EUROPEAN MELAMINE PRODUCERS ASSOCIATION

Melamine as a Substance of Very High Concern – FAQ – version 23 February 2024

Melamine – General Information

What is Melamine?

Melamine (1,3,5-triazine-2,4,6-triamine), CAS Number: 108-78-1, is a heterocyclic organic compound existing as a white solid. It is a nitrogen-rich trimer of cyanamide, with a 1,3,5-triazine skeleton.

Major use of Melamine

Melamine in laminates	A decorative film layer (like a wood grain, solid colour or pattern) impregnated with a melamine resin that consists of melamine and formaldehyde (MF resin) is attached to a wooden substrate like fibreboard or particleboard core materials. The resulting products are used in furniture, counter tops, walls, floors and elsewhere. The contained melamine is adding properties like heat, water and chemical resistance to the end product. Also, antibacterial properties are included, making melamine high-pressure or low-pressure laminates the ideal choice for e.g., kitchen counter tops.
Melamine in wood adhesives	The wooden substrates mentioned above also contain melamine – plywood, particle boards (PB), medium density fibreboards (MDF), as well as high density fibreboards (HDF), oriented strand boards (OSB) or laminated veneer lumber (LVL) are bonded with melamine containing urea-formaldehyde (UF) adhesives. Also, here melamine adds its unique properties to the product; it reduces the release of free formaldehyde, improves the water resistance of the boards.
Melamine in surface coatings	Specially formulated melamine resin systems are used to produce highly durable coatings. This includes clear finishes for paper, fabrics, wood and metals. By pigmenting the resin systems opaque enamel finishes can be obtained. You find them on refrigerators, washing machines, hospital equipment and kitchen utensils, where they show their strengths: chemical and water resistance and mechanical properties like scratch resistance. One popular application is within the automotive industry. MF resins in coatings help to reduce solvent emissions and thus have a positive impact on the environment.
Melamine in moulding compounds	Melamine resins are strongly thermosetting and can be moulded into a variety of products for our daily life. The moulds are heat-resistant, odour- and tasteless, as well as non-conductive. By adding pigments to the resin, various colour and combinations thereof are possible. Final moulding products include household appliances, table- and dinnerware, utensil handles, electric sockets and much more.
Melamine in textiles and paper	Applied to textiles, MF resins improve wrinkle resistance and add flame-retardant properties. Paper treated with melamine is more resistant to wrinkle and impregnated against moisture. Best example are banknotes – despite years of intensive use, they do not wrinkle much and survive the washing machine.

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Flame retardants	Naturally, melamine has a very high nitrogen content. This leads to sublimation or decomposition of the molecule when heated above a determined value. The sublimation or decomposition of melamine is absorbing considerable heat energy and thus serves as a heat sink in fire situations. Thus, melamine is an excellent alternative towards halogen-based flame retardants (FR). It is mainly used in specialised paints, textile products like firefighting apparel and in flexible urethane foam that is used in the furniture and bedding industry, as well as in electronics products.
Concrete plasticisers	Melamine also enters the fabrication of melamine poly-sulfonate used as a superplasticiser for making high-resistance concrete. Sulfonated melamine formaldehyde (SMF) is a polymer used as a cement admixture to reduce the water content in concrete while increasing the fluidity and the workability of the mix during its handling and pouring. It results in concrete with a lower porosity and a higher mechanical strength, exhibiting an improved resistance to aggressive environments and a longer lifetime.

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How is Melamine regulated in the European Union?

Melamine is a registered substance under the EU REACH Regulation (Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals). A dossier on the properties and hazards of melamine is maintained by the Melamine REACH Consortium[1] and made publicly available on the website of the European Chemicals Agency (ECHA). It can be viewed here: https://echa.europa.eu/registration-dossier/-/registered-dossier/15978

Melamine is also subject to the provisions of the CLP Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures. The Harmonised classification of Melamine was published in the 18th ATP of Annex VI to CLP on 22 May 2022: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692

Melamine is a regulated substance under the EU Food Contact Materials (FCM No 239) and is authorised in the manufacture of plastic food contact materials, subject to a Specific Migration Limit (SML) of 2,5 mg/kg: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:328:0022:0029:EN:PDF

Melamine as a Substance of Very High Concern (SVHC)

Why is Melamine listed in the candidate list of Substance of Very High Concern (SVHC)?

Substances fulfilling one or more of the criteria defined in Article 57 of the REACH Regulation can be identified as Substances of Very High Concern (SVHC) and placed on the SVHC 'Candidate List'.

On 21 June 2022, the German Competent Authority (CA) formally indicated their intention to propose melamine as SVHC[2]. A dossier constructed according to REACH Annex XV and detailing the reasons for the proposed SVHC candidate listing of melamine was submitted by the German CA to ECHA on 4 August 2022.

The legal basis for identifying melamine as SVHC was the catch-all Article 57(f) which deals with substances that do not fulfil the formal criteria listed in Article 57(a, b, c, d or e), but for which there is 'scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern (ELoC) to those of other SVHC substances, and which are identified on a case-by-case basis'.

During a meeting of ECHA's Member State Committee (MSC) from 13-15 December 2022, 22 Member States voted in favour of adding melamine to the SVHC candidate list, with 4 Member States abstaining.

