EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003630-82-04/F Helsinki, 10 December 2013

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

For [redacted] CAS No 1229648-98-9 (EC No 641-088-6), 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)(d) thereof for [redacted], CAS No 1229648-98-9 (EC No 641-088-6), by [redacted] (Registrant).

- Viscosity of Liquids (OECD Guideline 114);
- Bioaccumulation in Sediment-dwelling Benthic Oligochaetes (OECD Guideline 315);
- Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (OECD Guideline 218);
- Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*) (OECD Guideline 222);
- Repeated Dose 90-Day Oral Toxicity in Rodents (OECD Guideline 408), no species nor route specified;
- Prenatal Developmental Toxicity Study (OECD Guideline 414), no species nor route specified.

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 20 June 2013, 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 to initiate a compliance check on the present dossier at a later stage.

On 28 November 2010, 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 proposals from 16 August 2011 until 30 September 2011. ECHA did receive information from third parties (see Section III below).

On 26 September 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 24 October 2012 ECHA received comments from the Registrant. On 17 December 2012 the Registrant updated his registration dossier. In the updated dossier the Registrant modified the proposed bioconcentration test as explained in Section III below.

ECHA considered the Registrant's comments received. On the basis of the comments and updated registration dossier, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 20 June 2013 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 regarding the testing required for fulfilling the information requirement of Annex IX, 9.3.2.

On 26 July 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 change the Statement of Reasons (Section III) of the draft decision.

On 5 August 2013 ECHA referred the draft decision to the Member States Committee.

On 22 August 2013 the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 25-27 September 2013, a unanimous agreement of the Member State Committee on the draft decision was reached on 26 September 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

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. Bioaccumulation in aquatic species (Annex IX, 9.3.2; test method OECD 315);
3. Effects on terrestrial organisms (Annex X, 9.4; Test on toxicity to invertebrates; test method: OECD 222);
4. Long-term toxicity to sediment organisms (Annex X 9.5.1; test method OECD 218)

OR

Long-term toxicity to sediment organisms (Annex X 9.5.1; test method OECD 225);
5. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408);
6. Pre-natal developmental toxicity study in rats or rabbit, oral route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

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

1. Effects on terrestrial organisms (Annex IX, 9.4.; Test on toxicity to soil micro-organisms; test method: EU C.21/OECD 216);
2. Effects on terrestrial organisms (Annex X, 9.4.; Test on toxicity to terrestrial plants; test method: OECD 208 with at least six species tested (and as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline); or Chronic toxicity in higher plants – ISO 22030).

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome 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.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **10 December 2015** 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 proposals submitted by the Registrant for the registered substance and scientific information submitted by third parties.

1. Viscosity

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

A viscosity study 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 provide information for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Viscosity (Annex IX, 7.17.; test method: OECD 114) using the registered substance.

2. Bioaccumulation in aquatic species

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.

Bioaccumulation in aquatic species is a standard information requirement as laid down in Annex IX, section 9.3.2 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 provide information for this endpoint.

The Registrant proposed in the updated dossier (submission nr [redacted]) to perform the test according to OECD Guideline 315 (Bioaccumulation in Sediment-dwelling Benthic Oligochaetes) instead of the originally submitted testing proposal OECD 305 (Bioaccumulation: Static Fish Test with modification *'Based on intrinsic properties of the test (high sorption potential)'* as submitted in the dossier with submission nr [redacted] to cover the endpoint Bioaccumulation in aquatic species, Annex IX, 9.3.2 of the REACH Regulation.

ECHA considers that due to the substance characteristics, the argumentation of the Registrant for changing the initially proposed test in favour of an OECD 315 study is acceptable. The Registrant argued that the sediment compartment is expected to be the compartment of concern based on the high adsorption potential of the substance. Furthermore, in the IUCLID dossier, section 4.7, the Registrant provides reasoning why the measured octanol-water partition coefficient cannot be used reliably to predict partitioning behaviour for this substance. The substance is an UVCB surfactant, adding complexity to the bioaccumulation assessment.

ECHA considers the interpretation and use of the results generated from a test guideline fundamental to the selection of a relevant guideline. In this aspect the Bioaccumulation in aquatic species (Annex IX 9.3.2; test method: Bioaccumulation in Fish: Aqueous and Dietary Exposure test, OECD 305), generates a BMF value which could be normally used to estimate a kinetic bioconcentration factor (BCF_k) as described in annex 8 of TG 305. However, given that the properties of the registered substance affect the reliability of the logKow for prediction of the partitioning behaviour and given that the logKow would be needed for the estimation of the gill uptake rate, the assumptions described in annex 8 of TG 305 may not be fulfilled. Consequently, the calculation of a reliable (BCF_k) from dietary exposures may not be possible.

