EUROPEAN CHEMICALS AGENCY

~~HIGHLY RESTRICTED~~

Decision number: TPE-D-0000004401-86-03/F Helsinki, 12 June 2014

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

For Thiodamascone, CAS No 878665-13-5 (EC No 456-350-3), 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, as well as Annex 1, section 0.5, paragraph 4 thereof for Thiodamascone, CAS No 878665-13-5 (EC No 456-350-3), submitted by [redacted] (Registrant).

- OECD 222 long term toxicity test on Earthworm

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 10 to 100 tonnes per year.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. This decision does not take into account any updates submitted after 6 March 2014, 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. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 10 May 2013.

On 5 November 2013 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 5 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision but requesting prolongation for the deadline given in Section II.

ECHA considered the Registrant's comments received. On basis of this information, the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 6 March 2014 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

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:

> Long-term toxicity on terrestrial invertebrates (Annex IX, section 9.4., column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD Test Guideline 222)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **21 December 2015** 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 submitted by the Registrant for the registered substance.

1. Long-term toxicity on terrestrial invertebrates

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 long-term toxicity test on invertebrates is a standard information requirement (unless already provided as of part of Annex IX requirements) according to Annex X, section 9.4.4., of the REACH Regulation. At Annex IX level, Annex IX, section 9.4., column 2, read together with the respective section 9.4.1., column 1, provides that the registrant shall consider long-term toxicity testing on invertebrates instead of short-term testing in particular for substances that have a high potential to adsorp to soil or that are very persistent. There is no standard information requirement for long-term toxicity on terrestrial invertebrates at Annex VIII level.

According to Annex I, section 0.5., paragraph 4 of the REACH Regulation, if the manufacturer or importer considers that further information is necessary for producing his chemical safety report (CSR) and this information can only be obtained by performing tests in accordance with Annex IX and X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the CSR under the appropriate heading.

Annex VI, step 4, of the REACH Regulation provides that in some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.

In the present case, ECHA considers that although the current registration dossier concerns a substance manufactured in quantities of 10-100 tonnes per year and is hence at Annex VIII level, the Registrant has indicated a need to generate information on effects on terrestrial organisms. More specifically, the Registrant has proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), with the following justification in the CSR section 9.02:

"The risk was assessed based on a tentative PNEC (1 mg/kg dw) because

i) no mortality was observed in the acute toxicity study on earthworm (OECD Guideline 207) up to an extremely high exposure concentration,

ii) *the resulting endpoint value (expressed in mg/cm²) cannot be used for PNEC derivation as it is not possible to extrapolate from mg/cm² to mg/kg soil dw. Therefore, a tentative PNEC was derived for risk assessment purposes, using an acute endpoint value (EC50) at 1000 mg/kg. This estimation has also been based on the consideration that no ecotoxicity and no systemic toxicity has been found for mammals for this substance and the log Kow is so high that significant bioaccumulation is not expected. In order to substantiate this tentative PNEC, an earthworm reproduction study is proposed to confirm there is no toxicity to terrestrial organisms."*

ECHA considers that the Registrant has justified the proposed testing by stating that it is needed in order to obtain a PNEC soil as there is no PNEC aquatic. ECHA, thus, considers that, in accordance with Annex 1, section 0.5., paragraph 4, the study is necessary for completing the CSR.

For this specific case, based on the substance properties: the substance is considered as being highly adsorptive to soil (with log Kow 9.5 and log Koc 6.3) within the meaning of Annex IX, section 9.4., column 2 and on the fact that no toxicity was observed on aquatic organisms; as well as on the wide dispersive uses of the substance as indicated in the technical dossier with consumer uses, ECHA also considers that the proposed test is necessary in order to assess the risk to terrestrial invertebrates.

This proposed long term soil toxicity test is further considered as appropriate and suitable as no PNEC on aquatic compartment could be derived following the aquatic toxicity tests performed by the Registrant. Therefore the equilibirium partitioning method approach as indicated in Annex IX, section 9.4., column 2 and as per guidance R7.C (November 2012, version 1.1, p. 134) table R7.11.2 could not be applied even for assessing a screening PNEC soil, while the long-term toxicity test on earthworm (OECD 222) is the first test method recommended to establish a PNEC soil. The proposed test guideline OECD 222 is considered as appropriate to be used for assessing the effects of chemicals in soil on the reproductive output and other sub-lethal end points of the earthworm species.

The Registrant has indicated in his comments that due to the substance properties and the absence of effects found in the previous experiments he intends to accomplish the testing in two phases: first a preliminary test with limit test, and then, in case of toxicity to the range finding, a definitive test. This matches with ECHA's Guidance on the necessity to proceed to a confirmatory long term toxicity test (R.7 C table R7.11-2, version 1.1, 2012) and is in line with the OECD 222 guideline on when to proceed to a limit and range finding test. Furthermore, the Registrant commented on the technical difficulties related to substance properties. ECHA agrees with the possible difficulties in performing the test due to the properties of the registered substance. This is taken into account in the deadline for the requested study (see section III.2 below).

Therefore pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD Test Guideline 222, using the registered substance.

ECHA would like to point out to the Registrant that section R.10.6.2., Chapter R.10 of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) provides that a lower assessment factor may potentially be applied if information on additional long-term terrestrial toxicity test of two trophic levels were available. In order to obtain this the Registrant would in addition to the proposed long-term earthworm study need to submit a testing proposal for a long-term plant study.

2. Deadline for submitting the required information

In the draft decision, ECHA indicated that the Registrant should submit the required information to ECHA in an updated registration dossier within 9 months from the date of the decision. In his comments, the Registrant requested to prolong the timeline from 9 to 18 months. The Registrant based his request on technical difficulties due to the the physico-chemical properties of the registered substance (measured log P of 9.5), difficulties associated with dosing and the analytical confirmation of this substance in this matrix. Also Registrant submitted documentation concerning laboratory capacity and on the time frame for the development of the analytical method.

ECHA accepts the Registrant's argument that further 9 months are required. Therefore, ECHA acknowledges the Registrant's request to extend the deadline due to substance properties and issues with test laboratory facilities capacity and agrees to extend the timeline from 9 months to 18 months.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets 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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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 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. 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.

[redacted]

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