

12 April 2023

## 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<sup>1</sup> as well as the MSC opinion<sup>2</sup> were taken into consideration when finalising the recommendation and are reflected in the present document. For 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers no comments were received in the consultation.

## Contents

<b>1. Identity of the substance</b> .....	<b>2</b>
<b>2. Background information for prioritisation</b> .....	<b>2</b>
2.1. Intrinsic properties .....	2
2.2. Volume used in the scope of authorisation.....	2
2.3. Wide-dispersiveness of uses .....	3
2.4. Further considerations for priority setting.....	3
2.5. Conclusion.....	3
<b>3. Background information for the proposed Annex XIV entry</b> .....	<b>4</b>
3.1. Latest application and sunset dates .....	4
3.2. Review period for certain uses .....	4
3.3. Uses or categories of uses exempted from authorisation requirement .....	4
<b>4. References</b> .....	<b>6</b>
<b>Annex I: Further information on uses</b> .....	<b>7</b>

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<sup>1</sup>As of the last day of the consultation, i.e. 2 May 2022

<sup>2</sup>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<sup>3</sup>:

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 (ECHA, 2020). 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 in ECHA (2022a).

The prioritisation results of the substances included in the draft 11<sup>th</sup> recommendation have been updated as necessary after the consultation. The updated results are available in ECHA (2023).

### 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, 2022b) above 10,000 t/y.

Uses by consumers are falling under the generic restriction of CMR substances sold to the general public (since 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 and the use in cosmetics. 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 1,000 - >10,000 t/y based on the estimations provided.

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

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

### 2.3. Wide-dispersiveness of uses

Registered uses of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers in the scope of authorisation include uses at industrial sites (as fragrance in cleaning products, in industrial spraying and treatment of articles) and uses by professional workers (e.g. washing and cleaning products, polishes and waxes) (ECHA, 2022b).

Consumer uses e.g. in cleaning and air care products are also registered (ECHA, 2022b). However, the recent classification of the substance as Repr. 1B is legally binding since March 2022. The substance is included in Appendix 6 to REACH, relevant for the entry 30 of REACH Annex XVII, thus it falls under the generic restriction on Reprotoxic substances used as substance or in mixtures sold to the general public. 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 (ECHA, 2022b).

More detailed information on uses is provided in 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)	
<p>2-(4-tert-butylbenzyl)propionaldehyde is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c)</p> <p>Score: 1</p>	<p>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 - &gt;10,000 t/y</p> <p>Score: 12-15</p>	<p>2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers is used at industrial sites and by professional workers.</p> <p>Initial score: 10</p> <p>Furthermore, the substance is used in articles from which release is intended.</p> <p>Refined score: 15</p>	<p>28-31 (30)</p>

#### 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 (ECHA, 2023). Therefore, **2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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, 2020) and as further specified in the practical implementation document (ECHA, 2020). 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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers:

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

Sunset date:                                    18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (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 proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

ECHA made the final LAD allocation using all available relevant information.

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

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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers.**

#### 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 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.

During the consultation ECHA did not receive any requests for exemptions for the substance.

ECHA therefore **does not 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.

### **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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 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 had been submitted by the end of the consultation.

ECHA therefore **does not recommend exempting any use of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers for PPORD** from authorisation.

## 4. References

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

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers

- 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 (2022a): ECHA's 11th draft recommendation. 2 February 2022.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers

- 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): 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers. 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 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers

ECHA (2023): ECHA's final 11<sup>th</sup> recommendation. 12 April 2023.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers

- 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).

## 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<sup>4</sup> and SCIP databases (ECHA, 2022c) 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 were made on the structure and complexity of supply chains associated to uses in the scope of authorisation based on currently available information and were used, together with relevant information from public consultation, to allocate the substance group 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 (ECHA, 2022b). 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<sup>5</sup> 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, personal care products (relevant product categories: PC 3, PC 28, PC 31, PC 35).

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).

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<sup>4</sup> <http://spin2000.net/> (accessed on 1 August 2021)

<sup>5</sup> 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](https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf)