7 February 2024

Draft background document for melamine

Document developed in the context of ECHA's twelfth 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 melamine in the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 7 May 2024) 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: melamine, IUPAC name:1,3,5-triazine-2,4,6-triamine
EC Number: 203-615-4
CAS Number: 108-78-1

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, 2020a). Results of the prioritisation of all substances included in the Candidate List by July 2023 and not yet recommended or included in Annex XIV of the REACH Regulation is available in ECHA (2024a).

2.1. Intrinsic properties

Melamine was identified as a substance meeting the criteria of Article 57(f) of Regulation (EC) 1907/2006 (REACH) as it is a substance for which there is scientific evidence of probable serious effects to the environment and 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 of REACH. Melamine was included in the Candidate List for authorisation on 17 January 2023, following ECHA's decision D(2022)9120-DC.

2.2. Volume used in the scope of authorisation

The amount of melamine manufactured and/or imported into the EU is according to registration data above 10,000 t/y (ECHA, 2023). 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 (including use as monomer at industrial sites) (ECHA, 2023). The tonnage for uses falling outside the scope of authorisation is unclear in registrations, however, according to comments from industry during the SVHC consultation these are estimated as 95 % of the total tonnage (RCOM, 2022).

The volume in the scope of authorisation is estimated to be still > 10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of melamine in the scope of authorisation include uses at industrial sites (e.g. use as additive in foams and coatings, use in resins) and uses by professional workers (use as additive in intumescent coatings) (ECHA, 2023).

Furthermore, according to registrations and substance in article notifications, the substance is used in plastic, metal, leather, textile, and wood articles. Releases of the substance from these articles cannot be excluded. The volume used in those articles is >10 t/y.

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.

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Melamine has equivalent level of concern having probable serious effects to human health and to the environment meeting the criteria of Article 57 (f). Score: 13	The amount of melamine used in the scope of authorisation is > 10,000 t/y. Score: 15	Melamine is used at industrial sites and by professional workers Initial score: 10 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 12	40	None

Conclusion
On the basis of the prioritisation criteria, melamine receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise melamine 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 (ECHA, 2024b):

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 (ECHA, 2020b) and the criteria described in the implementation document (ECHA, 2020c). 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 12th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA does not propose to include in Annex XIV any review period for melamine.

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 melamine 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 general responses to Art. 58(2) exemption requests (ECHA, 2020d). 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 (ECHA, 2024c), 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 melamine 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 melamine[2].

[2] As of 20 July 2023.

4. References

Note: Documents supporting the draft Annex XIV recommendations are available under Recommendations for inclusion in the Authorisation List - ECHA (europa.eu) (filter by substance melamine (EC 203-615-4)). Further information relevant for the consultation can be accessed at Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu). In absence of specific links in the references listed below, the above links are relevant.

Annex XV SVHC report (2022): 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: melamine; 1,3,5-triazine-2,4,6-triamine, EC Number: 203-615-4, CAS Number: 108-78-1. Submitted by Germany, August 2022. Registry of SVHC intentions until outcome - ECHA (europa.eu).

ECHA (2024a): Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2023 and not yet recommended for inclusion in Annex XIV. ECHA's 12th draft recommendation. 7 February 2024.

ECHA (2024b): Draft 12th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation). 7 February 2024.

ECHA (2024c): Generic exemptions from the authorisation requirement. 7 February 2024.

ECHA (2020a): Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.

ECHA (2020b): Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.

ECHA (2020c): Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2020d): ECHA's general responses on issues commonly raised in consultations on draft recommendations.

ECHA (2023): Substance melamine (EC 203-615-4). ECHA's dissemination website on registered substances. Accessed on 20 July 2023. https://echa.europa.eu/search-for-chemicals

RCOM (2022): Comments on an Annex XV Dossier for identification of a substance as SVHC and responses to these comments. Substance name: melamine, EC Number: 203-615-4, CAS Number: 108-78-1. Registry of SVHC intentions until outcome - ECHA (europa.eu).