ECHA considers that in the present case the proposed OECD Guideline 315 (Bioaccumulation in Sediment-dwelling Benthic Oligochaetes), is as likely to produce relevant information as the OECD Guideline 305. ECHA acknowledges that for the OECD 315 there is no agreed guidance to the interpretation of the generated results,that would correspond to annex 8 of OECD 305. Nevertheless, due to the properties of the registered substance annex 8 of OECD 305 cannot be applied reliably to the dietary BMF. ECHA considers that in this case, OECD 315 may provide results of sufficient quality to enable a reliable PBT assessment, even in the absence of a BCF, or at least facilitate the identification of further testing needs. ECHA further notes that Article 12(1) of the REACH Regulation lays out the minimum information requirements and that it is the responsibility of the Registrant to evaluate the results yielded by the OECD 315 study and to propose further studies, should the bioaccumulation potential of the registered substance remain unclear (see also Annex I, 4.1. of the REACH

Regulation). As in this case OECD 305 and OECD 315 are equally appropriate to produce relevant information, ECHA agrees to the proposal of the Registrant to carry out a test on non-vertebrate species, although the fish test is normally the preferred option pursuant to Annex IX, Section 9.3.2.

Since the registered substance has a pKa of 8.6 and is likely to ionise under the pH range recommended for the OECD 315 study, the Registrant shall ensure that an appropriate pH is selected within the recommended range that optimises bioavailability.

Taking into consideration the UVCB nature of the substance, the Registrant shall further explain which are the constituents covered by the available analytical method, so that interpretation of the results may be facilitated.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the originally submitted testing proposal for a bioaccumulation study in fish by dietary exposure, according to OECD 305. However, since after the closing of the third party consultation, the Registrant has changed the proposed test to a Bioaccumulation in Sediment-dwelling Benthic Oligochaetes (OECD 315), the comments received by the third parties are no longer directly relevant for this decision.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes (OECD Guideline 315) The pH shall be adjusted (within the range specified in the guideline) to ensure that the substance is in its least ionised form. The Registrant shall explain precisely which constituents are covered by the available analytical method.

d) Notes for consideration of the Registrant

The Registrant may consider to modify the test to allow the reporting of a bioconcentration factor (BCF) by measuring or estimating pore water concentrations and decapitation of one group of adult organisms so that duplicate experiments can be carried out with headed and headless worms. The Registrant may refer to the UK report called "Predicting the exposure of benthic infauna to chemicals, particularly pesticides, bound to sediment", available at http://randd.defra.gov.uk/Document.aspx?Document=OC9607_172_FRP.pdf).

3, 7 and 8. Effects on terrestrial organisms

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

In order to fulfil the standard information requirements set out in Annex IX, section 9.4., the Registrant should provide the following studies: (i) effects on soil micro-organisms (Annex IX, section 9.4.2), (ii) long-term toxicity testing on invertebrates (Annex IX, section 9.4.1, column 2), and (iii) long-term toxicity testing on plants (Annex IX, section 9.4.3, column 2). Column 2 of Annex IX, section 9.4. advises the Registrant to consider long term toxicity testing instead of short term in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The Registrant has submitted a testing proposal for long-term toxicity testing on invertebrates in order to fulfil the standard information requirements for effects on terrestrial organisms. The Registrant has waived the testing on soil micro-organisms and long-term toxicity testing on plants with the following justification: *"One chronic terrestrial toxicity test is planned (OECD 222). Therefore, no other terrestrial test is currently proposed. Indeed, if the chemical safety assessment indicates no need to investigate further, no other test will be proposed."* This justification for data waiving on other terrestrial toxicity endpoints is not in line with the specific rules for adaptation indicated in column 2 of Annex IX, 9.4. or the general rules for adaptation under Annex XI. The test proposed by the Registrant is therefore not sufficient, on its own accord, to fulfil all the information requirements outlined in Annex IX, 9.4, since, as explained below, the substance is considered to fall into Hazard Category 4. Therefore, the testing proposal submitted by the Registrant does alone not fulfil the information requirements laid down in Annex IX, sections 9.4.2. and 9.4.3.

Based on the available aquatic toxicity information and the physico-chemical properties of the substance ECHA considers that according to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7c, Table R.7.11-2 page 131, the substance can be considered to fall into Hazard Category 4 (as there is no information yet available from ongoing biodegradation study to confirm otherwise). In the context of an integrated testing strategy for soil toxicity, this would not permit the Registrant to perform an initial screening assessment on one terrestrial toxicity endpoint in order to identify the need to perform further studies. Consequently, adequate information should be provided for all terrestrial trophic levels outlined in Annex IX, 9.4.

The assignment of the registered substance to soil hazard category 4 may need to be revised following completion of the ongoing biodegradation screening test. Therefore it is advisable that the impact of the results of this study and, if appropriate, other required tests would be evaluated before proceeding with the required terrestrial toxicity tests.

