12 April 2023

Background document for glutaral

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 glutaral 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 document.

Contents

[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

1. Identity of the substance

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

Name: glutaral
EC Number: 203-856-5
CAS Number: 111-30-8

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 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 in ECHA (2023).

2.1. Intrinsic properties

Glutaral 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 glutaral 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. Glutaral 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 8 July 2021, following ECHA's decision D(2021)4569-DC.

2.2. Volume used in the scope of authorisation

The amount of glutaral manufactured and/or imported into the EU is according to registration data in the range of 1,000 - <10,000 t/y. Part of this tonnage is exported outside the EU (ECHA, 2022b).

Some uses appear not to be in the scope of authorisation, such as uses as intermediate, and, to the extent they meet the conditions for the generic exemptions, uses as laboratory reagent in scientific research and development, use in medical devices and formulation of biocidal products. Based on information from registration dossiers on the volume corresponding to those uses, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

More detailed information on uses is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of glutaral in the scope of authorisation include uses at industrial sites (e.g. uses in leather tanning, as hardener in X-ray film developers, corrosion inhibitor, crosslinker and auxiliary for polymerisation reactions) and uses by professional workers (e.g. leather tanning,

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

X-ray film developer and corrosion inhibitor) (ECHA, 2022b).

There is uncertainty on the presence of the substance in articles. There are indications that glutaral could remain in leather articles as a result of leather tanning. Those residual amounts would, however, be limited to concentrations below 0.1% if a proposed restriction on skin sensitisers in textiles will be adopted (see section 2.4 further consideration). Presence in articles may potentially result from other registered uses e.g use as crosslinker, use as auxiliary for polymerisation reactions and use in X-Ray film developer. The substance is expected to mainly react during the use, however there is uncertainty on potential residual unreacted amount.

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

Restriction

FR and SE submitted in June 2019 a restriction proposal on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances. The final opinion of RAC and SEAC was sent to COM for decision making in September 2020. Glutaral has a harmonised classification as Skin sens. 1A. Therefore, leather articles containing glutaral are within the scope of this proposed restriction. For current status, see ECHA (2020b).

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Glutaral is classified as respiratory sensitiser (effects to human health) meeting the criteria of Article 57 (f) Score: 1	The amount of glutaral used in the scope of authorisation is in the range of 1,000 - <10,000 t/y Score: 12	Glutaral is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance might be present in articles. Refined score: 10-12	23-25 (24)

Conclusion

On the basis of the prioritisation criteria, glutaral receives priority among the substances on the Candidate List (ECHA, 2023). Therefore, **glutaral 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, 2020a), as further

specified in the practical implementation document (ECHA, 2020a). 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 glutaral:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **21 months**
Sunset date:	18 months after LAD

The LAD slots are generally set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV). Allocation of recommended (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 allocates those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain.

During the consultation requests for a long LAD of 24 months and for a SD longer than 18 months was received from companies active in the medical sector and leather tanning, justified by the lack of alternatives. ECHA does not see the lack of alternative as a justified reason to deviate from the standard LAD slots and from the SD of 18 months after LAD suggested in the legal text (ECHA, 2023). ECHA recommends a LAD of 21 months based on the assessment that the supply chain of glutaral is of medium complexity compared to other substances included in the recommendation.

ECHA made the final LAD and SD 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 glutaral.

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 glutaral**.

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

During the consultation ECHA received some requests for exemptions e.g. for uses in the tanning process, uses covered by the upcoming restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances uses in scientific laboratories for research and diagnostic purposes.
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 all 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 glutaral.

ECHA therefore **does not recommend exemptions for uses of glutaral** 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 glutaral 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 have been submitted for glutaral by the end of consultation.

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

4. References

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

Recommendations for inclusion in the Authorisation List - ECHA (europa.eu), filter by substance glutaral, EC Number: 203-856-5

- 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 (2020b): Registry of restriction intentions until outcome- ECHA (europa.eu), filter by 'skin sensitising substances'

- Background document to the Opinion on the Annex XV dossier proposing restrictions on skin sensitising substances.

ECHA (2021): Registry of SVHC intentions until outcome - ECHA (europa.eu), filter by substance glutaral, EC Number: 203-856-5

- 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: Glutaral, EC Number: 203-856-5, CAS Number:111-30-8.

- Comments on an Annex XV Dossier for identification of a substance as SVHC and responses to these comments. Substance name: Glutaral, EC Number: 203-856-5.

ECHA (2022a): ECHA's 11th draft recommendation. 2 February 2022.
Recommendations for inclusion in the Authorisation List - ECHA (europa.eu), filter by substance glutaral, EC Number: 203-856-5.

- 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): Glutaral. 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 glutaral (EC 203-856-5)

ECHA (2023): ECHA's final 11th recommendation. 12 April 2023.
Recommendations for inclusion in the Authorisation List - ECHA (europa.eu), filter by substance glutaral (EC 203-856-5)

- 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 glutaral 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 glutaral 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

Registered uses of glutaral in the scope of authorisation include formulation, uses at industrial sites and uses by professional workers. Some registered uses seem to be outside the scope of authorisation, such as the uses as intermediate and, to the extent they meet the conditions for the generic exemptions, uses as laboratory reagent in scientific research and development, use in medical devices and formulation in biocidal products. The majority of the registrants did not provide tonnage per use information in their IUCLID files. Information on tonnage provided in Chemical Safety Reports did not allow a more precise assessment of tonnage falling outside the scope of authorisation.

Use in leather tanning

Leather tanning appears to be the main use in scope of authorisation and is reported at industrial sites and by professional workers (ECHA, 2022b). According to information in the Annex XV SVHC report (ECHA, 2021), glutaral is the most common alternative to chromium-based tanning for a range of types of leather. The leathers are typically soaked in a solution containing 0.5-2 % of glutaral. Though there are apparently investigations ongoing to find alternatives to glutaral or chromium-based tanning, only few alternatives seem to be available (ECHA, 2021).

