2 February 2022

Draft 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 (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: 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[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

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 >10,000 t/y (ECHA, 2021).

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 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 >10,000 t/y.

More detailed information on uses is provided in section 1 of 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, X-ray film developer, cleaning agent and corrosion inhibitor).

[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

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 section 1 of 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 https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

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 above 10,000 t/y Score: 15	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	26-28 (27)

Conclusion

On the basis of the prioritisation criteria, glutaral receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise glutaral 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 glutaral.

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] 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

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 glutaral 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 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.

[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

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 glutaral 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 glutaral[7].

[7] As of 1 August 2021

4. References

Annex XV SVHC report (2021): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Glutaral. Submitted by Sweden, March 2021.

https://echa.europa.eu/documents/10162/832664b0-0ce4-b99c-89a6-50b60016e801

ECHA (2020): Background document to the Opinion on the Annex XV dossier proposing restrictions on skin sensitising substances. June 2020.

https://echa.europa.eu/documents/10162/82d6f20a-af6c-9a42-3cc5-77649900f348

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

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

RCOM (2021): "*Responses to comments*" document. Document compiled by Sweden from the commenting period 09/03/2021-23/04/2021 on the proposal to identify glutaral as a Substance of Very High Concern..

https://echa.europa.eu/documents/10162/247ab0c4-c21e-d0a6-3e62-10dd3deec7ac

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 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, 2021). According to information in the Annex XV SVHC report (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 Annex XV SVHC report, 2021).
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, 2021), However, glutaral has a harmonised classification as skin sens. cat 1A and is listed in the proposed restriction on skin sensitisers in textiles[8]. 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 (RCOM, 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 (Annex XV SVHC report, 2021).

Formulation of biocidal products is reported in registration dossiers (ECHA, 2021). 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 (Annex XV SVHC report, 2021), leading this use to be potentially outside the scope of authorisation. However, information is missing to conclude on volume effectively falling outside the scope of authorisation (ECHA, 2021).

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, 2021). 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

[8] 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)

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, 2021). 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).

X-ray film developer

According to the SVHC Annex XV report (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, however it is responsibility of the companies to assess whether their specific uses comply with the requirements relevant for the exempted uses. 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.

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 to a specific LAD slot in the final recommendation.

Glutaral is manufactured and/or imported by a limited number of registrants (ECHA, 2021). 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[9] 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: Ink and toners, products such as ph-regulators, flocculants, precipitants, neutralisation agents, leather treatment products, polymer preparations and compounds, washing and cleaning products (relevant product categories: PC 18, 20, 23, 32, 35).

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, plastic products, general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, manufacture of furniture and health services (relevant sector of use categories: SU 5, 7, 11, 12, 17, 18, 20).

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

[9] 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

from information on uses available in registration dossiers (ECHA, 2021), the Annex XV SVHC report (2021) and/or the SPIN database.