2 February 2022

Draft background document for ethylenediamine

Document developed in the context of ECHA's eleventh 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 the 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 consultation on the inclusion of ethylenediamine in the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 2 May 2022) 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: ethylenediamine
EC Number: 203-468-6
CAS Number: 107-15-3

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 July 2021 and not yet recommended or included in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/17232/prior_results_cl_subst_february_2022_en.pdf.

2.1. Intrinsic properties

Ethylenediamine is classified in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Respiratory Sensitiser cat. 1. Taking into account all available information on the intrinsic properties of ethylenediamine and their adverse effects, it was concluded that the substance can be regarded as substance for which in accordance with Article 57 (f) of REACH there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Ethylenediamine was identified as a Substance of Very High Concern (SVHC) according to Article 57 (f) and was therefore included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

2.2. Volume used in the scope of authorisation

The amount of ethylenediamine manufactured and/or imported into the EU is according to registration data above 10,000 t/y (ECHA, 2021). Part of the registered tonnage is related to monomer imported as part of polymers and is therefore not considered for priority assessment. Some uses appear not to be in the scope of authorisation, such as uses as intermediate and, to the extent the conditions for the generic exemption are met, uses in scientific research and development.

Taking into account the information on the volume corresponding to those uses provided in registrations, the volume in the scope of authorisation is estimated to be >10,000 t/y.

More detailed information on the main uses and the relative share of the total tonnage is provided in section 1 of 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 https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf

2.3. Wide-dispersiveness of uses

Registered uses of ethylenediamine in the scope of authorisation include uses at industrial sites (e.g. use as processing aid / scavenging agent in refinery streams / corrosion inhibitors; use as process additive) and uses by professional workers (e.g. use as process additive or corrosion inhibitor, use in control of odour emission).

According to registrations the substance is used in plastic articles. Furthermore, the substance has been reported for use in consumer mixtures in the Nordic Product Registers (SPIN database) every year for more than 15 years (last year disseminated: 2019). The use in consumer mixtures is not confirmed in registration dossiers.

More detailed information on uses is provided in section 1 of Annex I.

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
The substance has respiratory sensitising properties with effects to human health meeting the criteria of Article 57 (f) Score: 1	The amount of ethylenediamine used in the scope of authorisation is above 10,000 t/y. Score: 15	Ethylenediamine is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in plastic articles and may be used in consumer mixtures. Refined score: 12-15	28-31 (middle value 30)

Conclusion
On the basis of the prioritisation criteria, ethylenediamine receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise ethylenediamine 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 when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[3] and the criteria described in the implementation document[4]. 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 section 2 of 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 11th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for ethylenediamine.

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 ethylenediamine 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*'.

[3] General approach can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/
[4] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

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 ethylenediamine 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 ethylenediamine [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/10162/17232/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/17232/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[6] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf

[7] As of 1 August 2021.

4. References

Annex XV SVHC report (2018): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Ethylenediamine (ethane-1,2-diamine). Submitted by European Chemicals Agency (ECHA) at the request of the European Commission, February 2018.

https://www.echa.europa.eu/documents/10162/9331faab-92e5-d09a-9239-abb318bce0e5

ECHA (2021): Ethylenediamine. ECHA's dissemination website on registered substances. Accessed on 1 August 2021.

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

RCOM (2018): Comments on an Annex XV dossier for identification of a substance as SVHC and responses to these comments. 15 May 2018.

https://www.echa.europa.eu/web/guest/registry-of-svhc-intentions/-/dislist/details/0b0236e18156fa71

Annex I: Further information on uses

1. Detailed information on uses

The amount of ethylenediamine manufactured and/or imported into the EU is according to registration data above 10,000 t/y (ECHA, 2021). A significant share of the total tonnage for use in the EU is for intermediate uses and would therefore fall outside the scope of authorisation. In 2018, the Ethylene Amines REACH consortium commenting during the SVHC public consultation (RCOM, 2018) indicated having conducted a survey leading to the conclusion that 92% of ethylenediamine was used as intermediate. However, the survey was flagged as not being complete and information is lacking to assess the representativity of the outcome. Based on information currently available in registration dossiers, the volume in the scope of authorisation is estimated to be >10,000 t/y.

The substance is reported in registration dossiers for professional uses e.g. use as process additive or corrosion inhibitor and use in control of odour emission. Professional use as monomer in epoxy, poly urethane and other polymers is also reported for applications in adhesives and coatings. It is to be noted that these registered uses by professional workers are not considered intermediate use and therefore are in the scope of authorisation. The volume for professional uses has been claimed to be low by the REACH consortium (RCOM, 2018) with no further precision of the exact tonnage. There is no information available in registrations on volumes.

There is uncertainty on possible consumer uses. The substance has been reported for use in consumer mixtures in the Nordic Product Registers (SPIN database) every year for more than 15 years (last year disseminated: 2019). However, the use in consumer mixtures is not confirmed in registration dossiers.

Information from registrations, further substantiated by information from the SCIP database (ECHA, 2021) indicates that the substance is present in articles. Some registrants report article service-life (plastic articles). It is assumed that the concentration of ethylenediamine in those articles is above 0.1 % (w/w).

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 consultation, to allocate the substance group to a specific LAD slot in the final recommendation.

Ethylenediamine 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 substances is currently used. According to the Annex XV SVHC report (2018), approximately 22 of 149 ethylenediamine suppliers are based in the EU or EEA countries.

The supply chain can be characterised[8] by the following actors: formulators, users at industrial sites, and professional workers, consumer, articles producers, articles assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, and C, SL). Uncertainty remains on possible consumer uses.

Ethylenediamine seems to be used in the following product categories: Adhesives, sealants, coatings, paints, thinners, paint removes, fuels, heat transfer and hydraulic fluids, ph-regulators,

[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/10162/17224/information_requirements_r12_en.pdf

flocculants, precipitants, neutralisation agents, fillers, putties, plasters, modelling clay, polymer preparations and compounds and water treatment chemicals (relevant product categories: PC 1, PC 9a, PC 9b, PC 13, PC 16, PC 17, PC 20, PC 32, PC 37).

A number of sectors is relying on the substance in some of their uses including manufacturers of fine chemicals and electricity, steam, gas water supply and sewage treatment (relevant sector of use categories: SU 9, SU 23).

Uses of ethylenediamine in the scope of authorisation seem to be relevant for the production of plastic articles (relevant article categories: AC 13). This is confirmed in SCIP notifications.

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers (ECHA, 2021), the Annex XV SVHC report (2019) and/or the SPIN database.