2 February 2022

Draft background document for 2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers

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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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: 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers
EC Number: -
CAS Number: -

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

2-(4-tert-butylbenzyl)propionaldehyde was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is covered by index number 605-041-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B, H360Fd ("May damage fertility. Suspected of damaging the unborn child") 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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers manufactured and/or imported into the EU is according to registration data (ECHA, 2021) above 1,000 t/y. Part of this tonnage is exported outside the EU.
Uses by consumers will soon fall under the generic restriction of CMR substances sold to the general public (starting from 1 March 2022). Volumes corresponding to those uses are mostly unknown.
Furthermore, some uses appear not to be in the scope of authorisation, such as the use as intermediate in the production of biocidal active substances. 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 the main uses and the relative share of the total tonnage is provided in section 1 of Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers in the

[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

scope of authorisation include uses at industrial sites (as fragrance in cleaning products, such as industrial spraying and treatment of articles) and uses by professional workers (e.g. washing and cleaning products, polishes and waxes).
Consumer uses e.g. in cleaning and air care products are also registered. However, the recent classification of the substance as Repr. 1B will be legally binding from March 2022 onwards. Once the substance is included in the appendix relevant for the entry 30 of REACH Annex XVII, it will fall under the generic restriction on Reprotoxic substances used as substance or in mixtures sold to the general public. After that, consumer uses of the substance above the specific concentration limit should not take place anymore and are therefore not considered for the priority assessment.

Furthermore, according to registrations the substance is used in scented articles, from which release is intended.

More detailed information on uses is provided in section 1 of 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)	
2-(4-tert-butylbenzyl)propionaldehyde is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c) Score: 1	The amount of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers used in the scope of authorisation is in the range of 1,000 - <10,000 t/y Score: 12	2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles from which release is intended. Refined score: 15	28

Conclusion
On the basis of the prioritisation criteria, 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers.

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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers[7].

[7] As of 1 August 2021.

4. References

ECHA (2021): 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers. ECHA's dissemination website on registered substances. Accessed on 1 August 2021.

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

Annex I: Further information on uses

1. Detailed information on uses

Information on uses of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers reported by registrants (section 2.3 of this document) can be complemented by the following information available in SPIN[8] and SCIP databases (ECHA, 2021) on the use of the substance in consumer mixtures and articles.

According to SPIN database, 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers is used as fragrance in a wide range of mixtures, such as rinsing agents, washing for textiles, polishing, car care products, air cleaners.

The presence of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers in scented articles is reported in the SCIP database. This confirms what is reported in the registration dossiers with regard to the use in scented articles.

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.

2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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 substance is currently used.

The supply chain can be characterised[9] by the following actors: formulators, users at industrial sites, professional workers, articles producers (relevant life cycle stages: F, IS, PW, SL).

2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers seems to be used in the following product categories: polishes and wax blends, washing and cleaning products, air care products, perfumes, fragrances, cosmetics, personal care products (relevant product categories: PC 3, PC 28, PC 31, PC 35, PC 39).

A number of sectors is relying on the substance in some of their uses including manufacturers of fine chemicals, formulators and re-packagers of mixtures (relevant sector of use categories: SU 9).

Uses of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers in the scope of authorisation seem to be relevant for the production of scented articles (Article category: AC 0).

[8] http://spin2000.net/ (accessed on 1 August 2021)
[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