Document developed in the context of ECHA's ninth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of 2-methoxyethanol on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: 2-methoxyethanol
EC Number: 203-713-7
CAS Number: 109-86-4

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[2]. Results of the prioritisation of all substances included in the Candidate List by January 2018 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

2.1. Intrinsic properties

2-methoxyethanol was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360FD ("May damage fertility. May damage the unborn child") and was therefore included in the Candidate List for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

2.2. Volume used in the scope of authorisation

The amount of 2-methoxyethanol manufactured and/or imported into the EU is according to registration data in the range of 1,000 - 10,000 t/y (ECHA, 2018). Some uses appear not to be in the scope of authorisation, such as use as intermediate in the manufacture of chemicals and use as laboratory chemical in scientific research and development. Based on the registration information on volumes corresponding to different uses of the substance, the volume in the scope of authorisation is estimated to be in the range of 1,000 - 10,000 t/y.

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of 2-methoxyethanol in the scope of authorisation include uses at industrial sites (formulation of mixtures, use as solvent, processing aid and extraction agent).

More detailed information on uses is provided in Annex I.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.4. Further considerations for priority setting

2-methoxyethanol is considered together with 2-ethoxyethanol as a group, as based on structural similarities and similar uses reported in registrations it appears that 2-methoxyethanol could replace 2-ethoxyethanol in (some of) its uses.

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
2-methoxyethanol is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c). Score: 1	The amount of 2-methoxyethanol used in the scope of authorisation is in the range of 1,000 - <10,000 t/y. Score: 12	2-methoxyethanol is used at industrial sites. Score: 5	18	Grouping with 2-ethoxyethanol

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, 2-methoxyethanol receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise 2-methoxyethanol for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation only when finalising the recommendation and will use all available relevant information including that received in the public consultation. ECHA will apply the Annex XIV entries approach[3] and the criteria described in the implementation document[4].

[3] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

[4] Practical implementation document can be accessed at https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 9th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

ECHA will allocate to the same slot substances considered as a group (see Section 2.4), i.e. 2-methoxyethanol will be allocated to the same slot as 2-ethoxyethanol.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for 2-methoxyethanol.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of 2-methoxyethanol on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the

substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[5]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[6], there is no need to propose an additional specific exemption.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of 2-methoxyethanol for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for 2-methoxyethanol[7].

[5] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/b80fccc0-c055-7cd7-4743-8d3c26956b15, or section C.2 in https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

[6] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

[7] As of 1 February 2018.

4. References

Annex XV SVHC report (2010): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 2-methoxyethanol. Submitted by Austria, August 2010.

https://echa.europa.eu/documents/10162/b6b959c2-14c8-4612-9e91-cf181a867dd2

ECHA (2018): 2-methoxyethanol. ECHA's dissemination website on registered substances. Accessed on 1 February 2018.

https://echa.europa.eu/search-for-chemicals

RCOM (2010): "*Responses to comments*" document. Document compiled by Austria from the commenting period 30/08/2010 – 14/10/2010 on the proposal to identify 2-methoxyethanol as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/8d11abdf-9416-4f6f-9bd2-19292333cb3c

Annex I: Further information on uses

1. Further details on the type of applications, functions and market trend per use

The main manufacturers of the substance state that the manufacture/import of 2-methoxyethanol declined in the last decades (RCOM, 2010), which is confirmed by volumes reported in registration dossiers (<10,000 t/y), compared to 13,787 to 47,870 t/y estimated in the Annex XV SVHC report (2010) submitted before registrations were received for the substance. It is noted, however, that the volume of the substance used within the scope of authorisation has not changed significantly in recent years (ECHA, 2018).

Information submitted in the SVHC public consultation indicated a higher number of uses for 2-methoxyethanol than currently reported in registrations under REACH, e.g. in paints, surface protection, printing, dyeing, hydraulic fluids (RCOM, 2010). The number of uses has been reduced considerably in the last years. Substitution seems to have happened in many sectors, and alternatives for both 2-ethoxyethanol and 2-methoxyethanol, which are structurally very similar solvents, seem to be available (Annex XV SVHC report, 2010).

Comments received during SVHC public consultation indicate that 2-methoxyethanol is used as solvent in the pharmaceutical/medicinal sector RCOM (2010).

In registrations professional uses of the substance as laboratory chemical in scientific research and development are reported, which however are considered outside the scope of authorisation.

2. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from public consultation, to allocate the substance group to a specific LAD slot in the final recommendation.

2-methoxyethanol is manufactured and/or imported by a limited number of registrants. No precise and up-to-date information is available on the number of industrial sites where the substance is currently used.

The supply chain can be characterised[8] by the following actors: Formulators and end-users at industrial sites (relevant life cycle stages: F, IS).

2-methoxyethanol is used as a solvent or extraction agent, for pharmaceutical products or preparations, in the production of photo-chemicals and washing and cleaning products (relevant product categories, PC0: Solvent, PC29, PC30, PC35, PC40).

The following sectors rely on the substance for some of their uses: manufacturers of fine chemicals and bulk chemicals (relevant sector of uses: SU9, SU8).

Some categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from the information on uses available in the registration dossiers.

[8] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf