Decision number: TPE-D-0000001799-58-05/F Helsinki, 5 April 2012

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

For ADCA (Azodicarbonamide), CAS No 123-77-3 (EC No 204-650-8), 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 testing proposals set out in the registration dossier for ADCA (Azodicarbonamide), CAS No 123-77-3 (EC No 204-650-8), submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

In accordance with Articles 10(a)(ix) and 12(1)(d) 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 Annex IX:

- Annex IX, 9.2.1.2.: Simulation testing on ultimate degradation in surface water, according to OECD Guideline 303A (Simulation Test - Aerobic Sewage Treatment. A: Activated Sludge Units)

- Annex IX 9.1.5.: Long-term toxicity testing on aquatic invertebrates, according to OECD Guideline 211 (*Daphnia magna* Reproduction Test)

The examination of the testing proposals was initiated on 15 October 2010.

ECHA examined the testing proposal and drafted a decision in accordance with Article 40 of REACH.

On 4 August 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.

The Registrant did not provide any comments on the draft decision.

On 4 November 2011 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. Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 8 December 2011 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 within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to modify the draft decision.

On 19 December 2011, the draft decision was referred to the Member State Committee.

On 19 December 2011 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 6-10 February 2012, the Member State Committee further modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 9 February 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 following test using the indicated test method:

- Long-term toxicity testing on aquatic invertebrates (Annex IX 9.1.5.), according to OECD Guideline 211 (*Daphnia magna* Reproduction Test) or EU test method C.20 of Regulation (EC) No 440/2008

Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

- Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.), according to OECD Guideline 309 (mineralisation in surface water) or EU test method C.25 of Regulation (EC) No 761/2009

while the originally proposed test OECD Guideline 303A for provision of Annex IX, 9.2.1.2. is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by 5 April 2013 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. Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may take a decision requiring the Registrant to carry out the proposed test. Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may take a decision rejecting a testing

proposal but requiring the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X and XI.

Examination of the testing proposals

a) Long-term toxicity to aquatic invertebrates

According to Section 9.1.5 of Annex IX of the REACH Regulation, long-term toxicity testing on aquatic invertebrates is required to fulfil the standard information requirements. As the proposed test for long-term toxicity to aquatic invertebrates is not available for the registered substance but needs to be present in the technical dossier to meet the information requirement of Section 9.1.5 of Annex IX of the REACH Regulation, it is necessary to generate the data and to perform the test.

The Registrant is, therefore, requested to cover the endpoint by performing the OECD Guideline 211 (*Daphnia magna* Reproduction Test) or EU test method C.20 of Regulation (EC) No 440/2008.

b) Simulation testing on ultimate degradation in surface water

According to Column 1, Section 9.2.1.2 of Annex IX of the REACH Regulation, simulation testing on ultimate degradation in surface water is required to fulfil the standard information requirements. 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 Registrant has submitted a testing proposal to cover this standard information requirement and noted that "*in order to have more information on the biodegradability properties of ADCA, and in accordance with REACH Annex IX, we propose to realise a simulation test on biodegradation in water and sediment*".

However, the test cannot be used to cover the simulation biodegradation endpoint, as indicated in the Guidance on Information requirements (R7b). This Guidance (R.7.9.5.1, page 193) states that "*Results from tests simulating the conditions in a sewage treatment plant (STP) (e.g. the OECD 303) cannot be used for assessing the degradation in the aquatic environment*". The results from the OECD 303A test cannot be used for classification purposes (R.7.9.5.1, page 192), over the preferred Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (OECD 309). Furthermore, the OECD 303 studies are not included in the relevant tests to assess persistence in the environment (R.7.9.5.2, page 194).

The Registrant has further commented that certain screening studies for biotic degradation may be pursued in order to confirm the need for further simulation testing. ECHA does not object to the undertaking of screening studies in order to conclude on ready biodegradability. Nevertheless, the results from such studies would not, by themselves, fulfil the information requirement of Annex IX section 9.2.1.2, but may provide the basis for adaptation of the standard information requirements provided by the REACH Regulation.

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 your dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. You 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 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.

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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Director of Regulatory Affairs