12 April 2023

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[1] as well as the MSC opinion[2] were taken into consideration when finalising the recommendation and are reflected in the present final background document.

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1. Identity of the substance

[1] As of the last day of the consultation, i.e. 2 May 2022.
[2] Opinion of the Member State Committee on the draft eleventh recommendation of the priority substances to be included in Annex XIV, adopted on 8 February 2023.

Identity of the substance as provided in the Candidate List[3]:

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 (ECHA, 2020). 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 are available in ECHA (2022a).

The prioritisation results of the substances included in the draft 11th recommendation have been updated as necessary after the consultation. The updated results are available at in ECHA (2023).

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, 2022b). Part of the registered tonnage is related to monomer imported as part of polymers and is therefore not considered for priority assessment. Part of the tonnage is reported as directly exported outside the EU. Some uses appear not to be in the scope of authorisation, such as uses as intermediate (including use as monomer at industrial sites) 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 as provided in registrations, the volume in the scope of authorisation is estimated to be 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 ethylenediamine in the scope of authorisation include uses at industrial sites

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

(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). During consultation, the use a process additives in formulations used in different sectors was confirmed (ECHA, 2023).

According to registrations the substance is used in plastic and wood articles (ECHA, 2022b).

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 Annex I.

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	
Ethylenediamine 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 1,000-10,000 t/y. Score: 12	Ethylenediamine is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in plastic and wood articles and may be used in consumer mixtures. Refined score: 12	25

Conclusion

On the basis of the prioritisation criteria, ethylenediamine receives priority among the substances on the Candidate List (ECHA, 2023). Therefore, **ethylenediamine 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 (ECHA, 2020) and as further specified in the practical implementation document (ECHA, 2020). The draft Annex XIV entries for all the substances that underwent consultation are available in ECHA (2022a).

The final draft Annex XIV entries that ECHA recommends are available in ECHA (2023).

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for ethylenediamine:

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 recommended 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.

During the consultation, comments supported in general the LAD slot of 24 months (ECHA, 2023).

Based on the assessment performed, the supply chain of ethylenediamine is however concluded as being of relatively lower complexity compared to other substances included in the final recommendation. Therefore, a latest application date of 18 months is recommended.

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

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

ECHA therefore **does not recommend to include in Annex XIV any review periods for uses of ethylenediamine.**

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 uses of ethylenediamine on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the consultation ECHA received requests for exemptions for the use of ethylenediamine in the manufacture of water miscible coolants for steel cord and for the use of ethylenediamine in the production of semiconductor substrates (electronic sector).

In its opinion MSC expresses the view that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

ECHA has carefully assessed the requests made (ECHA, 2023). ECHA concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of ethylenediamine.

ECHA therefore **does not recommend exemptions for uses of ethylenediamine** 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 ethylenediamine for PPORD.

During the 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 the consultation.

ECHA therefore **does not recommend exempting any use of ethylenediamine for PPORD** from authorisation.

4. References

ECHA (2018): Registry of SVHC intentions until outcome - ECHA (europa.eu), filter by substance ethylenediamine (EC 203-468-6).

- Annex XV report. Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Substance name: Ethylenediamine (ethane-1,2-diamine), EC Number: 203-468-6, CAS Number: 107-15-3.

- Comments on an Annex XV Dossier for identification of a substance as SVHC and responses to these comments. Substance name: Ethylenediamine, CAS number: 107-15-3, EC number: 203-468-6.

ECHA (2020): Agreed and applied approaches. 5 March 2020.

Recommendations for inclusion in the Authorisation List - ECHA (europa.eu), filter by substance ethylenediamine (EC 203-468-6)

- Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.

- Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.

- Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2022a): ECHA's 11th draft recommendation. 2 February 2022.
Recommendations for inclusion in the Authorisation List - ECHA (europa.eu), filter by substance ethylenediamine (EC 203-468-6)

- Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2021 and not yet recommended for inclusion in Annex XIV.

- Draft 11th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation).

ECHA (2022b): Ethylenediamine. ECHA's dissemination website on registered substances. Accessed on 2 May 2022.