ECHA (2015): ECHA's guidance on use description: https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf

Annex I: Further information on uses

1. Main (sector of) uses and relative share of the total tonnage

Melamine is a starting material for various polymerisation reactions. According to comments received during the SVHC identification process (RCOM, 2022), melamine is used as a monomer in the manufacture of reactive uncured amino resins (or aminoplasts), primarily melamine-formaldehyde (MF) and melamine-urea-formaldehyde (MUF) resins. These resins are used by the woodworking industry to produce different types of wood-based panels (including composite pallet blocks) and melamine-impregnated papers and foils for surface-coating panels for a wide variety of applications including laminate flooring. In addition, these resins are used as amino crosslinkers in coatings, for the production of foams and for the production of consumer goods such as table ware (Annex XV SVHC report, 2022).

Melamine is also used as an intermediate for the production of other melamine derivatives (salts) such as melamine phosphate, melamine polyphosphate, melamine cyanurate, melamine-poly(zinc phosphate) or melamine borate, which are used as flame retardants in intumescent (fire protective) coatings. Most applications of melamine compounds for fire safety are in intumescent coatings of building structures, rigid foams used in technical applications or in technical plastics in industrial applications (Annex XV SVHC report, 2022).

In smaller quantities, melamine itself is also used as such as a flame retardant in certain specific applications, in particular to reduce flammability of foams, especially polyurethane foams (e.g., in furniture, transport seating, …) and also of rubbers, thermosets, and in intumescent coatings (Annex XV SVHC report, 2022).

As summarised in the Annex XV SVHC report (2022), the BUA report 105 (GDCh, 1992) clarified that the dominant use of melamine is the manufacture of resins, which are manufactured by reactions with alcohols, aldehydes and amines. Formaldehyde adds readily to the amino-groups of melamine, generating hydroxymethylmelamines. These crosslink (harden) readily, with elimination of water. More highly condensed resins are insoluble in water. Further processing of the aminoplastics obtained in this way mainly involves addition of fillers. Melamine resin renders cellulose, starch and other compounds bearing hydroxyl groups waterproof. Relevant application areas are as follows:

- Surface coatings and paints: etherification of melamine and alcohols in conjunction with a) plasticising resins yields stoving finishes for automotive applications that have high alkali resistance, b) epoxide or epoxide ester resins affords wood finishes for floor seals.
- Laminates: in furniture industry, paper or fabric webs are impregnated with melamine resin to generate impact-resistant and scratch-resistant coatings for particle board and plywood.
- Glues and binders: melamine resins are used as binders for top-quality, water-proof particle board and for reinforcing wood glues.
- Paper finishing: addition of melamine resin increases the wet strength and wetabrasion resistance of paper
- Compression-moulding materials: melamine resins are processed with cellulose or cotton linters to produce thermosetting, impact-resistant plastics for the manufacture of household appliances or kitchen utensils
- Textile and leather finishing: cellulose-containing fabric is impregnated with melamine resins in order to enhance dimensional stability, abrasion resistance and wet strength. To some extent, the flammability of fibres is also decreased.
- Melamine resins are moreover used to increase durability and abrasion resistance in the tanning of leather.
- Other: literature reports the possible use of melamine resins as filler in the rubber industry and as matrix for ion-exchanger resins.

According to information in registrations, the industrial use of melamine includes use as monomer / intermediate in the production of melamine resins and melamine salts. Use of resins with unreacted residual melamine is also reported. Other reported industrial uses are in the manufacture of coating, adhesives and inks, production of formica, recycling, textile coatings/applications, leather manufacturing process and use as additive in intumescent coatings/ foams and as laboratory agent (ECHA, 2023). According to comments received during the SVHC consultation, melamine is used in intumescent coatings as a flame retardant or as a synergist. Intumescent coatings are passive fire protection coatings applied typically to building structures/installations e.g. to protect uncovered steel structures (RCOM, 2022).

The use in intumescent coatings is the only use in scope of authorisation registered for the professional workers (ECHA, 2023).

