ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002298-69-02/F Helsinki, 24 April 2012

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

**For Tetrakis(hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea, CAS No 27104-30-9 (EC No 500-057-6), 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 a testing proposal set out in the registration dossier for Tetrakis(hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea, CAS No 27104-30-9 (EC No 500-057-6), 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 proposal as part of the registration dossier to fulfil the information requirements set out in Annex IX:

Repeated dose 90-day oral toxicity study (OECD Guideline 408).

The examination of the testing proposal was initiated on 2 November 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 1 September 2011 until 17 October 2011. ECHA received information from third parties (see section III below).

On 2 December 2011 ECHA sent a draft decision to the Registrant for comments. The Registrant did not provide any comments on the draft decision.

On 20 January 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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 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 proposed test using the indicated test method and the registered substance concerned by the present decision:

> Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2., test method: EU B.26/OECD 408).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by 24 October 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 submitted by the Registrant for the registered substance and scientific information submitted by third parties.

**Sub-chronic toxicity (90 day)**

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.

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. 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 testing by the oral route. 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 oral route is appropriate.

The Registrant did not specify the species to be tested. According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the registered substance.

In addition, the Registrant has indicated in conjunction with the testing proposal that the experimental study shall be used also to seek for additional information by extending the test method with "specific assessment of effects on the reproductive cycle". While the Registrant may proceed with this generation of additional information, ECHA notes that such

specification would only cover effects on the parent generation, but not the effects on a first nor a second offspring generation. Thus, the Registrant should take into account that the proposed extension would not satisfy the information requirement for a two-generation reproductive toxicity study at Annex X, 8.7.3.

b) Consideration of third party information

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party has proposed to use the results from a sub-chronic toxicity study (90-day) performed in rats and mice by oral route with Tetrakis(hydroxymethyl) phosphonium chloride (THPC) to fulfil the information requirements set in Annex IX, 8.6.2. of the REACH Regulation. The references provided by the third party are:

- International programme on chemical safety. Environmental Health Criteria 218. Flame retardants: Tris(2-butoxyethyl) phosphate, Tris(2-ethylhexyl) phosphate and Tetrakis(hydroxymethyl) phosphonium salts. World Health Organization. Geneva. 2000.
- US NTP (1987) Toxicology and carcinogenesis studies of tetrakis(hydroxymethyl)phosphonium sulfate (THPS) (CAS No. 55566-30-8) an tetrakis(hydroxymethyl)phosphonium chloride (THPC) (CAS No. 124-64-1) in F344/N rats and B6C3F1 mice (gavage studies). Research Triangle Park, North Carolina, US Department of Health and Human Services, National Toxicology Program (Technical Report Series No. 29; NIH Publication No. 87-2552).

It is not clear whether the third party considers that this study was done with the registered substance or whether read-across from this study is proposed. THPC is both the starting material and a constituent of the registered substance but it is not as such the registered substance concerned by the present decision. As for the possibility of a read-across, the third party has not provided scientifically sound rationale to justify it. In view of the inadequacy of the documentation, ECHA cannot conclude that the provisions of Annex XI, section 1.5, have been fulfilled.

Therefore, ECHA concludes that testing cannot be omitted based on the information provided by the third party.

IV. 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.

## V. 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