Why was melamine included in the 12th draft recommendation for inclusion in Annex XIV?

The 12th draft recommendation for inclusion in Annex XIV to the REACH Regulation was published on the ECHA website on 7 February 2024. Melamine was included among the substances recommended for inclusion in Annex XIV (Authorisation List) due to having received a total score of 40 given by ECHA.

[1] https://www.reachcentrum.eu/consortia/melamine/

[2] https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e187b21d68

Melamine received a score of 13 for inherent properties, 15 for volumes and 12 for wide-dispersive use.

What is the Prioritisation in the context of Authorisation?

Substances identified as meeting the SVHC criteria are included in the Candidate List for eventual inclusion in Annex XIV (Art. 59(1) of REACH). ECHA prioritises substances from the Candidate List to determine which ones should be included in the Authorisation List (Annex XIV of the REACH Regulation) as a priority.

Any substance on the Candidate List can be included in Annex XIV. In any particular prioritisation round, the relative priority assigned to a substance needs to be seen in the context of that particular round. A lower priority does not mean that the substance is 'deprioritised.' In subsequent prioritisation rounds, each substance that is not already included or recommended for inclusion in Annex XIV will be reassessed, considering any new information relevant for the prioritisation.

Prioritisation of SVHCs for inclusion on the Authorisation list is subject to the criteria provided in REACH Article 58(3)[3,4]. The prioritisation is based on information on the intrinsic properties, wide dispersive use and/or high volumes. Prioritisation for Authorisation is based on a scoring system, details of which are published here:
https://www.echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8.

What are the next steps in the prioritisation process?

This publication initiated a 90-day public consultation, in which interested parties are invited to comment on the prioritisation results and general issues, the proposed latest application and sunset dates and the uses that should be exempted. Link to the public consultation:
https://comments.echa.europa.eu/comments_cms/InclusionRecommendation.aspx?SubstanceName=Melamine&ECNumber=203-615-4&CASNumber=108-78-1

At the same time, there is also a parallel call for information by the European Commission on the possible socio-economic consequences of the inclusion of melamine in the Authorisation List. Link to the call for information:
https://comments.echa.europa.eu/comments_cms/CallForInfo.aspx?SubstanceName=Melamine&ECNumber=203-615-4&CASNumber=108-78-1

ECHA will publish the comments received at the end of the consultation. Responses to the comments are provided with the final recommendation. The Member State Committee (MSC) prepares its opinion on the draft recommendation considering the comments received during the consultation. The opinion of the MSC and the comments received are considered when ECHA finalises its recommendation. As consequence it is very relevant at all interested parties participate in the public consultation and bring elucidating information before final decisions are made by EU authorities.

[3] https://reachonline.eu/reach/en/title-vii-chapter-1-article-58.html

[4] https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8

The recommendation is then submitted to the European Commission (EC), who makes the final decision on which substances to include (or not) in the Authorisation List. The final recommendation should be submitted to the EC mid-2025.

What is REACH Authorisation?

The authorisation procedure aims to progressively replace substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible. Until substitution is achieved, authorisation aims to ensure the good functioning of the internal market while assuring that risks arising from SVHCs are properly controlled.

The path to REACH Authorisation involves three main phases, which are clearly outlined on the ECHA website: https://echa.europa.eu/authorisation-process.

Will melamine be subject to REACH Authorisation?

REACH Annex XIV lists the substances subject to authorisation obligations. If the EC decides not to include melamine in the Authorisation List, the process temporarily stops, until a potential new prioritisation. In case melamine is included in the Authorisation List, ECHA typically proposes a period of 18, 21 or 24 months between the decision of the EC and the Latest Application Date. After the Sunset Date (Latest Application Date + 18 months), the placing of melamine on the market and its use is generally prohibited in Europe, unless the companies concerned, who are unable to find a safer substitute, are granted an authorisation for the specific use(s).

Authorisation is granted per use for each company, and therefore may bring significant administrative burdens. Important to note is that the placing on the market or the use of an article which contains an Annex XIV substance is not subject to the authorisation requirement. However, if not specifically exempted otherwise, the incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement[5].

Based on industry information, ECHA considers that over 95% of melamine uses will be exempted from the Authorisation requirement under the current regulations. This is because uses of melamine as a monomer in resins qualifies as an intermediate use and such uses are not subject to Authorisation.

The regulatory process is well defined. However, the outcome of this process, i.e. a possible inclusion of melamine in the Authorisation List, is open, including the expected exemption of uses as monomer in resins, and will depend on the information provided during the public consultation, the MSC opinion and the final judgement of the EC.

What is EMPA doing?

- The Melamine REACH Consortium has updated the Registration Dossier with the latest data.
- EMPA is closely working with Downstream Users and others who could be affected.

[5] https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation

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- EMPA has created a Task Force (EMPA, REACH Consortium, Downstream Users, experts) to work on the Public Consultation submission and will provide a summary document that may be used as a template for other stakeholders when submitting their own responses.
- EMPA will create an Advocacy Task Force to discuss the next steps in the prioritisation process.
- EMPA is working with downstream users on a socio-economic assessment.
- EMPA will seek meetings with relevant EU Member State Competent Authorities and Commission to clarify the industry position and share new data findings.
- EMPA will support stakeholders by providing regular updates on progress (via newsletters and the EMPA website).