ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002568-66-05/F Helsinki, 30 July 2013

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

For cyanoguanidine, CAS No 461-58-5 (EC No 207-312-8), 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 jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12 (1)(d) thereof for cyanoguanidine, CAS No 461-58-5 (EC No 207-312-8) by [redacted] Registrant).

- Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test (OECD 309),
- Terrestrial Plants, Growth Test (OECD 208)

This decision is based on the registration dossier as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 18 January 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 from initiating a compliance check on the registration at a later stage.

On 13 September 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.

On 19 June 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 9 July 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 18 January 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, one Competent Authority of a Member State submitted proposals for amendment to the draft decision.

On 21 February 2013 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 amended the draft decision accordingly.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

The Registrant provided comments on the proposals for amendment on 20 March 2013. 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 8 April 2013 in a written procedure launched on 27 March 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 Articles 40(3)(a) and (b) of the REACH Regulation using the indicated test methods 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);
2. Short-term toxicity testing on plants (Annex IX, 9.4.3.) test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2 and Annex X, 9.4.6.); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

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:

3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **30 July 2014** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on toxicity to terrestrial plants are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on terrestrial organisms, the Registrant shall consider submitting further testing proposals for tests on terrestrial organisms.

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. 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, section 9.2.1.2. 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 Registrant has therefore proposed to perform an Aerobic Mineralization in Surface Water – Simulation Biodegradation Test (OECD Guideline 309) to fulfil this end-point. The Registrant has indicated that due to its physico-chemical properties (high water solubility, hydrophilic and low n-octanol-water partition coefficient) the substance will not adsorb to soil or sediment organic matter fractions. Accordingly, this surface water test is the appropriate biodegradation simulation test.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study.

2. Short- / Long-term toxicity to plants

a) Examination of the testing proposal

Pursuant to Article 40(3)(b) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test but modifying the conditions under which the test is to be carried out.

The Registrant must address the standard information requirements set out in Annexes IX and X, Section 9.4. for short-term toxicity testing on plants (Annex IX, Section 9.4.3.) and long-term toxicity testing on plants (Annex X, Section 9.4.6.). 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 proposed a short-term terrestrial plant growth test (OECD 208) and justified the testing proposal for this endpoint with the following statements:

'As no information on short-term or long-term toxicity of dicyandiamide to plants is available, an experimental study according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) is proposed (study performance in 2013). DCD is neither classified as dangerous, nor does it meet the criteria for PBT/vPvB substances. DCD is not toxic to aquatic organisms and is non-toxic in acute toxicity tests and repeated dose (90 d) feeding studies with mammals. In addition, from the available

avian toxicity tests it can be concluded that DCD constitutes no hazard to birds in the environment, and the LC0 in the 14 d acute toxicity study with Eisenia foetida was 3200 mg/kg dw soil. Furthermore, DCD is not toxic towards micro-organisms. Therefore, it is not assumed that toxic effects will be observed in the proposed test on short-term toxicity to plants. However, if this assumption proves false further testing regarding plant toxicity will be considered.'

This test is suitable to address the information requirement of Annex IX, section 9.4.3. However, ECHA notes that the Registrant has proposed a simulation test on ultimate degradation in water (section 1 of the present Decision) and that the results of this test may lead to a change in the perceived persistence of the registered substance. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category, according to table R7.11-2, Chapter R.7c, page 131 of ECHA's Guidance on information requirements and chemical safety assessment (May 2008), is not possible at this time.

Consequently, ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.3.) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.6. for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, section 9.4.6. and Annex IX, section 9.4.3. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test on terrestrial plants that the Registrant has proposed.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. Alternatively, for long-term toxicity testing, ECHA considers six species as the minimum and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species. The Registrant should consider if testing on additional species is required to cover the information requirements. In addition, the ISO 22030 (chronic toxicity in high plants) test is also considered by ECHA as appropriate for the fulfilment of the standard information requirements of Annex X, section 9.4.6. under REACH.

b) Outcome

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation the Registrant is required to carry out the proposed study under modified conditions: Short-term toxicity to plants (Annex IX, 9.4.3.); test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or may, as alternative to the short-term test, opt to carry out one of the following studies: Long-term toxicity testing on plants (Annex X, 9.4.6.); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030), using the registered substance.

3. Effects on soil microorganissms

a) Examination of the testing proposal

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

The hazard to soil microbial communities is a standard information requirement under Annex IX, Section 9.4.2. of the REACH Regulation. In his registration dossier, the Registrant sought to address this endpoint via a weight of evidence approach consisting of two non-guideline published studies. He also referred to this fact in his comments on the proposal for amendment. However, ECHA considers that the data provided by these studies is insufficient to derive a NOEC for microorganisms and subsequently a robust PNECsoil cannot be determined. Furthermore, the substance is reported by the Registrant as a strong inhibitor of the nitrification process and has justified the effects reported as not relevant on the basis that the mechanism of action is bacteriostatic instead of bactericidal. However, ECHA considers that this justification is insufficient since the microbial function is clearly affected. Furthermore, ECHA guidance indicates that testing on soil microorganissms is required if effects are observed in the activated sludge microbial activity.ECHA therefore concludes that the proposed adaptation is not justified. Therefore there is an information gap and effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential column 2 adaptation outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

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 new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, 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 joint registrants of the same substance to agree to the test[s] proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally 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 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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Geert Dancet
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