Some companies commenting during the consultation on the inclusion of the substances in Annex XIV (ECHA, 2023) claimed the use in leather tanning an intermediate use. For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use and concluded that the conditions required are not met (ECHA, 2023).

Several substance in articles notifications have been received in the SCIP database in relation to glutaral in leather parts of vehicles and other leather articles (ECHA, 2022c), However, glutaral has a harmonised classification as skin suns' cat 1A and is listed in the proposed restriction on skin sensitisers in textiles[4]. Leather articles with glutaral content above 0.1 % should be restricted in the near future. Therefore, for the purpose of prioritisation, article service life for this use has not been taken into account.

Use in biocidal product

During the SVHC public consultation (ECHA, 2021), comments were received in relation to the use of glutaral in biocidal products. BASF SE indicated having received an authorisation in 2018 under BPR for its biocidal product. The European Oilfield Speciality Chemicals Association indicated that glutaral is an important biocidal active in the oil and gas industry (ECHA, 2021).

Formulation of biocidal products is reported in registration dossiers (ECHA, 2022b). Registrations only include the formulation of biocidal products and do not include information on the tonnage specific to that use. In absence of further information, it could not be concluded which part of the total tonnage manufactured/imported reported in registrations could fall outside the scope of authorisation based on use in biocides.

Use in Cleaning agent

Uses in cleaning products are registered. In some products, glutaral seem to have a function as biocides (ECHA, 2022b), leading this use to be potentially outside the scope of authorisation. According to one registrant, glutaral is used in cleaning agents for medical devices. Such use seems covered by the Regulation (EU) 2017/745 on medical devices and would therefore be

[4] Proposed restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances (https://echa.europa.eu/registry-of-restriction-intentions)

exempted from authorisation. The uses and the related volumes (when available) have not been taken into account for prioritisation purpose[5]. However, information is missing to conclude on volume effectively falling outside the scope of authorisation (ECHA, 2022b).

Crosslinker or auxiliary for polymerisation reactions

Registered uses considered in the scope of authorisation include industrial use in cross-linking and industrial use as auxiliary for polymerisation reactions (ECHA, 2022b). Those uses may potentially lead to the presence of the substance in articles. Information available on the substance properties and technical functions suggests that the substance will mainly react during the uses and might therefore not be present anymore. However, the reaction rate and the stability of the bounds created may depend on the reaction conditions. There is uncertainty on the presence of unreacted substance in the final articles produced. Article service life is not registered, however, a number of substance in articles notifications in the SCIP database suggests that glutaral may be present in articles above 0.1 % (w/w) (ECHA, 2022c). For the purpose of prioritisation ECHA has reflected the uncertainty on the presence of the substance in articles by not assigning 2 points for the presence in articles (as would be the case if the presence in articles would be confirmed) but rather giving a range score (i.e. 0 to 2 points) reflecting the uncertainty.

Some companies commenting during the consultation on the inclusion of the substances in Annex XIV (ECHA, 2023) claimed the use as cross-linking agent an intermediate use. For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use and concluded that the conditions required are not met (ECHA, 2023).

X-ray film developer

According to the SVHC Annex XV report (ECHA, 2021), glutaral is incorporated into developing solutions for black and white x-ray photography as a hardening (or crosslinking) agent to minimise drying time. X-ray developers are usually diluted by the professionals to a solution containing less than 1% glutaral. The developers containing glutaral appear to be used mainly in the medical field, and to a lesser extent in engineering applications. The use in the medical field might fall under the generic exemption on medical devices[5]. Overall, the volume going to the use as X-ray developer is small and potential exemptions, depending on the application (e.g. in a medical device), would not have an impact on the priority of the substance.

Use in research and diagnostics

According to the information provided during the consultation on the inclusion of the substances in Annex XIV (ECHA, 2023), glutaral is used in clinics applying electron microscopy for the purpose of research, diagnostics and in pathology. These uses might fall under the generic exemptions from the authorisation requirement for the use in scientific research and development or for the use in medical devices. The uses and the related volumes (when available) have not been taken into account for prioritisation purpose[5].

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 were made to allocate the substance to a specific LAD slot.

[5] It is stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are exempt from the authorisation requirement. It remains the responsibility of companies to assess whether any of their uses fulfils the conditions for such exemptions.

Glutaral is manufactured and/or imported by a limited number of registrants (ECHA, 2022b). Generic information on number of sites provided in registrations for the formulation and industrial use of glutaral for leather tanning and as crosslinker and auxiliary for polymerisation reactions could take place at more than 100 industrial sites within the EU.

The supply chain can be characterised[6] by the following actors: formulators, users at industrial sites and professional workers as well as article producers and assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, SLs (multi-layer)).

Glutaral seems to be used in the following product categories: processing aids such as ph-regulators, flocculants, precipitants, neutralisation agents, leather treatment products, polymer preparations and compounds (relevant product categories: PC 20, 23, 32).

A number of sectors is relying on the substance in some of their uses including manufacture of textiles, leather, fur, printing and reproduction of recorded media, manufacture of rubber products, manufacture of plastic products including compounding and conversion, , general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, manufacture of furniture (relevant sector of use categories: SU 5, 7, 11, 12, 17, 18).Uses of glutaral in the scope of authorisation seem to be relevant for the production of a number of article types such as vehicles, leather, rubber and plastic articles (relevant article categories: AC 1, 6, 10, 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), the Annex XV SVHC report (ECHA, 2021) and/or the SPIN database.

[6] 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