EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002260-88-05/F Helsinki, 17/07/2012

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

For methyl undec-10-enoate, CAS No 111-81-9 (EC No 203-910-8), 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 proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for methyl undec-10-enoate, CAS No 111-81-9 (EC No 203-910-8), by [redacted] (Registrant), latest submission number [redacted] for the tonnage band of 1000 tonnes or more per year:

- Viscosity (OECD Guideline 114);
- Biodegradation in water and sediment: simulation tests (OECD Guideline 308);
- Biodegradation in water and sediment: simulation tests (OECD Guideline 303A); and
- Long-term toxicity testing on invertebrates (OECD Guideline 211).

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 8 November 2010.

On 5 January 2012 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 6 February ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received and did not amend the draft decision.

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

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

On 25 April 2012 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 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 REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Viscosity (Annex IX, 7.17., test method: OECD 114);
2. Long-term toxicity testing on invertebrates (*Daphnia* sp.) (Annex IX, 9.1.5., test method: EU C.20/OECD 211);
3. Sediment simulation testing (Annex IX, 9.2.1.4., test method: EU C.24/OECD 308); and
4. Degradation (Annex X, 9.2., test method: OECD 303A).

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

5. Long-term toxicity testing on fish (Annex IX, 9.1.6.1., test method: OECD 210).

The Registrant shall determine the appropriate order of the studies taking into account the possible outcomes and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation. More specifically, prior to conducting the tests 2. and 5. above, the Registrant shall take into account the guidance related to integrated testing strategy for aquatic toxicity testing to determine the sequence in which the tests are to be conducted.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 17 January 2014** 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 proposals submitted by the Registrant for the registered substance.

1. Viscosity

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

Information on viscosity is a standard information requirement as laid down in Annex IX, section 7.17. 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 to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint. Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed test: Viscosity of liquids (test method: OECD 114) using the registered substance.

2. Long-term toxicity testing on invertebrates

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

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, 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 to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant notes that based on claimed uses of methyl undec-10-enoate exposure of the aquatic compartment is likely. However, no data is available for characterising long-term effects of the substance on aquatic organisms. Moreover, the Registrant has proposed the test to refine the predicted no effect concentration (PNEC) value. ECHA considers this justification appropriate for the testing of the registered substance.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008) Figure R.7.8-4 p. 53) 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. 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 an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

Due to the problems in maintaining substance concentrations within the required 80 % in the acute aquatic studies reported by the Registrant, ECHA reminds the Registrant of the need for analytical monitoring in the long-term study to be conducted. Furthermore, the Registrant shall take account of the high volatility of the substance and shall follow the correct procedure for volatile substances as defined in the EU C.20/OECD 211 Guideline and the OECD Guidance document No. 23 on aquatic toxicity testing of difficult substance and mixtures (ENV/JM/MONO(2000)6) when performing the test and interpreting the results.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: *Daphnia magna* reproduction test (test method: EU C.20/OECD 211) using the registered substance.

3. Sediment simulation testing

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

Sediment simulation testing is a standard information requirement as laid down in Annex IX, 9.2.1.4. 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 to meet the information requirements. Consequently, there is an information gap and it is necessary to

generate the data for this endpoint.

The Registrant has proposed to conduct the sediment simulation study according to OECD 308 guideline since the registered substance was not shown to be readily biodegradable in an OECD 301B ready biodegradation study. Furthermore, the Registrant notes that simulation biodegradation tests are required due to the adsorption potential of the registered substance.

In addition, prior to conducting the sediment simulation study proposed, the Registrant intends to repeat a biodegradation screening study. ECHA does not object to the undertaking of a screening study in order to conclude on ready biodegradability. Nevertheless, the results from such a study would not, by themselves, fulfil the information requirement of Annex IX section 9.2.1.2, but may provide the basis for adaptation of the standard information requirements provided by the REACH Regulation.

ECHA considers the Registrant's justification for conducting the sediment simulation test appropriate. ECHA would like to remind the registrant to take account of the high volatility of the substance when choosing which ready biodegradation test method to use. Furthermore, the Registrant shall follow the correct procedure for volatile substances when performing both the biodegradation and the EU C.24/OECD308 studies and interpreting their results, as defined in the study guidelines and the OECD Guidance document No. 23 on aquatic toxicity testing of difficult substance and mixtures (ENV/JM/MONO(2000)6).

