LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

Initial E-consultation

10th August 2020

Dear Colleagues,

Latvian CA would like to consult MSCAs regarding Lactic acid (Annex I of the BPR, EC No. 200-018-0, E 270) and applicability of RAC opinion for L(+)-Lactic acid (approved active substance under the BPR, CAS-No. 79-33-4, EC-No. 201-196-2).

Background:

For biocidal product the active substance Lactic acid is provided as a concentrated solution in water (≥ 80%). According to the SDSs, Lactic acid (EC No. 200-018-0) is classified Skin Irrit. 2 (H315) and Eye Dam. 1 (H318). The classification is based on the studies provided in a scope of REACH registration dossier.

According to BPR, the biocidal product under the simplified authorisation procedure can be authorised if concentration of active substance is limited so that biocidal product does not require classification according to Regulation (EC) No 1272/2008.

Concerns

(E 270) Lactic acid consists of a mixture of Lactic acid and lactic acid lactate. In its turn, Lactic acid is chiral, consisting of two optical isomers, usually racemic lactic acid (DL-lactic acid) as a mixture of the D and L stereoisomers in equal amounts.

In 2018 RAC has adopted opinion for L(+)-Lactic acid: Skin Corr. 1C (H314) and Eye Dam. 1 (H318).

Theoretically, Lactic acid (EC No. 200-018-0) as a mixture D,L Lactic acid should be classified Skin Corr. 1C (H314) if content of L(+)-Lactic acid in this mixture ≥ 5%.

Issue

LV CA kindly asks to provide opinions in the following options:

Option 1

eCA should ask the applicant to provide information on content[1] of L(+)-Lactic acid in active substance Lactic acid and to assess the classification of the final biocidal product based on the presence of L(+)-Lactic acid and consequently in line with RAC opinion. In case, if according to approach "mixture-in-mixture" the product meets the classification criteria, the applicant should provide the relevant studies.

In practise it would mean, that biocidal product with content of Lactic acid ≥ 2% should be classified as Skin Irrit. 2 (H315) and Eye Irrit. 2 (H319) in case if Lactic acid is 50%/50% mixture of D,L Lactic acid (in this case the presence of L(+)-Lactic acid in product would be ≥ 1%). The simplified authorisation can be granted only based on the studies which show no effects.

[1] *The applicants are not sure that such information can be available from substance supplier, as no requirement to identify the presence of stereoisomers in food additives.*

Option 2[2]

eCA takes into account information provided via SDSs (in line with REACH registration dossier) without consideration of potential content of L(+)-Lactic acid (CAS-No. 79-33-4, EC-No. 201-196-2) in active substance Lactic acid (EC No. 200-018-0).

Conclusion:

RAC opinion for L(+)-Lactic acid should be taking into account for Lactic acid (Annex I of the BPR, EC No. 200-018-0, E 270).

Additional issues considering the overall conclusion

1. How to deal with SAs granted **before RAC opinion** (March 2018) including notifications already approved across EU and notifications which are still coming?
   LV opinion*:* Document *CA-May13-Doc.5.4-Final.rev1 on "Classification and labelling of biocidal products*" clarifies that new CLH has to be implemented in already authorised products in accordance with the transitional period set in the ATP Regulations[3]. In this case no ATP regulation is available (the official publication date has not been defined yet). Therefore, we propose to await 15th ATP publication and to apply the relevant transitional period according to ATP Regulation. During transitional period the applicants will have an opportunity: (1) to support non-classification by testing (2) to submit application for changes with aim to reduce the concentration of active substance or (3) to agree that authorisations will be cancelled. With regards to "new" notifications LV CA is in opinion that legally it is not possible to restrict applicants. The notifications should be approved based on the assessment done before RAC opinion and consequently to cancel notifications in case if applicants will not be able to support non-classification of the products during above mentioned transitional period. No formal referrals should be initiated on this point.

2. Do MSs agree that applications submitted **after RAC opinion** (March 2018) should be amended?
   LV proposal: Considering the fact that only in mid of 2019 MSs which act as eCAs for Union authorisations for L-Lactic acid containing products agreed that RAC opinion should be followed as in CA-May13-Doc.5.4-Final.rev1 is written "*This being said, where – at the time of the product assessment – a proposal for harmonised C&L for a substance contained in the product has been submitted, and a RAC opinion has been adopted, the evaluating authority should, in the absence of evidence to the contrary, consider this opinion as the latest reliable scientific evidence even if the procedure for formal inclusion of the substance into Annex VI to the CLP Regulation is still on-going*.", LV CA is in opinion, that in this "specific" case Art.48 of the BPR should be applied.

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[2] *Option applied till the moment*

[3] E.g. such approach was followed for anticoagulant rodenticides.

Reference MSs will set a "time limit[4]" at least 180 days with aim to give the opportunity to submit skin corrosion/irritant studies and to evaluate them considering the following steps:

- eCA sends a request on studies via R4BP3 informing all MSs;
- eCA informs all MSs via R4BP3 when the studies are submitted;
- no formal referrals should be initiated on this point during agreed time limit (to stop the clock in R4BP3 for "SN-NOT in progress" by requesting additional information);
- eCA assesses a new data, amends PAR and informs all MSs on results via R4BP3;
- eCA cancels authorisation in case of positive studies results informing all MSs via R4BP3;
- all MSs apply Art.52 of the BPR for already approved products.

3. According to *WGII2020_TOX_7.2* the WG agreed that when skin irritation/corrosion studies on the product are available and show no effects, a risk assessment is needed using dermal NOEC of 10% (L-Lactic acid) to assess potential irritation effects after repeated exposure (issue in a context of UA/NA). Do MSs agree that no risk assessment should be performed for SA as not exposure assessment not risk assessment is required for simplified procedure according to BPR?

Conclusion

1. For biocidal products authorized **before RAC** opinion was available to apply transitional period according to *Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures* (transitional period till 1st March 2022). This approach is in line with CA-May13-Doc.5.4-Final.rev1 on "Classification and labelling of biocidal products".

2. For applications submitted **after** the publication of the **RAC opinion**, the RAC opinion should be taken into account during assessment of application.

3. For simplified procedure a risk assessment is not required according to BPR.

[4] Art.48 of the BPR "Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it **the opportunity to submit** comments or **additional information within a specified time limit.**