SCREENING REPORT

TO ASSESS WHETHER THE USE OF SIXTEEN 1,3-DIOXANES IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH REACH ARTICLE 69(2)

Annex XIV entry	Substance name	Latest application date	Sunset date	Intrinsic property
50	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	27 February 2022	27 August 2023	vPvB

Source: https://echa.europa.eu/authorisation-list

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY
P.O. BOX 400, FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

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1. Conclusion

Following an assessment of the available evidence, ECHA considers that there is no use of the group of substances covered by entry 50 of Annex XIV in articles (domestic or imported).

The sixteen 1,3-dioxanes (cf. table below) currently covered by entry 50 of Annex XIV are very persistent and very bioaccumulative (vPvB) for which no threshold can be determined below which exposure would be safe.

Following an assessment of the available evidence, from the EU regulatory documents, registration dossiers, SiA notifications, SCIP database and online searches, and given the technical function of these substances (fragrance), ECHA considers that there is no use of the sixteen 1,3-dioxanes covered by entry 50 of Annex XIV in articles (domestic or imported). Therefore, ECHA's view is that at present there is no need to prepare an Annex XV dossier for restriction under REACH Article 69(2).

The call for evidence which took place from 14/06/2023 to 31/07/2023 did not bring any new information as regards to the findings and conclusions of the report.

Note that this group of substances (also known as 'Karanal') has the following member substances:

Substance name	**EC**	**CAS**
Reaction mass of 5-[(2R)-butan-2-yl]-2-[(1R,2R)-2,4-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2R)-butan-2-yl]-2-[(1R,6R)-4,6-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2S)-butan-2-yl]-2-[(1R,2R)-2,4-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2S)-butan-2-yl]-2-[(1S,2R)-2,4-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2S)-butan-2-yl]-2-[(1S,6R)-4,6-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane	700-927-7	-
1,3-Dioxane, 2-[(1S,2S)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, trans-	-	676367-06-9
5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane	-	-
1,3-Dioxane, 2-(2,4-dimethyl-3-cyclohexen-1-yl)-5-methyl-5-(1-methylpropyl)-	-	186309-28-4
1,3-Dioxane, 2-[(1R,2R)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, cis-	-	676367-05-8
1,3-Dioxane, 2-[(1R,2R)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, cis-rel-	-	343934-04-3
1,3-Dioxane, 2-[(1R,2R)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, trans-	-	676367-09-2
1,3-Dioxane, 2-[(1R,2R)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, trans-rel-	-	343934-05-4
1,3-Dioxane, 2-[(1R,2S)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, cis-	-	676367-04-7
1,3-Dioxane, 2-[(1R,2S)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, trans-	-	676367-08-1
1,3-Dioxane, 2-[(1S,2R)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, cis-	-	676367-03-6
1,3-Dioxane, 2-[(1S,2R)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-	-	676367-07-0

Substance name	EC	CAS
methylpropyl)-, trans-		
1,3-Dioxane, 2-(2,4-dimethyl-3-cyclohexen-1-yl)-5-methyl-5-(1-methylpropyl)-	601-499-3	117933-89-8
Reaction mass of 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane and 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane	413-720-9	-
1,3-Dioxane, 2-[(1S,2S)-2,4-dimethyl-3-cyclohexen-1-yl]-5-methyl-5-(1-methylpropyl)-, cis-	-	676367-02-5
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane	-	-

Source: https://echa.europa.eu/authorisation-list

Background and scope of Article 69(2) screening

Screening reports are prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006. The article requires that ECHA, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), considers if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepares an Annex XV restriction dossier.

Thus, REACH Article 69(2) screening reports are targeted at the potential release or exposure to the Annex XIV substance(s) from an article throughout its lifecycle (including the waste stage) and whether such use(s) should be restricted. Screening reports are focused on the human health and/or environmental hazards due to which the substance is placed on the Annex XIV. Other hazards are not required to be taken into account for the purpose of the screening. Similarly, in the event ECHA proposes that an Annex XV dossier for restrictions is prepared, the scope of the work will be restricted to the risks arising from the Annex XIV intrinsic properties only unless the scope is expanded on request by the European Commission to include other endpoints. It is to be noted that REACH restrictions do not apply in certain cases. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of the screening reports. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH[1]. The incorporation process carried out in third countries is outside the scope of EU legislation (and REACH Authorisation). However, it should be noted that articles, if imported to the EU, are within the scope of these investigations. The incorporation is regarded to cover two types of uses[2]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture, is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g., coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

[1] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564 Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

[2] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c