EUROPEAN CHEMICALS AGENCY

Helsinki, 26 September 2016

Addressee: [redacted]

Decision number: TPE-D-2114343378-44-01/F
Substance name: 8,9,10-trinorborn-2-ene
EC number: 207-866-0
CAS number: 498-66-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 03.08.2015
Registered tonnage band: 1000+T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your following testing proposals are rejected:

1. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2., column 2; test method: EU B.31./OECD TG 414) in a second species (rabbits), oral route using the registered substance.**
2. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU /OECD TG 443) in rats, oral route; using the registered substance.**

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.]

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you.

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2., column 2) in a second species

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The dossier contains a pre-natal developmental toxicity study in rats as first species. However, there is no information available for a pre-natal developmental toxicity study in a second species. Consequently there is an information gap for Annex X, Section 8.7.2. and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study in a second species (rabbits) according to EU B.31/OECD TG 414. In addition, your testing proposal indicated that you consider that the substance qualifies for an adaptation of Annex XI, 1.3, substance tailored exposure-driven testing, with the following justification:

"As demonstrated in the CSR and the Norbornene process description, demonstrating the prevalence of strictly controlled conditions during the manufacture and use of norbornene (both given in section 13 of the IUCLID dossier), the substance qualifies for an adaptation of the standard testing regime according to REACH, Annex XI, 3. substance-tailored exposure driven testing.
For reasons of animal welfare further testing should not be proposed under Annex X. However, according to annex IX, 8.7.3 a decision to perform a study on a second species should be based on the outcome of the first test and all relevant available data:
1. The OECD 414 performed on the first species showed a dose dependant significantly reduced fetal weight. This was not observed in an OECD 422 study conducted by the same laboratory and with the same strain of rat,
2. While contradictory, the finding seems to justify classifying the substance as reprocat. 2
3. Manufacture and use of the substance are strictly controlled. More than 95% of the substance manufactured are used on-site under strictly controlled conditions, therefore adequate RMM are in place and human or environmental exposure is not likely.

We are submitting a proposal to conduct an oral OECD 414 on a second species (rabbit) in view of the considerations iterated above. We would appreciate ECHA's guidance, if a test on a second species is actually justified or should be omitted for animal welfare reasons."

In addition, you have provided information describing your manufacturing process in Section 13 of your IUCLID dossier, as well as information on uses and exposure in your Chemical Safety Report (CSR).

Regarding your testing proposal, ECHA states that the information requirements in REACH are cumulative, so that every time a new tonnage level is reached, the requirements of the corresponding Annex(es) have to be added. Annex X establishes the highest standard information requirements which are applicable to substances manufactured or imported in quantities of 1000 tonnes or more per year. As the substance is registered at the tonnage level of 1000 tonnes or more per year, a pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.) is also part of the standard information requirements. For that reason it is not relevant for the purposes of using an adaptation in Annex XI, whether the same test would need to be conducted already at Annex IX level based on column 2, Section 8.7.2. of Annex IX. Thus, for this endpoint, it is the standard information requirements of the highest applicable Annex against which you need to assess whether any possible adaptations based on Annex XI is applicable and whether you may omit the testing on second species.

Based on Annex XI, Section 3.2(b) and (c) testing required in Annexes IX and X may be omitted if any one of the following criteria is met: where the substance is not incorporated in an article, you sufficiently prove you (b) apply strictly controlled conditions or (c) if the substance is not released if incorporated into articles where it is rigorously contained and other conditions mentioned under points 3.2.(c)(ii) and (iii) are met.

In the registration dossier,you assert the use within exposure scenarios is only within closed plant and have proposed PROC 1 as the only process descriptor for the processing of the registered substance. In your supporting argumentation you sufficently document how the procedural, management and personal protection steps that are required by Article 18.4 (a) to (f) to ensure minimisation of exposure are fulfilled. You claim and document that any residues of the unreacted monomer are below the limit of detection of your methods and at least below 1 ppm within the resultant polymer and as such the likelihood that workers or the general public are exposed to the substance from articles under normal or reasonably foreseeable conditions is negligible.

You also claim that you have received confirmation from downstream users that they also operate under strictly controlled conditions and, as such, this may be verifiable on site. For downstream users you state that all uses are as an intermediate or in the production of polymers. ECHA understands that closed systems are required to prevent reaction with oxygen and consequently SCC can be further anticipated.