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

ECHA (2022c): WFD - Waste Framework Directive, SCIP Database, SCIP-Database - ECHA (europa.eu), search by substance ethylenediamine (EC 203-468-6)

ECHA (2023): ECHA's final 11th recommendation. 12 April 2023.
Recommendations for inclusion in the Authorisation List - ECHA (europa.eu), filter by substance ethylenediamine (EC 203-468-6)

- Updated priority assessment results of the substances included in the draft 11th recommendation for inclusion in Annex XIV. 12 April 2023.

- Recommendation of the European Chemicals Agency of 12 April 2023 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation).

- “Responses to comments” document. Document compiling the responses to comments from commenting period 02/02/2022 – 02/05/2022 on ECHA’s proposal to include ethylenediamine in its 11th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

- “Comments and references to responses” document. Document compiling comments and references to respective answers from commenting period 02/02/2022 – 02/05/2022 on ECHA’s proposal to include ethylenediamine in its 11th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

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, 2022b). A significant share of the total tonnage for use in the EU appear to be 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 (ECHA, 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. During the consultation on the eleventh draft recommendation (ECHA, 2022b) the same consortium assessed that the volume for uses falling in the scope of authorisation is likely to be below 1.000 t/y. This could however not be confirmed based on information available in registration dossiers. For a number of registrations, it is possible to conclude on the share of the tonnage outside the scope of authorisation, however, no information is available for a number of non-updated registration dossiers accounting all together for >1.000 t/y. Where the information was available, ethylenediamine volumes not in scope of authorisation have been subtracted from the manufactured and imported volumes to achieve a proper prioritisation score. Volumes subtracted included: Monomer volumes imported as polymer, volumes manufactured in the EU but directly exported for use outside the EU and intermediate uses including use as monomer in polymerisation reactions at industrial site. Based on information currently available in registration dossiers, the volume in the scope of authorisation is estimated to be in the range 1,000- 10,000 t/y

Uses likely to fall under the scope of authorisation includes industrial uses as processing aid / scavenging agent in refinery streams / corrosion inhibitors and use as process additive. During the consultation on the draft recommendation (ECHA, 2023) the use of ethylenediamine in water miscible coolants for processing steel cord for all kind of tires was confirmed. Use as a formulation additive at a certain stage in the processing line of gallium arsenide wafers and as an essential ingredient in a specialty chemical for nickel electroless deposition and in specific photolithography chemicals within the semiconductor manufacturing process were also informed during consultation.
The substance is reported in registration dossiers also for professional uses falling in the scope of authorisation e.g. use as process additive or corrosion inhibitor and use in control of odour emission. Professional use as monomer in epoxy, polyurethane 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 (ECHA, 2018) with no further precision of the exact tonnage. Some registration dossiers have been recently updated and professional uses have been removed, but professional uses was still reported in a number of registrations at the end of the consultation period. There is no information available in registrations on volumes for professional use (ECHA, 2022b).

There is uncertainty on possible consumer uses falling in the scope of authorisation. 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, 2022c) indicates that the substance is present in articles. Article service-life (plastic and wood articles) is reported in some registrations, including in a recent update. It is assumed that the concentration of ethylenediamine in those articles is above 0.1 % (w/w). During the consultation one comment has been received indicating that the substance may also potentially be present in manufactured tires (but in low concentration and with probably limited potential for exposure/release)[4].

[4] The substance is used at concentration <0.5 % in coolants emulsion used to draw steel cord and improve adhesion performance between the steel cord and rubber in the manufactured tire.

2. Structure and complexity of supply chains

The following assumptions were made on the structure and complexity of supply chains associated to uses in the scope of authorisation based on currently available information and were used, together with relevant information from public 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.

The supply chain can be characterised[5] 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, fillers, putties, plasters, modelling clay, fuels, heat transfer and hydraulic fluids, processing aids such as ph-regulators, flocculants, precipitants, neutralisation agents, 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 bulk, large scale chemicals (including petroleum products); manufacture of computer, electronic and optical products, electrical equipment; general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; health services, electricity, steam, gas water supply and sewage treatment (relevant sector of use categories: SU 8, SU 16, SU 17, SU 20, SU 23).

Uses of ethylenediamine in the scope of authorisation seem to be relevant for the production of a number of articles such as vehicles; machinery, mechanical appliances, electrical/electronic articles, plastic and wood articles (relevant article categories: AC 1, AC 2, AC 11, AC 13).

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers (ECHA, 2022b) and the Annex XV SVHC report (ECHA, 2018).

[5] 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