Decision number: TPE-D-2114297169-34-01/F Helsinki, 24 March 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For decan-4-olide, CAS No 706-14-9 (EC No 211-892-8), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for decan-4-olide, CAS No 706-14-9 (EC No 211-892-8), submitted by [redacted] (Registrant).

- Testing proposal: Long-term toxicity test to aquatic invertebrates, OECD Guideline 211 (Daphnia magna Reproduction Test), on the analogue substance (undecan-4-olide, EC No 203-225-4).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 15 January 2015, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his 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.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 4 March 2013.

On 7 November 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 15 December 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 15 January 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the analogue substance undecan-4-olide (γ-undecalactone), CAS No 104-67-6 (EC No 203-225-4):

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **4 January 2016** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal and read-across justification submitted by the Registrant for the registered substance.

With respect to the testing proposal subject to the present decision, the Registrant has used a read-across approach based on Annex XI, 1.5. of the REACH Regulation and proposed to perform the tests on the analogue substance undecan-4-olide (γ-undecalactone), CAS No 104-67-6 (EC No 203-225-4). ECHA has considered the documentation and the scientific validity of the proposed read-across (Section 0, below), before assessing the testing proposal submitted according to Annex IX of the REACH Regulation.

ECHA notes that the present decision concerns the one-to-one read-across proposal from undecan-4-olide (γ-undecalactone), CAS No 104-67-6, EC No 203-225-4 (source substance) to decan-4-olide, CAS No 706-14-9, EC No 211-892-8 (target substance), the substance subject to present decision, as submitted in the registration dossier for decan-4-olide for the endpoint of long-term toxicity testing on aquatic invertebrates only. ECHA did not evaluate the read-across used in any other endpoints for compliance with the REACH information requirements. Such evaluation may be carried out in a compliance check under Article 41 of the REACH Regulation at a later stage.

0. Read-across approach

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), *"provided that the conditions set out in Annex XI are met"*. As far as the testing proposal addressed in this decision is concerned, the Registrant has described an analogue approach of related substances and proposes to use information from a member of this analogue aproach to predict the aquatic toxicity for the registered substance using read-across.

ECHA considers that the read-across proposed by the Registrant shows how the relevant properties of the registered substance can be predicted from the information on properties of the analogue substance. At present, the read across proposed by the Registrant fulfils the conditions, both in relation to the documentation provided (see section 0.1) and the scientific rationale of the read-across approach (see section 0.2).

0.1 Documentation of the read-across approach

It is a requirement of Annex XI, 1.5., that *"adequate and reliable documentation of the applied method shall be provided."*

In Section 7.1 of the chemical safety report (CSR) the Registrant explains that "Gama-decalactone is a linear saturated 4-hydroxycarboxylic acid derived-lactone with 10 carbons. gama-nonalactone and gama-undecalactone are structurally similar compounds of aliphatic lactones with 9 and 11 carbons, respectively. These substances are considered adequate for read-across purpose.
A compilation of QSAR results and available experimental values was made for these three lactones. QSAR results were obtained with ECOSAR v1.11 model (Ecological Structure Activity Relationships), which is a computerized predictive system that estimates a chemical's acute and chronic toxicities to aquatic organisms such as fish, aquatic invertebrates, and aquatic plants by using computerized Structure Activity Relationships (SARs).
A correlation between the chemical acute toxicity on each aquatic trophic level (fish, aquatic invertebrates and algae) and the number of carbons was observed, showing that the aquatic toxicity (whatever the organism) increased with the carbon chain length (See " Read-Across justification for gama-lactones" document in Chapter 13).."

In the IUCLID Endpoint study record for the endpoint for which testing is proposed the Registrant provides the following explanation for the read-across: "Long-term toxicity test to aquatic invertebrates need to be conducted as the chemical safety assessment indicates a need for further investigation. However, according to the test substance and the two other lactones used as read-across in this dossier (γ-nonalactone and γ-undecalactone), the test substance is not considered as the most toxic substance in acute studies. For this reason, a test plan on the most toxic lactone in acute studies (γ-undecalactone) is proposed, as a worst case."

ECHA considers the read-across from undecan-4-olide (γ-undecalactone), CAS No 104-67-6, EC No 203-225-4 (source substance) to decan-4-olide, CAS No 706-14-9, EC No 211-892-8 (target substance) for the endpoint of long term toxicity to aquatic invertebrates plausible.

0.2 Scientific assessment of the analogue approach

ECHA notes that as far as the present decision is concerned, the scientific assessment of the read-across concerns only the analogue approach proposed for the current testing proposal.

ECHA concludes that the Registrant has demonstrated that the effects of the registered substance "may be predicted" from the analogue substance for aquatic toxicity and that the requirements for general rules for adaptation of Annex XI, 1.5. have been met.

Therefore, the adaptation of the information requirements suggested by the Registrant is plausible.

A. Tests required pursuant to Article 40(3)

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier for the registered substance to meet this information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for long term toxicity on aquatic invertebrates (*Daphnia magna* reproduction test, OECD 211) with the following justification: "Long-term toxicity test to aquatic invertebrates need to be conducted as the chemical safety assessment indicates a need for further investigation. However, according to the test substance and the two other lactones used as read-across in this dossier (γ-nonalactone and γ-undecalactone), the test substance is not considered as the most toxic substance in acute studies. For this reason, a test plan on the most toxic lactone in acute studies (γ-undecalactone) is proposed, as a worst case".

As explained above, ECHA considers the read-across from undecan-4-olide (γ-undecalactone), CAS No 104-67-6, EC No 203-225-4 (source substance) to decan-4-olide, CAS No 706-14-9, EC No 211-892-8 (target substance) for the endpoint of long term toxicity to aquatic invertebrates plausible to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than Daphnia. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the analogue substance (undecan-4-olide, CAS No 104-67-6, EC No 203-225-4).

Notes for consideration by the Registrant:

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposal set out in Article 40 of the REACH Regulation aims at ensuring that the new study meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed test, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the test proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Guilhem de Seze
Head of Unit, Evaluation