ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 04/07/2012

Decision number: TPE-D-0000002023-90-05/F

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

For Triamine C16-18, C18-unsaturated, CAS [redacted] (EC No 628-863-4), 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 testing proposals set out in the registration dossier for Triamine C16-18, C18-unsaturated, CAS [redacted] (EC No 628-863-4), submitted by [redacted] (Registrant), latest submission number [redacted], for 100-1000 tonnes 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, 7.16: Dissociation Constant
OECD Guideline 112 (Dissociation Constants in Water).
Annex IX, 8.6.2: Subchronic toxicity study (90 day)
OECD Guideline 408 (Repeated Dose 90-day oral toxicity study in rodents). Oral exposure route
Annex IX, 8.7.2 Pre-natal developmental toxicity study
OECD Guideline 414 (Pre-natal developmental toxicity study).

The examination of the testing proposals was initiated on 29 November 2010

ECHA opened a third party consultation for the testing proposals, including testing on vertebrate animals that was held from 29 July 2011 to 12 September 2011. ECHA did not receive any comments from third parties.
On 21 November 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 19 December 2011 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received and did amend the draft decision.

On 2 March 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. ECHA has reviewed the proposals for amendment received and decided to amend the draft decision.

On 4 April 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.

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

On 20 April the Registrant provided comments on the proposed amendments. 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 21 May 2012 in a written procedure launched on 10 May 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 tests using the indicated test method and the registered substance Triamine C16-18, C18-unsaturated:

- Dissociation Constant (Annex IX, 7.16, OECD Guideline 112)
- Subchronic toxicity study (90 day) (Annex IX 8.6.2 OECD Guideline 408. EU test method B.26) in rat by oral route
- Pre-natal developmental toxicity study (Annex IX 8.7.2 OECD Guideline 414. EU test method B.31) in rat by oral route

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

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation, subject to the Annex IX, 8.7.2. column 2 requirements. If the Registrant considers that testing is necessary to fulfil this information requirement taking into account the outcome of the pre-natal developmental toxicity study on a first species and all other relevant and available data, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

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.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcomes 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.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance.

Dissociation Constant
The proposed test (Dissociation Constant) referred to in Section II is part of the information requirements as laid down in Annex IX 7.16 of the REACH Regulation. In his comments, the Registrant indicated the possibility to provide information on the dissociation constant based on QSAR estimates. As the information on this endpoint is still not available, but needs to be present in the technical dossier to meet the information requirements, it is necessary to generate data performing a study according to OECD Guideline 112 using the registered substance as the test material.

Subchronic toxicity study (90 day) in rat, oral route
A subchronic toxicity study (90 day) is a standard information requirement of Annex IX, 8.6.2 at the present tonnage level, which the Registrant has suggested to cover by a testing proposal concerning a subchronic toxicity study (90 day) (OECD Guideline 408).
The test material for this study should be the registered substance. Based on the low vapour pressure and corrosive nature of the registered substance the oral default route and the rat as default species are appropriate.
In his comments, the Registrant expressed consent to ECHA's draft decision on this endpoint.

Prenatal developmental toxicity study in rat, oral route
A prenatal developmental study is a standard information requirement of Annex IX, 8.7.2 at the present tonnage level, which the Registrant has suggested to cover by a testing proposal concerning a prenatal developmental toxicity study (OECD Guideline 414).
The test material for this study should be the registered substance. Based on the low vapour pressure and corrosive nature of the registered substance the oral default route and the rat as default species are appropriate.
In his comments, the Registrant expressed consent to ECHA's draft decision on this endpoint.
When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all

relevant available data provides scientific justification that the study in a second species is not needed.

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 reads:

> *"Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."*

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.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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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.

[redacted]

Geert Dancet
Executive Director