Helsinki, 10. 01. 2020

Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to review new information in relation to the harmonised classification and labelling of the substance N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA-H5, EC Number: 200-652-8); Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5, EC number: 404-290-3); and Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5, EC Number: 205-391-3)

The Committee for Risk Assessment (RAC) is requested to review the information provided by the dossier submitters in addition to the information already assessed by RAC during the opinion development in 2017, and, if necessary, to amend the opinion of 9 June 2017 in relation to the classification for reproductive toxicity of DTPA-H5, DTPA-K5 and DTPA-Na5 and/or the setting of specific concentration limits.

1. Background

On 9 June 2017, RAC adopted opinions on the harmonised classification and labelling of N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA-H5, EC Number: 200-652-8), Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5, EC number: 404-290-3), and Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5, EC Number: 205-391-3). While the industry consortium submitting the proposal for harmonised classification and labelling had proposed a classification as toxic for reproduction Cat. 2, the RAC opinion concluded that DTPA-H5, DTPA-K5 and DTPA-Na5 should be classified as toxic for reproduction Cat. 1B, based on malformations of offspring.

Following the opinion, the dossier submitters provided information, additional to the information assessed by RAC, on the differences in zinc metabolism between rat and humans. The dossier submitters claim that the additional information demonstrates that the mechanism of maternal zinc depletion, which they believe to be the reason for the developmental effect seen in rats, is not relevant for humans. The dossier submitters conclude that developmental effects are unlikely to occur in humans and that it is thus not warranted to classify the substance as toxic for reproduction Cat. 1B.

In addition, they bring forward arguments to justify the setting of a specific concentration limit higher than the generic concentration limit, in the event that the proposal for a classification for reproductive toxicity would be maintained.

2. Terms of Reference

RAC is asked to review the submitted information, and, if necessary, to amend its opinion of 9 June 2017 in relation to the classification for reproductive toxicity of DTPA-H5, DTPA-K5 and DTPA-Na5 and/or the setting of specific concentration limits.

3. Timescale for the RAC opinion

Bearing in mind 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 a harmonised classification dossier.

The European Commission requests that ECHA and RAC develop and adopt its opinion including a targeted public consultation on the information on the differences in zinc metabolism between rat and humans provided by the dossier submitters within 9 months after the receipt of the request.

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.

Bjorn Hansen
Executive Director

Cc: Christel Musset, Peter van der Zandt