Advancion

December 16, 2024

Dear Valued Business Partner,

As the lead REACH registrant, Advancion is informing you of a proposed change to the classification and labeling of 2-amino-2-methylpropanol (CAS No.: 124-68-5).

On December 16, 2024, the European Chemicals Agency (ECHA) published a harmonized classification and labeling (CLH) report submitted by Austria for 2-amino-2-methylpropanol. The proposed classification outlined in the report for entry in Annex VI of the Classification, Labeling, and Packaging (CLP) Regulation is “Repr. 1B, H360” and “STOT RE 2, H373.”

This is a proposal only and there is no change to the current classification of 2-amino-2-methylpropanol.

Advancion disagrees with the proposed classification and will continue to bring forward all relevant scientific information to validate the current classification, which is based on expert assessments of extensive data and CLP classification criteria. Advancion’s EU-REACH Registration dossier contains exhaustive data, notably covering those endpoints listed in Austria’s intention and proposal. Based upon all available study results, Advancion is confident in its current classification of 2-amino-2-methylpropanol based on a lack of human relevance of the data and effects outlined in the CLH report.

2-amino-2-methylpropanol has decades of proven safe use in a broad range of pharmaceutical, consumer and industrial applications supported by exhaustive environmental, health and safety data. This includes more than 70 years of use in oral over-the-counter (OTC) pharmaceuticals supported by numerous publications reporting no liver or reproductive effects. The safe and effective use of 2-amino-2-methylpropanol is also supported by independent chemical health and safety evaluations performed by internationally recognized third parties, such as the Cosmetic Ingredient Review (CIR), among many others.

Important Timelines and Next Steps

The publication of the CLH report is an early step in a very long process, during which the classification proposed for 2-amino-2-methylpropanol may evolve, or the proposal may be wholly withdrawn. Based on recent cases where Annex VI ends up being modified, the deadline for changing labels throughout the supply chain would, at a minimum, be three (3) to four (4) years from today.

- On December 16, 2024, a 60-day ECHA public consultation period began on the CLH proposal submitted by Austria. Advancion will actively submit comments during the 60-day public consultation period. Other interested parties are invited to comment on the hazard classes covered by the CLH report by visiting the public comment page for 2-amino-2-methylpropanol on the ECHA website. All comments received will be forwarded by ECHA to Austria as the dossier submitter, inviting them to provide their response to the comments. The compiled comments and non-confidential attachments are also published on the ECHA website.

- After February 14, 2025 – Following the close of the public consultation period, Advancion, together with its scientific experts, will be actively involved in the Committee for Risk Assessment (RAC) opinion-making process. As part of this process, Advancion will argue our data-driven position for non-classification based on a transparent, harmonized and well-established World Health Organization / International Programme on Chemical Safety (WHO / IPCS) mode of action / human relevance framework.

- After a thorough assessment of the relevant data and information, RAC will ultimately form its opinion on the proposed CLH. There are several previous cases where the final RAC opinion included a different classification from what was initially proposed in the CLH report.

Additional information is available and future updates will be provided via the Regulatory Resource Page at https://www.advancionsciences.com/regulatory. If you have immediate questions, please contact your Advancion Account Manager or me directly.

Sincerely,

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