

## **PMI comments on dossier proposing harmonised classification and labelling of L-(+)-lactic acid**

Philip Morris International (PMI) welcomes the opportunity to participate in the public consultation of the CLH report "Proposal for Harmonised Classification and Labelling of L-(+)-lactic acid" initiated in February 2017 by the German Federal Institute for Occupational Safety and Health (BAuA).

PMI supports the proposed classification of L-(+)-lactic acid as Skin Irritant Category 2, H315 and Eye Damage Category 1, H318. However, PMI disagrees with the proposed classification of L-(+)-lactic acid as irritating to the respiratory tract (STOT SE 3; H335) as this classification is not supported by human data or by "severe respiratory tract irritation" animal studies, hence does not meet the criteria set forth in the CLP regulation.

PMI disagrees with the STOT SE 3, H335 classification for the following reasons:

- (i) BAuA's conclusion does not meet the criteria for classification established by the CLP regulation. In fact, Annex I, point 3.8.2.2.1, specifies that the classification STOT SE 3 (respiratory tract irritation) should be "based primarily on human data". As the report correctly mentions in section 4.5.3 "No human data available/reported." Animal studies can only be used as part of weight of evidence evaluation.
- (ii) BAuA based its proposal for CLH classification on only one acute inhalation toxicity study in rats (David, 1987) and they justify their interpretation stating that the "signs of respiratory irritation in rat" reported in the David's study (rapid, shallow, labored breathing, gasping) were transient but indicative for respiratory tract irritation.  
The CLP regulation states that "there are currently no validated animal tests that deal specifically with RTI [respiratory tract irritation]", however "animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g. hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above".  
CLP regulation sets forth that, in the absence of validated animal tests for RTI, animal data can be used only as part of weight of evidence if severe RTI effects are observed. The "rapid, shallow, labored breathing, gasping" are not considered severe signs for RTI. In addition, the absence of "gross lesions at necropsy" and the lack of histopathological data confirms that no relevant supportive data for the classification as STOT SE 3, H335 are available.  
PMI was not able to retrieve and review the David study from 1987 as it is not published in a peer reviewed journal nor otherwise publically available.
- (iii) BAuA claims "For precautionary reasons [...] it is considered adequate to propose a classification as respiratory tract irritant STOT SE 3".  
L-(+)-lactic acid is a registered chemical under REACH for a high tonnage band (100 000 – 1 000 000 tonnes per annum) and it is classified in the REACH dossier as *Eye Damage Category 1*. The Guidance on the Application of the CLP criteria clarifies that "a classification for corrosivity is considered to implicitly cover the potential to cause RTI and so the additional Category 3 is considered to be superfluous". Category 3 would be considered only in case functional or morphological changes occur in the upper respiratory tract (nasal passage, pharynx and larynx) which, as mentioned above, was not reported in any scientific study.

For the above mentioned reasons, PMI disagrees with the proposed classification (STOT SE 3, H335) for L-(+)-lactic acid as the justifications provided by BAuA does not meet the criteria set forth in the CLP regulation.

## **References**

- CLH report proposal for harmonised classification and labelling of L-(+)-lactic acid, February 2017
- ECHA, March 2016. REACH Dossier on L-(+)-lactic acid (<https://echa.europa.eu/registration-dossier/-/registered-dossier/14252>)
- ECHA, 2015. Guidance on the application of the CLP criteria. Ver.4.1, June 2015
- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP)