2 March 2017

Draft background document for 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)

Document developed in the context of ECHA's eighth 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 public 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.

5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] is a group entry covering for example the product with the trade name "karanal". Only for the purpose of easier reading, **karanal group** is used throughout this document when referring to 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof].

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of the karanal group on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 2 June 2017) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

Contents

1. Identity of the substance

Chemical name:	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]
EC Number:	-
CAS Number:	-
IUPAC Name:	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]

The support document for the identification of the substance as SVHC contains a non-exhaustive list of substances that are covered by this group entry[1].

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 December 2015 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_en.pdf.

2.1. Intrinsic properties

5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (e) as it meets the criteria of a vPvB substance. The substance was therefore included in the Candidate List for authorisation on 15 June 2015, following ECHA's decision ED/39/2015.

2.2. Volume used in the scope of authorisation

One substance of this group entry had been notified under Directive 67/548/EEC (NONS) and is therefore considered registered under Regulation (EC) No 1907/2006 (REACH)[3].

[1] https://echa.europa.eu/documents/10162/a4fac134-09e6-43c1-a65f-dfaee5f85731
[2] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[3] Number of registrations as of 25 October 2016.

A further substance covered by the group entry is pre-registered with an envisaged registration deadline of May 2018. This substance was commented on by a company during the public consultation indicating a volume used of < 10 t/y (RCOM, 2015).

Based on the available information, the volume in the scope of authorisation is assumed to be > 1 t/y.

2.3. Wide-dispersiveness of uses

Based on public information sources the main use of the karanal group in the scope of authorisation is as fragrance ingredient in applications such as fine fragrances, soaps and detergents. It is assumed that these uses cover uses at industrial sites, uses by professional workers and consumer uses (IND, PROF and CONS).

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
The karanal group is identified as vPvB meeting the criteria of Article 57e) Score: 13	The amount of the karanal group used in the scope of authorisation is in the range of > 1t/y Score: >3	The karanal group is used at industrial sites, by professional workers and by consumers. Score: 15	>31

Conclusion
On the basis of the prioritisation criteria, the karanal group receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise the karanal group 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[4] and as further specified in the practical implementation document[5]. The draft Annex XIV entries for all the substances included in this draft recommendation are available at https://echa.europa.eu/documents/10162/13640/8th_recom_draft_axiv_entries_en.pdf.

[4] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[5] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_implementation_en.pdf

3.1. Latest application and sunset dates

ECHA proposes to recommend the following transitional arrangements:

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.

Applying the criteria described in the implementation document[5] the time required for the preparation of application(s) for authorisation for the karanal group is assumed to be relatively shorter than for other (groups of) substances prioritised for this recommendation.

Therefore the substance is assigned to the 1st slot (LAD 18 months after inclusion in Annex XIV).

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for the karanal group.

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 the karanal group 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)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of the karanal group for PPORD.

4. References

Annex XV report (2015): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethyl-cyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]. Submitted by the Netherlands, February 2015.

https://echa.europa.eu/documents/10162/eaead2fc-dc16-4d0d-8b87-7e97212c702d

ECHA (2016): 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethyl-cyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]. ECHA's dissemination website on registered substances. Accessed on 25 October 2016.

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

RCOM (2015): "*Responses to comments*" document. Document compiled by the Netherlands from the commenting period 02/03/2015 - 16/04/2015] on the proposal to identify 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethyl-cyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] as a Substance of Very High Concern.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1806e6a88

ANNEX I: Further information on uses

No further information.