EUROPEAN CHEMICALS AGENCY

Helsinki, 21 June 2012

Decision number: TPE-D-0000002379-67-05/F

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

For Vinyl laurate, CAS No 2146-71-6 (EC No 218-414-7), 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 testing proposals set out in the registration dossier for Vinyl laurate, CAS No 2146-71-6 (EC No 218-414-7), submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annex X:

- *Daphnia magna* reproduction test, Annex IX, 9.1.5 Long-term toxicity testing on invertebrates.
- Subchronic toxicity study (90-day) in rat by the oral route, extended with examination of male and female fertility parameters, Annex IX, 8.6.2.

The examination of the testing proposals was initiated on 15 March 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 16 May 2011 until 30 June 2011. ECHA received information from third parties (see section III below).

On 18 November 2011 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 13 December 2011 the Registrant provided to ECHA comments on a Draft Decision expressing consent to the testing proposals subject to the present decision. The Registrant indicated in the comments also to adapt the testing strategy and on 1 February 2012 the Registrant updated his registration dossier (submission number [redacted]) removing one (Testing proposal for Subchronic toxicity study (90-day) in rats by the oral route, extended with examination of male and female fertility parameters to cover Annex X, 8.7.3) out of the three previously submitted testing proposals.

ECHA considered the Registrant's comments received and amended the draft decision accordingly.

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On 2 March 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 4 April 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision.

On 16 April 2012 ECHA referred the draft decision to the Member State Committee.

By 4 May 2012 the Registrant did not provide comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 20 May 2012 in a written procedure launched on 10 May 2012.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following proposed tests using the indicated test methods:

a) *Daphnia magna* reproduction test, Annex IX, 9.1.5 Long-term toxicity testing on invertebrates, test method: EU C.20/OECD 211.
b) Subchronic toxicity study (90-day) in rat by the oral route, Annex IX, 8.6.2, test method: EU B.26/OECD 408.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **23 December 2013** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance and scientific information submitted by third parties.

a) Long-term toxicity testing on invertebrates

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test. The Registrant has submitted a testing proposal for long term toxicity testing on invertebrates: *Daphnia magna* reproduction test (EU Method C.20 or OECD 211) to meet the information requirement of Section 9.1.5 of Annex IX of the REACH Regulation. The proposed test forms the part of standard information requirements for a

substance registered for over 1000 tones per year and the respective data is not available for the registered substance. Consequently there is an information gap and ECHA considers it necessary to generate the data for this endpoint.

Pursuant to article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Long term toxicity testing on invertebrates: *Daphnia magna* reproduction test (EU Method C.20 or OECD 211).

b) Subchronic toxicity study (90-day) in rat by the oral route

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test. According to Section 8.6.2. of Annex IX of the REACH Regulation the sub-chronic toxicity study (90 day) is a standard information requirement that is currently not available in the technical dossier. The Registrant proposes to perform a study according to OECD 408 (EU Method B.26; Sub-chronic oral toxicity test repeated dose 90-day oral toxicity study in rodents) where the standard study protocol is extended with examination of male and female fertility parameters.

It is at the Registrant's discretion to perform the intended additional examinations during the testing program and use the results to ensure the safe use of the substance. However, the Registrant is reminded that the proposed extension of this study to include additional examinations concerning reproductive toxicity does not fulfil the standard information requirements in the registration dossier for reproductive toxicity set out in Annex X, 8.7.3. unless Annex X, 8.7. column 2 adaptations apply.

ECHA has examined the information submitted by third parties, as follows:

The third party has proposed a QSAR estimation of repeated dose 90-day oral toxicity in rodents for ECHA to consider. Since this information was claimed as confidential it could not be provided to the Registrant. However, ECHA concludes that the information submitted does not meet the conditions for the (Q)SAR adaptation set out in Annex XI, Section 1.3 and, as such, it cannot constitute an acceptable adaptation to the standard test in question.

c) Deadline of the decision

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of the adoption of the decision. This period of time took into account the fact that the draft decision contained the request to carry out also either a two-generation reproductive toxicity study in rats, oral route (Annex X, 8.7.3, test method: EU B.35/OECD 416) or an extended one-generation reproductive toxicity study in rats, oral route (test method: OECD 443) including the extension of Cohort 1 B to mate the F1 animals to produce the F2 generation which shall be kept until weaning. As this testing proposal is no longer present in the updated dossier and therefore no longer requested in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 18 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the

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test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Director of Regulatory Affairs