Based on the above, ECHA considers that you have provided sufficient justification and documentation to demonstrate that the substance fulfills the requirements for substance-tailored exposure driven testing for this endpoint. Therefore, in accordance with Annex XI, Section 3.2(b) and (c), the study may be omitted.

b) Outcome

Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, your testing proposal for a pre-natal developmental toxicity study in a second species rabbits, oral route (test method: EU B.31./OECD TG 414) is rejected.

Notes for your consideration

Your testing proposal has been rejected because the study may be omitted in accordance with Annex XI, Section 3, as the substance is manufactured and used under strictly controlled conditions. If there are changes in your dossier or in (new) members of the registration which would affect the current adaptation, a new testing proposal for the present endpoint would – in accordance with the REACH Regulation – have to be submitted, unless compliance with this information requirement is scientifically justified and

documented with reference to (other) specific or general rules of adaptation in column 2 of Annexes IX and X or Annex XI of the REACH Regulation.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

The basic test design of an extended one-generation reproductive toxicity study (Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X of the REACH Regulation. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3.

The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for an extended one-generation reproductive toxicity study according to EU B.56/OECD TG 443 with the following justification:

"As demonstrated in the CSR and the Norbornene process description, demonstrating the prevalence of strictly controlled conditions during the manufacture and use of norbornene (both given in section 13 of the IUCLID dossier), the substance qualifies for an adaptation of the standard testing regime according to REACH, Annex XI, 3. substance-tailored exposure driven testing:
Manufacture and use of the substance are strictly controlled. More than 95% of the substance manufactured are used on-site under strictly controlled conditions, customers of commercially available volumes likewise confirmed SCC. Therefore adequate RMM are in place and human or environmental exposure is not likely.
For reasons of animal welfare further testing should not be proposed under annex X. However, according to guidance R7a Version 4.0 of July 2015 certain triggers would also justify the EOGRTS at the Annex IX level:
- Reduced body weight of offspring in a screening or equivant study. Reduced fetal body weight was observed in the recently conducted OECD 414 on rat, reaching significant levels (>10%) in the highest dose group of 600 mg/kg
- Changes in reproductive organ weights in repeated dose study. Significant increase in female ovary weights, that we attributed to a high number of corpora lutea, were found in the high dose females of the recently conducted inhalative 90d repeated dose toxicity study.

Based on the triggers stipulated for annex IX and in spite of the controlled exposure conditions to the substance we are therefore proposing to conduct an oral extended one-generation reproductive toxicity study in the basic test design (cohorts 1A and 1B without extension to the F2 generation unless observation during the study should so warrant). Due the fact, that a valid adaptation according to Annex XI, 3. is justified, we would appreciate ECHA's guidance if the test is actually justified or should be omitted for animal welfare reasons."

In addition, you have provided information describing your manufacturing process in Section 13 of your IUCLID dossier, as well as information on uses and exposure in your Chemical Safety Report (CSR).

ECHA considerst that as the substance is registered at the tonnage level of 1000 tonnes or more per year, the basic test design of an extended one-generation reproductive toxicity study (Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X of the REACH Regulation. As already specified above in section 1, it is not relevant for the purpose of using an adaptation in Annex XI, whether this study would need to be conducted already at the tonnage level of 100 to 1000 tonnes per year. Therefore, you may adapt this testing requirement according to the general rules contained in Annex XI of the REACH Regulation. For the same reasons as explained in section 1 above, ECHA considers that you have provided sufficient justification and documentation to demonstrate that the substance fulfills the requirements for substance-tailored exposure driven testing. Therefore, in accordance to Annex XI, Section 3.2(b) and (c), the study may be omitted also for this endpoint.

b) Outcome

Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, your testing proposal for an extended one-generation reproductive toxicity study (OECD TG 443) is rejected.

Notes for your consideration

Your testing proposal has been rejected because the study may be omitted in accordance to Annex XI, 3, as the substance is manufactured and used under strictly controlled conditions. If there are changes in your dossier or in (new) members of the registration which would affect the current adaptation, a new testing proposal for the present endpoint would – in accordance with the REACH Regulation – have to be submitted, unless compliance with this information requirement is scientifically justified and documented by means of (other) specific or general rules of adaptation in column 2 of Annexes IX and X or Annex XI of the REACH Regulation.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 3 August 2015.

ECHA held a third party consultation for the testing proposal(s) from 1 November 2015 until 16 December 2015. ECHA did not receive information from third parties.

This decision does not take into account any updates after **6 April 2016**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance;

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.