



Date : November, 30th, 2023

Object: Self Classification: **Updated toxicological information (Augeo® Clean Multi | CAS 100-79-8)**

To whom it may concern:

Solvay follows the principles of **Responsible Care** and is therefore keeping its customers regularly updated with the latest relevant information on its products.

Solvay would like to inform you that following decisions on the testing proposal by the **European Chemical Agency (ECHA)** under the framework of Regulation (EC) No 1907/2006 (REACH), Solvay (Rhodia Operations-1) as a Lead Registrant was required to perform a number of scientific studies regarding the substance **2,2-dimethyl-1,3-dioxolane-4-methanol (CAS 100-79-8)**, including a developmental toxicity study on rabbits (**OECD 414**).

Based on the results of the initial rabbit study, Solvay decided for **precautionary reasons** to apply the Self-classification as Reprotox, cat 2 (H361d), in April, 2023. Since these developmental effects were unexpected considering the available toxicological profile of this substance (including the Developmental study in rats), further investigations were launched to perform **additional mechanistic studies to clarify those results**.

A key principle in science is that any result should be reproducible in similar test conditions to be considered as robust. The developmental effects observed in the 1st study are not reproducible even though the conditions of the second test are as similar as they could be and the **statistical power of this 2nd study is increased**. These additional investigations were purposely performed by the same Contract Research Organization that performed the OECD 414 study, in the same laboratory, in the same conditions, with the same personnel and with samples of the test substance that are almost identical, in order to reduce as much as possible the presence of confounding factors.

As a result of the additional mechanistic studies, **no adverse effects on development of the tested species were observed** at the same high dose. Taking into account the results of all the available data on Reproduction studies, **a classification for Reproduction toxicity is not considered justified** (more details in Annex 1).

This conclusion has been confirmed and endorsed by the external regulatory consultant which assessed the results of the mechanistic studies using the same methodology followed for the assessment of the previous OECD 414 study results that justified the self-classification carried out earlier this year.

For your information, an update of the REACH dossier, including the new scientific information stemming from the mechanistic studies and the consequent self-classification, was submitted to ECHA on November, 24th, 2023.

In the meantime, the Chemical Safety Report (CSR) has been updated based on the results of the mechanistic study. The data in the Chemical Safety Assessment supports the safety of **all uses currently covered in our REACH dossier and will be displayed in the extended Safety Data Sheet**.

The Safety Data Sheets will be issued shortly and reflect the updated classification of the substance as referenced in the REACH dossier, and when applicable as for the European Safety Data Sheet, there is an extended section covering the risk assessment conclusions.

If you are further distributing our product, we ask you to inform your downstream users of this change without delay.

We remain available for any question you may have regarding the above.

Please contact your usual sales representative.


Yours sincerely,



Annex 1

According to UN GHS Recommendation and EU CLP Regulation (EC) No 1272/2008 and UN GHS Recommendation , the updated classification of Augeo® Clean Multi will be as follows:

EU CLP Regulation (EC) No. 1272/2008

Category	Signal Word	Hazard Statement	Pictogram
Eye Irritation, Category 2/2A	Warning	H319: Causes serious eye irritation.	

UN GHS Recommendation

Category	Signal Word	Hazard Statement	Pictogram
Flammable Liquid, Category 4	Warning	H227 : Combustible Liquid	
Eye Irritation, Category 2/2A	Warning	H319: Causes serious eye irritation.	