The tonnage used as intermediate in the production of the resins and melamine salts cannot be derived from registration data. However, during the SVHC consultation phase, comments from industry indicated that up to 95% of the total tonnage of melamine manufactured or imported is used as intermediate and not in scope of authorisation (RCOM, 2022).

'Addition to food or feed products' is a 'use advised against' in registrations (ECHA, 2023).

The use of melamine is prohibited in all cosmetic products since 1 December 2023[3].

Melamine is authorised for use as monomer/macromolecule and additive or polymer processing aid in plastic food contact materials with specific migration limits [4].

2. Structure and complexity of supply chains

The following assumptions on the structure and complexity of supply chains associated to uses in the scope of authorisation are made. They are based on currently available information and will be used, together with any relevant information from consultation, to allocate the substance to a specific LAD slot in the final recommendation.

Melamine is manufactured and/or imported by a high number of registrants. No precise and up-to-date information is available on the number of industrial sites where the substance is currently used for uses falling in the scope of authorisation.

The supply chain can be characterised (according to ECHA, 2015) by the following actors: *formulators, users at industrial sites (including articles producers), articles assemblers (multi-layer assembling chain), professional workers* (relevant life cycle stages: F, IS, PW, SLs).

Melamine seems to be used in the following product categories: Adhesives, sealants, coatings and paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, non-metal-surface treatment products, ink and toners, leather treatment products, paper and board treatment products, polymer preparations and compounds, textile dyes, and impregnating products, washing and cleaning products, oil and gas exploration or production products (relevant product categories: PC 1, 9a, 9b, 9c, 15, 18, 23, 26, 32, 34, 35, 41).

A number of sectors is relying on the substance in some of their uses including agriculture, forestry and fishing, mining (without offshore industries), manufacture of textiles, leather, fur, manufacture of wood and wood products, manufacture of pulp, paper and paper products, manufacture of bulk, large scale chemicals (including petroleum products), manufacture of fine chemicals, manufacture of rubber products, manufacture of plastics products, including

[3] EU. Prohibited Substances: Annex II, Regulation 1223/2009/EC on Cosmetic Products, as amended by Regulation (EU) 2023/1490, OJ L 183, 20 July 2023
[4] EU. Union List of Authorized Substances: Annex I, Plastics Food Contact Regulation 10/2011/EU, as amended by Regulation (EU) 2023/1627, OJ L 201, 11 August 2023

compounding and conversion, manufacture of other non-metallic mineral products, e.g. plasters, cement, general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, manufacture of furniture, building and construction work, electricity, steam, gas water supply and sewage treatment (use name: recycling) (relevant sector of use categories: SU 1, 2a, 5, 6a, 6b, 8, 9, 11, 12, 13, 17, 18, 19, 23).

Uses of melamine in the scope of authorisation seem to be relevant for the production of a number of article types such as vehicles covered by End of Life Vehicles (ELV) directive, machinery, mechanical appliances, electrical/electronic articles, stone, plaster, cement, glass and ceramic articles, fabrics, textiles and apparel, leather articles, metal articles, paper articles, rubber articles, wood articles, plastic articles, scented clothes (relevant article categories: AC 1, 2, 4, 5, 6, 7, 8, 10, 11, 13, 31).

The number of registrants and the variety of uses indicate that the supply chain is widely distributed. As clarified in the SVHC proposal, a more complex supply chain example is when formulations of melamine resins with free melamine are used for production of laminated papers (melamine impregnated paper, MIP) or Formica at industrial level, which are then further applied by another industry actor during the manufacture of consumer products e.g. furniture. For decorative purposes and to achieve scratch resistant surfaces the product may receive an additional coat of a melamine resin- based lacquer, which contribute to the article service life of the product. Moreover, the manufacturer may apply an additional intumescent coating with increased levels of free melamine for fire protection purposes (Annex XV SVHC report, 2022).

Information on uses has been retrieved from registration dossiers (ECHA, 2023) and the Annex XV SVHC report (2022).