Therefore, pursuant to Articles 40(3)(a) and 40(3)(c) of the REACH Regulation ECHA has accepted the Registrant's testing proposal on toxicity to terrestrial invertebrates (Annex IX, 9.4.1, column 2, test method: OECD 222) using the registered substance and requires the Registrant to carry out the following additional studies: Test on toxicity to soil micro-organisms (Annex IX, 9.4.2, column 2, test method: EU C.21/OECD 216) and Test on toxicity to plants (Annex IX, 9.4.3, column 2, test method: OECD 208 or ISO 22030) using the registered substance.

The OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on the relevant regulatory requirements and on the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing on plants (Annex IX, 9.4.3, column 2) ECHA considers six species as the minimum to achieve a reasonably broad selection. Should the Registrant opt for this alternative to provide information on long-term toxicity testing on plants, the test shall be conducted as a minimum with two monocotyledonous species and four dicotyledonous species from different groups, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is needed to cover the information requirement.

4. Long-term toxicity to sediment organisms

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

Long-term toxicity to sediment organisms is a standard information requirement as laid down in Annex X, section 9.5.1. of the REACH Regulation. Column 2 of Annex X, 9.5.1. of REACH specifies that long-term toxicity testing shall be proposed by the Registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on sediment organisms. The information on this endpoint is not available in the technical dossier for the registered substance and is not a standard information requirement for this tonnage band.

The Registrant proposed a sediment-water Chironomid toxicity test using spiked sediment (OECD 218). In proposing the test it is apparent that the Registrant considered that there is a need to perform long-term toxicity testing on sediment organisms. ECHA has examined this testing proposal considering all the relevant information available in the technical dossier. The substance is adsorptive and exposure to sediment cannot be excluded. Therefore, potential long-term effects to the sediment should be investigated. The information currently available in the dossier is not considered as sufficient to conclude on the long-term toxicity potential of the registered substance in sediment organisms and thus it is necessary to generate additional data for this endpoint.

For the endpoint Bioaccumulation in aquatic species, Annex IX, 9.3.2 of the REACH Regulation, the Registrant proposed in the updated dossier (submission nr [redacted]) to perform an alternative test according to OECD Guideline 315 (Bioaccumulation in Sediment-dwelling Benthic Oligochaetes) instead of the originally submitted testing proposal OECD 305 (Bioaccumulation: Static Fish Test with modification 'Based on intrinsic properties of the test (high sorption potential) as submitted in the dossier with submission nr [redacted]. The newly proposed test guideline OECD 315 specifies that one of the prerequisites to perform this test is:

'In addition to the properties of the test substance, other information required is the toxicity to the oligochaete species to be used in the test, such as a median lethal concentration (LC50) for the time necessary for the uptake phase, to ensure that selected exposure concentrations are much lower than toxic levels. If available, preference should be given to toxicity values derived from long-term studies on sublethal endpoints (EC50). If such data are not available, an acute toxicity test under conditions identical with the bioaccumulation test conditions, or toxicity data on other surrogate species data may provide useful information.'.

As the proposed study to address long-term toxicity to sediment organisms according to OECD 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment) addresses the toxicity to Chironomids and the OECD 225 test (Sediment-Water lumbriculus Toxicity Test Using Spiked Sediment study) addresses the toxicity to oligochaetes (as suggested by the bioaccumulation guideline), the registrant is given a possibility to perform either of the tests to meet the information requirement for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out either of the following studies: Long-term toxicity to sediment organisms (Annex X, 9.5.1, test method: OECD 218 or OECD 225) using the registered substance.

5. Subchronic toxicity study (90-day)

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.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. 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 provide information for this endpoint.

The Registrant did not specify the species to be tested. According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has indicated that due to the corrosive property of the substance, the administered dose in in vivo testing should not exceed 15 mg/kg bw/day based on Annex IX/X ('in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided').
ECHA notes that under certain conditions in vivo testing with corrosive substances is technically possible. As specified in the general part of Annexes VII-X "in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". The test methods for repeated dose toxicity and reproductive toxicity specify that the highest dose level should induce "toxicity but not death or severe suffering". It is the Registrant's responsibility to ensure that appropriate dose/exposure levels are used.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the registered substance.

6. Prenatal developmental toxicity study

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.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. 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 provide information for this endpoint.

The Registrant did not specify the species and route to be used for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has indicated that due to the corrosive property of the substance, the administered dose in in vivo testing should not exceed 15 mg/kg bw/day based on Annex IX/X ('in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided').
ECHA notes that under certain conditions in vivo testing with corrosive substances is technically possible. As specified in the general part of Annexes VII-X "in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". The test methods for repeated dose toxicity and reproductive toxicity specify that the highest dose level should induce "toxicity but not death or severe suffering". It is the Registrant's responsibility to ensure that appropriate dose/exposure levels are used.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Pre-natal developmental toxicity study in rats, oral route (test method: EU B.31/OECD 414) 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.

Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed.

V. 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).

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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