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: *Aerobic and Anaerobic Transformation in Aquatic Sediment Systems* (test method: EU C.24/OECD 308) using the registered substance.

4. Degradation

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

Further biotic degradation testing is a standard information requirement as laid down in Annex X, 9.2. 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 to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The chemical safety report (CSR) included in the technical dossier of the registered substance indicates risks associated with sewage treatment plants (STP). Consequently, the Registrant has proposed to carry out the OECD 303A test to improve the quantification of biodegradation at STPs. The Registrant states (CSR p. 18) that the OECD 303A test is to cover the Annex IX, section 9.2.1.2. information requirement on simulation testing on ultimate degradation in surface water. According to ECHA Guidance (R7b (version 1.1., August 2008), p. 181 and p. 193) the results from an OECD 303A study may be used to estimate substance removal in sewage treatment plants but can not be used for assessing degradation in the aquatic environment. Therefore, ECHA concludes that the study proposed does not cover the information requirement of Annex IX, section 9.2.1.2., but rather the information requirement under Annex X, section 9.2. for further testing on degradation.

In conclusion, the Registrant shall carry out the OECD 303A test as proposed to improve the quantification of biodegradation in STPs. The OECD 308 test required under point 3. above is considered to cover the information requirement of Annex IX, section 9.2.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: *Simulation test – aerobic sewage treatment, activated sludge units* (test method: OECD 303A) using the registered substance. ECHA reminds the Registrant to follow the optimal procedure for volatile substances, as defined in the OECD 303A guideline and the OECD Guidance document No. 23 on aquatic toxicity testing of difficult substance and mixtures referenced above, both when performing the test and interpreting the results.

5. Long-term toxicity testing on fish

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may accept a testing proposal in accordance with Article 40(3)(a), but requires the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI.

In order to fulfil the information requirements for aquatic toxicity (Annexes IX and X, 9.1.) the Registrant proposed the tests referred to in point 2 above. This has been accepted in accordance with Article 40(3)(a).

Long-term toxicity testing on fish is part of the standard information requirements as laid down in Annex IX, section 9.1.6. of the REACH Regulation. Furthermore, as laid down in Annex VIII, 9.1.3., Column 2 of the REACH Regulation, the long-term aquatic toxicity study on fish (Annex IX, section 9.1.6.) shall be considered if the substance is poorly water soluble. The substance is poorly water soluble and 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 generate the data for this endpoint. In that regard, the proposed experimental study on aquatic invertebrates above as well as the omission of the standard information requirement for a long-term fish study are not compliant with the information annexes of the REACH Regulation. Consequently, ECHA requires the Registrant to address this non-compliance by providing the relevant information.

The Registrant has waived the long-term fish study and proposed to conduct the long-term aquatic invertebrate study to refine the aquatic PNEC value. Based on the acute aquatic toxicity data contained in the registration dossier for the substance, fish is indicated to be somewhat more sensitive than invertebrates. However, no substantial difference in sensitivities is evident based on the reported acute aquatic toxicity data (fish approximately 1.5 times more sensitive based on the available data in the registration dossier). Furthermore, there are uncertainties with regards to the analytical concentration data and consequently the effect values in the daphnia acute toxicity study.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008), p. 51 and Figure R.7.8-4 p. 53) if based on acute aquatic toxicity data there would be compelling evidence to suggest that fish is substantially less sensitive than invertebrates or algae no further fish test would be necessary. In case neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies are required on both. 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 an applied assessment factor of 50 no risks are indicated, the long-term fish testing may no longer be necessary to be conducted. Therefore, prior to initiating the long-term fish study, the Registrant is to take account of this guidance related to the sequence of testing to determine whether testing on vertebrate animals is required.

Due to the problems in maintaining substance concentrations within the required 80 % in the acute aquatic studies reported by the Registrant and the volatile nature of the substance ECHA reminds the Registrant to follow the correct procedures for difficult to test substances

as referenced above.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is requested to carry out the following additional test: Fish early-life stage test (test method: OECD 210) using the registered substance.

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 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.

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Geert Dancet
Executive Director