AGREEMENT OF THE MEMBER STATE COMMITTEE ON THE IDENTIFICATION OF

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]

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59
of Regulation (EC) 1907/2006[1]

Adopted on 29 May 2015

This agreement concerns

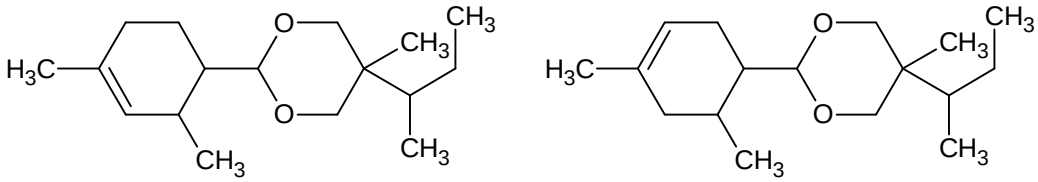
Substance name: **5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]**

EC number: **-**

CAS number: **-**

Molecular formula: $C_{17}H_{30}O_2$

Structural formula:



[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

The Netherlands presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (4 February 2015, submission number EB001399-60) on identification of *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]* as a substance of very high concern due to its very persistent and very bioaccumulative properties.

The Annex XV dossier was circulated to Member States on 2 March 2015 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 18 May 2015 and agreed in the written procedure of the Member State Committee with closing date of 29 May 2015.

Agreement of the Member State Committee in accordance with Article 59(8):

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 identified as a substance of very high concern because

- **it meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative (vPvB),**

in accordance with the criteria and provisions set out in Annex XIII of REACH.

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used 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-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]* as vPvB. All available relevant information (such as the results of standard tests, modelling and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence

The screening criterion for persistence (P) is fulfilled 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]*. The results from three biodegradation studies showed that the substance is neither readily, nor inherently biodegradable. Hydrolysis of this substance was shown to be at most very limited at environmentally relevant pH and temperature values. In a river water die-away test, the proposed substance degraded very slowly. This study was conducted with non-radio labelled substance. A best-case degradation half-life was estimated by attributing the observed dissipation to either biodegradation or hydrolysis, disregarding processes such as evaporation and binding of the substance. At an environmentally relevant temperature of 12°C this best-case degradation half-life corresponded to 74 days. Therefore, as the vP criterion of 60 days in freshwater is exceeded, the substance *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 regarded as fulfilling both the P and vP criterion.

Bioaccumulation

The screening criterion for bioaccumulation (B) is fulfilled 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]*. The substance has an estimated log K_{OW} of 5.3-7.3. The QSAR estimated BCF values

ranged from 583 to 14240 L/kg. Experimental bioaccumulation studies were conducted for the proposed substance in earthworm and fish yielding a $BSAF_k$ of 15.8 kg_{oc}/kg_{lipid} and a BCF_k of 9893 L/kg, respectively. Therefore, as the vB criterion of 5000 L/kg is exceeded, the substance is regarded as fulfilling both the B and vB criterion.

Toxicity

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] does not meet the toxicity (T) criterion of NOEC < 0.01 mg/L and is not classified as CMR and there is no evidence of chronic toxicity. The chronic NOECs for algae, daphnids and fish were 0.135, 0.096 and 0.03 mg/L, respectively. The substance has been classified in the ECHA's C&L inventory as a STOT RE2 substance. However, this classification is not a harmonised classification and therefore, *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]* cannot be considered T on this basis. The overall conclusion for the substance is that regarding toxicity it is considered to be a borderline case.

Conclusion

The substance *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]* meets the criteria for a vPvB substance according to Article 57(e) of REACH. In addition, it should be noted that the substance is considered to be borderline T.

Reference:

Support 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]* (Member State Committee, 29 May 2015)