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Decision number: TPE-D-0000002168-74-05/F Helsinki, 5 July 2012

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

For Activated Carbon - High Density Skeleton, EC No. 931-328-0, 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 Activated Carbon - High Density Skeleton (EC No. 931-328-0), 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)(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 Annex IX:

- Sub-chronic Inhalation Toxicity: 90-Day (OECD Guideline 413) with additional examination of the male and female reproductive organs;
- Earthworm, Acute Toxicity Test (OECD Guideline 207).

The examination of the testing proposals was initiated on 17 December 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 16 June 2011 until 1 August 2011. ECHA did not receive information from third parties.

On 1 December 2011 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 22 December 2011 ECHA received comments on the draft decision from the Registrant.

ECHA considered the Registrant's comments received and amended the draft 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

ECHA
EUROPEAN CHEMICALS AGENCY

receipt of the notification. Subsequently, one Competent Authority of a Member State 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 has reviewed the proposal for amendment received and decided not to amend the draft decision.

On 4 April 2012 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on that proposal for amendment within 30 days of the receipt of the notification.

On 16 April 2012, the draft decision was referred to the Member State Committee.

The Registrant did not provide comments on the proposed amendment.

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)(b) of the REACH Regulation, the Registrant shall carry out the following modified test using the indicated test method as specified and the registered substance subject to the present decision with a low content of respirable crystalline silica (<1% (w/w):

1. Sub-chronic toxicity study (90-day) in rats, inhalation route (Annex IX, 8.6.2., test method: OECD 413). The test shall include bronchoalveolar lavage (BAL) analysis. It is at the Registrant's discretion to perform other intended additional examinations during the testing program.

Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant shall carry out one of the following additional tests using the indicated test method and the registered substance subject to this decision for generation of data for long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.):

2. Enchytraeid reproduction test (test method: OECD 220); or
   Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (test method: OECD 222); or
   Collembolan reproduction test in soil (test method: OECD 232)

while the originally proposed Earthworm, acute toxicity test (test method: OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

ECHA
EUROPEAN CHEMICALS AGENCY

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **7 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 proposals submitted by the Registrant for the registered substance.

1. Sub-chronic toxicity (90 day)

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

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. In the registration dossier the Registrant refers to an old chronic inhalation study (tested substance included activated carbon and >6.5% silica), where only local effects were observed. Since only one dose was used, it is impossible to derive a derived no-effect level (DNEL) from that study. Sufficient 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 testing by the inhalation route. The significant route of exposure indicated by the Registrant in the registration dossier is inhalation. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the inhalation route is appropriate.

According to Annex IX, 8.6.2., column 2 of the REACH Regulation "further studies shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case of: (...) indication of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects.". The registered substance is a dust highly insoluble in water. The results of the particle size distribution provided in the registration dossier indicate that approximately 23 % (by mass) of particles are less than 10 µm. Since the available data on the substance solubility in water and particle size distribution indicate that the lower respiratory tract (i.e., the alveoli) might be the primary site of deposition and retention of the registered substance subject to the present decision and no information is yet available to characterize the risk, ECHA is requesting that bronchoalveolar lavage (BAL) analysis is being performed in the test. BAL fluid shall be analyzed for total and differential leukocyte counts, total protein, and lactate dehydrogenase. ECHA notes, that it is at the Registrant's discretion to consider examination of further parameters in addition to the above mentioned in the BAL analysis indicated in the OECD Guideline 413.

ECHA
EUROPEAN CHEMICALS AGENCY

The characterization of the test material should be documented and provided in the registration dossier as a part of the robust study summary.

The Registrant did not specify the species to be tested. According to the test method OECD 413 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is required to carry out the following modified study: Sub-chronic toxicity study (90-day) in rats, inhalation route (test method: OECD 413) using the registered substance, Activated Carbon - High Density Skeleton with low content of respirable crystalline silica (<1% (w/w). The test shall include bronchoalveolar lavage (BAL) analysis.

In his comments the Registrant expressed consent to the ECHA draft decision and proposed to extend the sub-chronic toxicity study (90 day) by including additional examinations of the male and female reproductive organs, as well as reproductive parameters such as sperm count and oestrocyclus. ECHA notes, that it is at the Registrant's discretion to perform the intended additional examinations during the testing program and use the results to ensure the safe use of the substance. However, the Registrant is reminded that the proposed extension of this study does not fulfil the standard information requirements in the registration dossier for reproductive toxicity set out in Annex X, 8.7.3. unless Annex X, 8.7. column 2 adaptation is applied.

2. Toxicity to terrestrial invertebrates

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require 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 of the REACH Regulation and pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex X, section 9.4.4. 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 proposed to perform an Earthworm, acute toxicity test justifying it by the following statement: "*there seems to be no justification in testing the effects of oral exposure of soil and sediment organisms. However, to confirm this statement, it is proposed to carry out a test with earthworms.*" However, at the tonnage level of this registration (1000 tonnes or more per year) the information on long-term toxicity to terrestrial invertebrates is a standard information requirement (Annex X, 9.4.4.). No exposure assessment and risk characterisation for environment is available for the substance. The registered substance concerned by this draft decision is very stable. The Registrant concluded that the substance is "*not amenable to break down by any natural chemical or enzymatic processes (...) is broken down only under extreme conditions*". Therefore, because of stability of the substance under standard environmental conditions, and the fact that the Registrant considers further testing necessary to confirm that the substance does

ECHA
EUROPEAN CHEMICALS AGENCY

not effect terrestrial organisms long-term toxicity testing to terrestrial organisms is necessary subject to Annex X, 9.4.4. of the REACH Regulation. At the same time, the originally proposed short-term test (test method: OECD 207) is not capable to generate information that would allow in a reliable way to conclude on the long-term toxicity of the substance to terrestrial invertebrates and is therefore not compliant with Annex X, 9.4.4. of the REACH Regulation. These considerations are also reflected in the ECHA Guidance on information requirements and chemical safety assessment Section R.7.11 Effects on terrestrial organisms (ECHA, 2008).

ECHA is not in a position to decide on the most appropriate test protocol, since that depends on species sensitivity and substance properties. The Registrant shall decide which of the three options provided above in section II fit best according to the properties of the registered substance.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following studies using the registered substance, Activated Carbon - High Density Skeleton:

- Enchytraeid reproduction test (OECD 220); or
- Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222); or
- Collembolan reproduction test in soil (OECD 232).

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 proposals. 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.

ECHA
EUROPEAN CHEMICALS AGENCY

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.

Geert DANCET
Executive Director