

<u>Health and Environment Alliance (HEAL) – Short comments following CARACAL 45 discussion on hazard classification of lithium salts compounds</u>

Comments sent by email to: GROW-CARACAL@ec.europa.eu and ENV-CARACAL@ec.europa.eu

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The Health and Environment Alliance (HEAL) thanks the European Commission for the opportunity to provide written comments as a follow-up to the discussion regarding the hazard classification of the three lithium salts (lithium carbonate, lithium chloride, lithium hydroxide) that took place during CARACAL 45 on 5th July 2022.

HEAL supports the classification of the three lithium compounds proposed by the ECHA Risk Assessment Committee (RAC) as toxic for reproduction 1A; H360D. We are very surprised by the arguments put forward by industry representatives during CARACAL 45 and consider that such arguments are not bringing any relevant evidence that would challenge the proposed RAC classification. In particular, we would like to highlight the following aspects:

1) <u>Developmental toxicity studies</u>

Taken together, the recent scientific evidence included in the dossier illustrates a clear pattern of developmental toxicity. Importantly, the dossier submitter has very transparently outlined the specifics of the different studies, including their respective limitations. As a result, an informed discussion took place during the RAC meetings that allowed reaching the conclusion that a classification as reprotoxicant 1A is warranted – this is well reported in the final RAC opinion.

Keeping in mind the meaningful discussion that took place in the RAC setting, the bottom line remains that the scientific evidence supports an emerging pattern of effects on developmental toxicity. Therefore, the evidence base as well as the rationale for the hazard classification proposed by RAC are indisputable.

2) Additional developmental toxicity study, Boyle et al (2016)

During CARACAL 45, industry claimed that a 'new' study (Boyle et al. 2016) challenges the association between exposure to lithium compounds during pregnancy and cardiac malformations. We cannot agree with this statement.

First of all, the above-mentioned study is everything but new, since it dates back from 2016. According to industry, it was only recently recovered in the process of the UK's own classification process, but not even picked up during the industry initial literature screening.

In fact, this omission makes sense, since the study does not address lithium compounds. The Boyle study brings light on the potential health effects of certain medications consumed in cases of mental illness. As such, the study does not include any significant element that allows questioning the relevance and reliability of the association between exposure to lithium compounds and developmental effects documented in other studies. The study may provide evidence to be used in the context of another discussion. However, in the context of the hazard classification of the lithium compounds, it is merely a distraction from the available evidence.

3) Fertility studies

Contrary to the arguments put forward by the industry presentation during CARACAL 45, the scientific literature considered in the RAC discussion with regards to fertility effects is rather recent and provides a robust evidence base. On the other hand, we note that questions remain regarding the dosing of the OECD 416 two-generation study, which fully justifies interpreting its negative findings with caution.

Once again, the dossier submitter transparently and comprehensively documented all the studies included in the dossier and the RAC opinion illustrates the strong support for the approach adopted. As such, there is currently absolutely no reason to question the validity and relevance of the supporting evidence that was relied on during the RAC discussions and led to the proposed hazard classification.

4) Attempts to bring in socio-economic considerations in the hazard classification discussion

Finally, we regret to witness attempts to bring in socio-economic considerations in order to challenge and delay appropriate hazard classification. This is unfortunately not the first time that such attempts occur in the context of CLP discussions. However, as rightly pointed out by several member states in the CARACAL 45 discussions, socio-economic considerations have nothing to do in a purely scientific discussion about the hazard properties of chemical compounds. Any consideration regarding socio-economic impacts is outside of the scope of the current discussion and must be kept separate from it.