EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002584-72-03/F Helsinki, 20 December 2012

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

For [redacted], 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 egistration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for [redacted] (Registrant).

- Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309);
- Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

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 2 November 2012, 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.

On 21 January 2011, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposal from 29 April 2011 until 13 June 2011. ECHA did receive information from third parties (see section III below).

On 20 August 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 19 September 2012 ECHA received comments from the Registrant agreeing to ECHA's

draft decision.

ECHA considered the Registrant's comments received.

The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Testing Required (Section II) were made.

On 2 November 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

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

1. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309).

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

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

while the originally proposed test on Fish, early-life stage toxicity test, OECD 210 for provision of Annex IX 9.1.6 is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Once results of the requested long-term toxicity test on aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. He shall furthermore consider whether there is a need to investigate further the effects on aquatic organisms in order to fulfil the information requirements of Annex IX, 9.1.6. If the Registrant concludes that further investigation of effects on aquatic organisms is required, he shall submit testing proposals for additional aquatic toxicity tests. If the Registrant concludes 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 information requirement of Annex IX, section 9.1.6. of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **20 June 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 and scientific information submitted by third parties.

1. Simulation testing on ultimate degradation in surface water

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.

Simulation testing on ultimate degradation in surface water is a standard information requirement as laid down in Annex IX, 9.2.1.2 of the REACH Regulation. Column 2 of Section 9.2 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. 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. The Registrant has submitted a testing proposal for a simulation biodegradation study in surface water (OECD 309) to cover this endpoint and has provided no adaptation of the standard information requirements according to column 2. The Registrant provided the following justification for conducting the proposed test: "The ready biodegradability of [redacted] was evaluated in a study performed in accordance with OECD testing guideline 301 F and GLP requirements. The maximum level of biodegradation was 0 % in 28 days. Therefore, according to these results, [redacted] is not considered as readily biodegradable. Nevertheless and based on the fact that the substance is characterized by a low potential of adsorption, no simulation test is proposed for the soil and sediment compartments. On the opposite, it is proposed to further assess the biodegradation potential of the substance in water".

ECHA notes that the proposed test can be used to fulfil the information requirement for simulation testing on ultimate degradation in surface water.
The Registrant expressed consent to the draft decision in his comments.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309) using the registered substance.

2. Long-term toxicity testing on aquatic invertebrates

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI.

According to Section 9.1 of Annex IX of the REACH Regulation, long-term aquatic toxicity

testing is required to fulfil the standard information requirements. The Registrant had identified an information gap for Section 9.1.6. of Annex IX of the REACH Regulation. This information gap caused the Registrant to propose a Fish early life stage toxicity test (OECD 210) to generate information covering this endpoint.

ECHA has examined this testing proposal considering all the relevant information available in the technical dossier. From the short-term toxicity studies available in the registration dossier on aquatic species it is clear that the Daphnids are substantially more sensitive than Fish: The results from the acute toxicity studies show LC50-48h Daphnia : 26.4 mg/L, Algae (P. subcapitata) EC50-72h >100 mg/L and Fish (P. reticulata) LC50-96h : 7500 mg/L. The Registrant included in the registration dossier some results from a study on long-term Daphnia for Section 9.1.5. that are reported but disregarded, in the registration dossier providing the following justification:

> 'The chronic toxicity of [redacted] was evaluated with Daphnia magna in a study performed with no guideline. The effects of prolonged exposure (21 days) to [redacted] were examined on survival, fecundity and growth of Daphnia Magna. The EC50 -21d was estimated equal to 18 mg/L. Inhibition of population growth was observed at levels below those which caused a significant reduction in survival. A significant reduction in mean carapace length of 21-day-old daphnids was generally detected at levels comparable with LC50 value. With [redacted], the carapace length was 1x10^4. However no NOEC was estimated during this study.'

Therefore there is an information gap for aquatic toxicity in general, both for section 9.1.6. and section 9.1.5. of Annex IX of the REACH Regulation. However, the acute aquatic toxicity data show that invertebrates are far more sensitive (> 10 factor) than fish. For that reason it is not justified to perform a long-term experimental study on fish. The corresponding testing proposal has to be rejected as non-compliant with the information requirements of Annex IX, 9.1. of the REACH Regulation. At the same time, the significantly higher sensitivity of Daphnids led to the conclusion that a long-term study on these invertebrates is needed to assess the toxicological potential for the aquatic and ensure compliance with the information requirements of Annex IX, 9.1. of the REACH Regulation instead of the test on fish. This conclusion is in line with ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53.

In his comments, the Registrant agreed to perform the long-term toxicity test on aquatic invertebrates but also proposed to conditionally perform the long-term toxicity test on fish if deemed necessary after re-evaluation of the Risk Characterisation Ratio (RCR) using data from the long-term toxicity to aquatic invertebrates test (OECD 211), requested in the present decision.

As the aforementioned Guidance advocates performing a long-term toxicity to aquatic invertebrates test, which the Registrant is requested to carry out by the present decision. ECHA considers that presently it is not possible to conclude that there is a need to further investigate the effects on aquatic organisms via a long-term toxicity to fish test. Therefore, the Registrant shall determine the need to perform further aquatic toxicity tests based on the outcome of the requested long-term toxicity test on aquatic invertebrates and the considerations set out in Figure R.7.8-4, chapter R7.B. of the ECHA *Guidance on information requirements and chemical safety assessment* (August 2008).

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal on Fish during the third party consultation. For the reasons explained further below the information provided by the third party might be sufficient to fulfil this information requirement.

The third party provided a reference to a journal article from 1986 on Fish test results that referred to the brand name of the registered substance.

Although ECHA recognises that the information as provided by the third party might be scientifically valid, it does not fulfil Annex XI requirements for adaptation and is therefore not sufficient to reject the testing proposal on its own. Nevertheless ECHA acknowledges that the Registrant may supplement in his own responsibility the argumentation and information provided by the third party in order to make use of adaptation possibilities. This would require that the Registrant documents and justifies that the registered substance has or has not particular hazardous properties, according to the criteria laid down in Annex XI of the REACH Regulation.

c) Outcome

Therefore pursuant to Article 40(3)(d) of the REACH Regulation, ECHA rejects the proposed test and pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following study using the registered substance: 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 registered substance.

IV. Adequate identification of the composition of the tested material

It is important to ensure that the particular sample of substance tested in the new studies 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

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

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

ECHA 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).

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.

VI. 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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