

Helsinki, 22 September 2023

Note for the attention of Mr Roberto Scazzola, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to review the RAC opinion in relation to the harmonised classification of lithium carbonate, lithium chloride, lithium hydroxide

The Committee for Risk Assessment (RAC) is requested to review the reproductive toxicity classification as adopted by RAC in its opinion of 16 September 2021.

1. Background

On 16 September 2021, RAC adopted an opinion on lithium carbonate (EC number: 209-062-5), lithium chloride (EC number: 231-212-3), lithium hydroxide (EC number: 215-183-4).

The dossier submitter (France) had proposed a classification as toxic for reproduction category 1A for adverse effects on development and on sexual function and fertility (Repr. 1A; H360FD).

RAC concluded on a classification as toxic for reproduction category 1A for adverse effects on development and on sexual function and fertility, and for effects on or via lactation (Repr. 1A; H360FD, Lact. H362).

Following the adoption of the opinion, industry stakeholders provided information on an additional publication concerning the epidemiology of cardiac malformation, as well as an analysis of this publication. According to industry stakeholders, this publication could challenge the causality of the association between lithium exposure during pregnancy and cardiac malformation.

The information contained in this publication, which was not considered in the RAC opinion, may have an impact on the classification of lithium carbonate, lithium chloride, lithium hydroxide as reproduction category 1A for adverse effects on development.

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2. Terms of Reference

In accordance with Article 77(3)(c) of REACH, the Commission asked ECHA to request RAC to:

- review the submitted information,
- clarify the evidence available and the association between exposure to lithium salts and cardiac foetal malformations,
- and, if necessary, amend the opinion of 16 September 2021 in relation to the classification for reproductive toxicity of lithium carbonate, lithium chloride, lithium hydroxide.

3. Timescale for the RAC opinion

Considering the limited scope of the request, it is considered that the opinion be prepared in a shorter time than usually required for an opinion on harmonised classification. The European Commission is also requesting ECHA to conduct a consultation on the new study (Boyle et al. (2016)) and to request any relevant additional data, for which the duration could be reduced compared to normal harmonised classification-related consultations given the limited amount of information that is new compared to the information considered in the original CLH dossier.

Within 9 months after the receipt of this request (1 September 2023), ECHA should finalise the analysis with a view to developing an opinion on the classification for reproductive toxicity for effects on development of lithium carbonate, lithium chloride, lithium hydroxide.

4. Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

*(e-signed)*¹

Dr Sharon McGuinness
Executive Director

Cc: Mike Rasenberg, Peter van der Zandt

¹ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.