ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002360-86-04/F Helsinki, 31 July 2012

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

For 1,3-diphenylguanidine, CAS No 102-06-7 (EC No 203-002-1) 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 1,3-diphenylguanidine, CAS No 102-06-7 (EC No 203-002-1) submitted by [redacted] (Registrant), 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 Annexes IX and X:

- Annex IX, 9.1.6: Long term toxicity to fish, test method: OECD 210;
- Annex IX, 9.2.1.4: Biotic degradation: Sediment simulation testing, test method: EU C.24/OECD 308; and
- Annex X, 9.5.1: Long-term toxicity to sediment organisms, test method: OECD 218.

The examination of the testing proposals was initiated on 9 November 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 15 April 2011 until 30 May 2011. ECHA received the following comments from third parties:

Information on harmonised classification of the substance according to the second adaptation to technical progress (ATP) of the CLP Regulation (EC) No 1272/2008.

On 5 October 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 4 November ECHA received comments from the Registrant proposing the testing strategy for the sediment compartment and the extension of the testing time due to the delay for work realisation and the laboratories' availabilities. On 16 December 2011 the Registrant updated the registration dossier building the better grounds for a testing strategy

proposed in the Registrant's comments. In addition upon the request of ECHA, on 27 February 2012 the Registrant substantiated his claim concerning the extension of time allowed to carry out the required studies.

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

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.

On 2 May 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 6-8 June 2012, a unanimous agreement of the Member State Committee on the draft decision as referred to MSC and modified at the meeting was reached on 7 June 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 proposed tests using the indicated test method:

1. Long term toxicity to fish: Early-life stage toxicity test, Annex IX, 9.1.6.1, test method: OECD 210;
2. Sediment simulation testing, Annex IX, 9.2.1.4, test method: EU C.24/ OECD 308; and
3. Long-term toxicity to sediment organisms, Annex X, 9.5.1, test method: OECD 218.

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 31 January 2014** 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.

(1) Long term toxicity to fish

Long-term toxicity testing on fish is a standard information requirement according to Annex IX, 9.1.6., that is not available in the registrations dossier and which can be omitted according to column 2. The testing proposal for long term toxicity to fish (test method: OECD 210) has been submitted by the Registrant. As it has been demonstrated in the registration dossier in various acute studies, the registered substance is toxic to fish and algae and harmful to daphnia.

According to CLP Regulation (EC) No 1272/2008 (Table 3.1) the registered substance is classified according to the harmonised classification as Aquatic Chronic 2 (H411) and pursuant to Directive 67/548/EEC Annex 1 as N; R51/53. Information submitted by the third party contained experimental results for the fish short term toxicity (LC50 of 17mg/l) and aquatic toxicity QSAR predictions. The third party has proposed that according to the new information provided and the criteria described in the second adaptation to technical progress (ATP) of the CLP Regulation, the substance should be classified as hazardous to the aquatic environment category acute 1 and category chronic 2.

The evaluation of the classification proposal made by the third party would require the consideration of the weight of evidence from QSAR data against the evidence from available experimental data and it is out of the scope of the testing proposal examination.

ECHA has concluded that the Classification and Labelling proposed by the third party is not directly related with the proposed testing and therefore cannot constitute a reason for rejecting the testing proposal.

The Registrant has proposed to perform the Fish Early-life stage toxicity test, Annex IX, 9.1.6.1, test method: OECD 210 to refine the PNEC in anticipation of a new European regulation to reduce CO2 emission from transport. These requirements request the usage of [redacted] which include 1,3-diphenylguanidine. As a consequence, it is logical to predict an increase of 1,3-diphenylguanidine manufacture in the EU, an increase of usage in [redacted] factory.

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Early-life stage toxicity test, Annex IX, 9.1.6.1, test method: OECD 210.

(2) Sediment simulation testing

The Registrant has submitted a testing proposal for biodegradation simulation testing in water and sediments (test method: EU C.24/OECD 308) to meet the information requirement of Section 9.2.1.4. of Annex IX of the REACH Regulation. The Registrant has justified the need for this test stating that there is no information available on the degradation potential of the registered substance in sediments and soil.

In the comments on the Draft Decision the Registrant expressed the intention to perform the Partition Coefficient testing using a test method that the Registrant considers as more appropriate for that substance, prior to further testing. Nevertheless the testing proposal for the Sediment simulation testing remains valid.

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 the comments on the Draft Decision the Registrant proposed a testing strategy based on verification of Partition Coefficient value followed by sediment toxicity testing and sediment degradation simulation testing. ECHA acknowledges this possibility.

The requirements for the sediment simulation testing may, according to column 2 of Annex IX, 9.2. and specifically 9.2.1.4., be adapted if the test is not needed according to a more reliable and refined Chemical Safety Assessment (CSA) made by the Registrant for the sediment compartment. and e.g. based on a more appropriate assessment of the adsorption of the registered substance to the sediment compartment within environmental relevant pH range.

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Biotic degradation: Sediment simulation testing, Annex IX, 9.2.1.4, test method: EU C.24/OECD 308, unless as a result of applying the testing strategy he adapts this information requirement with a sound justification.

(3) Long-term toxicity to sediment organisms

The testing proposal for sediment toxicity (OECD 218) has been submitted by the Registrant. 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.

In the comments on the Draft Decision the Registrant expressed the intention to perform the Partition Coefficient testing using a test method that the Registrant considers as more appropriate for that substance, prior the further testing. Nevertheless the testing proposal for the Sediment simulation testing remains valid.

Consequently, there is an information gap and it is necessary to generate the data for this endpoint. The need to perform this test was further justified by the Registrant by a statement that at the moment there is no data available for characterising the effect of the registered substance on organisms inhabiting sediments.

In the comments on the Draft Decision the Registrant proposed a testing strategy based on verification of Partition Coefficient value followed by sediment toxicity testing and sediment degradation simulation testing. ECHA acknowledges this possibility.

The requirements for the sediment toxicity testing may according to column 2 of Annex X, 9.5.1. be adapted if these tests are not needed according to a more reliable and refined CSA made by the registrant for the sediment compartment and e.g based on a more appropriate assessment of the adsorption of the registered substance to the sediment compartment within environmental relevant pH range.

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: Long-term toxicity to sediment organisms, Annex X, 9.5.1, test method: OECD 218.

(4) Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In the comments on the Draft Decision, the Registrant requested the extension of the testing time

up to maximum 2 years instead of the proposed 1 year. The Registrant motivated his request due to the delay for the work realisation and the laboratories' availabilities. In the information from the testing laboratory substantiating the claim it has been indicated that the sediment toxicity testing and sediment degradation simulation testing can start in the last quarter of 2012. Therefore, taking into account the length of the tests, confirmed by the testing laboratory to be up to 15 months for both tests even if carried out sequentially, ECHA considers 18 months as reasonable time period to perform the proposed tests (OECD 210; EU C.24/OECD 308, OECD 218).

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, however, that this information, or the information submitted by other Registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint Registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint Registrants. It is the responsibility of all the joint Registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint Registrant. Finally, the studies must be shared by the joint Registrants concerned.

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). 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.

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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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