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Jungbunzlauer

Marckolsheim, 07/04/2017

Object : Proposal for Harmonised Classification and Labelling - L-(+)-lactic acid;

Dear Evaluators;

Considering the public consultation for harmonised classification and labelling (CLH) of the substance:

L-(+)-lactic acid;

(2S)-2-hydroxypropanoic acid

EC Number: 201-196-2

CAS Number: 79-33-4

We are pleased to provide you with our comments :

1. Taking up the conclusions of chapter 4.5.3.proposing a classification as respiratory tract irritant STOT SE 3; we noted that this proposal is based on the precautionary principle with very little scientific evidence. The data used are based on animals and not on humans as recommended in Chapter 3.8.2.2.1 of Annex 1 to Regulation 1272/2008. (This assessment should rely primarily on human data); We also note that the report specifies that no human data are available or reported;

2. Furthermore, in contrary to what is foreseen by the CLP Regulation, Annex I, point 3.8.2.2.1(d); the chapter 4.3.1.2 of CLH report state that no histopathological findings or practical observations in humans and/or animals are available;

3. The study cited in the CLH report (David RM 1987, Report No. I - 7083.112) specifies that the symptoms, (page 24 CLH report - ie, hunched posture, red stained fur surrounding the eyes (tearing), ruffled fur, and appeared ungroomed with soiled fur (stained brown) one and three hours after exposure); were observed on all animals including the control group that was exposed to the fresh air only. It is therefore difficult to conclude that L-(+)-lactic acid has a direct relationship with these symptoms. Moreover, the exposure concentration mentioned in the CLH report was higher than the limit for inhalation toxicity tests (7.94 mg/L vs a limit of 5 mg/L).

4. According to the CLP Regulation, Annex I, point 3.8.2.2.1(e), "this special classification (i.e. STOT SE 3, H335) would occur only when more severe organ effects including in the respiratory system are not observed". Also, the classification as respiratory tract irritant STOT SE 3 (H335) risk is already covered by the H315 risk (skin irritation) and H318 risk (causes severe eye damage); and therefore it makes good sense not to add information that does not provide any additional benefit for the protection of users. As set out in subparagraph e) of Chapter 3.8.2.2.1 of Annex 1 to Regulation 1272/2008, "the introduction of this classification does not make sense";

In conclusion, taking as a reference the applicable regulations, as well as the lack of robustness of the scientific data used for this proposal; we consider the proposal to classify L-(+)-lactic acid as irritating to the respiratory tract (STOT SE 3) as not justified and ask to reject it.

Yours sincerely,

Jungbunzlauer S.A.

Michel Laval, General Manager

Luc Sablong, Safety, Environment and Regulatory