

1 October 2019

## 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<sup>1</sup>, as well as the MSC opinion<sup>2</sup> were taken into consideration when finalising the recommendation and are reflected in the present document.

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<sup>1</sup> As of the last day of the public consultation, i.e. 5 December 2018

<sup>2</sup> Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

## 1. Identity of the substance

Identity of the substance as provided in the Candidate List<sup>3</sup>:

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<sup>4</sup>. 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 are available at

[https://echa.europa.eu/documents/10162/13640/prioritisation\\_results\\_cl\\_substances\\_sept\\_2018\\_en.pdf](https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf).

The prioritisation results of the substances included in the draft 9th recommendation have been updated as necessary after the public consultation. The updated results are available at [https://echa.europa.eu/documents/10162/13640/prioritisation\\_results\\_draft9threc\\_substances\\_October2019\\_en.pdf](https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft9threc_substances_October2019_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 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).

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<sup>3</sup> For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

<sup>4</sup> Document can be accessed at [http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

More detailed information on uses is provided in Annex I.

## 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, 2-methoxyethanol is recommended for inclusion in Annex XIV.

## 3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV<sup>5</sup> and as further specified in the practical implementation document<sup>6</sup>. The draft Annex XIV entries for all the substances that underwent public consultation are available at

[https://www.echa.europa.eu/documents/10162/13640/9th\\_recom\\_draft\\_axiv\\_entries\\_en.pdf](https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf).

The final draft Annex XIV entries that ECHA recommends are available at [https://echa.europa.eu/documents/10162/13640/9th\\_axiv\\_recommendation\\_October2019\\_en.pdf](https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf).

<sup>5</sup> General approach can be accessed at

[https://echa.europa.eu/documents/10162/13640/recom\\_general\\_approach\\_draft\\_axiv\\_entries.pdf](https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf)

<sup>6</sup> Practical implementation document can be accessed at

[https://echa.europa.eu/documents/10162/13640/recom\\_general\\_approach\\_draft\\_axiv\\_entries\\_draft\\_implementation\\_en.pdf](https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf)

### 3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for 2-methoxyethanol:

Latest application date (LAD):	Date of inclusion in Annex XIV plus 18 months
Sunset date:	18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

ECHA made the final LAD allocation using all available relevant information including that received in the public consultation.

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

### 3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for 2-methoxyethanol.

During the public consultation, comments were received arguing for the need to have long review periods to ensure the availability of important pharmaceuticals. However, the setting of upfront review periods requires detailed use-specific information which should be provided in applications for authorisation. Furthermore, all authorisation decisions include review periods that are set case-by-case for each use applied for (see also RCOM, 2019).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of 2-methoxyethanol.

### 3.3. Uses or categories of uses exempted from authorisation requirement

#### 3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of 2-methoxyethanol on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation ECHA received some requests for exemptions, in particular for the use as a solvent in the synthesis of pharmaceuticals. Those requests were referring to other existing Community legislation, such as Directive 2010/75/EU on industrial emissions (IED) or Directive 98/24/EU on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD).

In its opinion MSC expresses the view that there appears to be no grounds for an exemption under Article 58(2).

ECHA has carefully assessed all the requests made (see detailed assessment in Section C, in particular C.2, of the response document (RCOM, 2019)). ECHA concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of 2-methoxyethanol, and therefore does not 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.

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

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of 2-methoxyethanol for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of public consultation.

ECHA therefore does not recommend exempting any use of 2-methoxyethanol for PPORD from authorisation.

## 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>

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include 2-methoxyethanol in its 9<sup>th</sup> recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

[https://echa.europa.eu/documents/10162/13640/9th\\_recom\\_comref\\_methoxyethanol\\_en.rtf](https://echa.europa.eu/documents/10162/13640/9th_recom_comref_methoxyethanol_en.rtf)

ECHA (2018): 2-methoxyethanol. ECHA's dissemination website on registered substances. Accessed on 5 December 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>

RCOM (2019): "Responses to comments" document. Document compiling the responses to comments by ECHA from the commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include 2-ethoxyethanol and 2-methoxyethanol in its 9<sup>th</sup> recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

[https://echa.europa.eu/documents/10162/13640/9th\\_recom\\_respdoc\\_methoxy\\_ethoxyethanol\\_en.pdf](https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_methoxy_ethoxyethanol_en.pdf)

## Annex I: Further information on uses

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

During the SVHC public consultation, the main manufacturers of the substance stated 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 were made to allocate the substance to a specific LAD slot. For the purpose of LAD assignment groups of substances are considered together. The information for the group is summarised below.

2-methoxy- and 2-ethoxyethanol are manufactured and/or imported by a limited number of registrants. According to updated registration information (ECHA, 2018) and comments received (ComRef, 2019), the substances are used as solvents at a limited number of sites.

The supply chain can be characterised<sup>7</sup> by the following actors: formulators, users at industrial sites and professional workers (relevant life cycle stages: F, IS, PW).

2-methoxy- and 2-ethoxyethanol are used as solvents or extraction agents, 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 seem to rely on the substances for some of their uses in the scope of authorisation: manufacturers of fine chemicals and bulk chemicals (relevant sector of uses: SU9, SU8).

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<sup>7</sup> 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](https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf)

Some of the categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from information on uses available in registration dossiers, comments received (ComRef, 2019) and the Annex XV SVHC report (2010).