Decision number: CCH-D-0000003064-83-03/F Helsinki, 28 February 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Tetrakis (hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea (Monomer) 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for Tetrakis (hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea (Monomer) CAS No 27104-30-9 (EC No 500-057-6), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Section 8.4. of the REACH Regulation.

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 5 September 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 28 September 2012.

On 17 December 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 8 January 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Testing Required (Section II) were made.

On 5 September 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, 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.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

In vitro gene mutation study in bacteria (Annex VII, 8.4.1.; test method: EU B.13/14/OECD 471);

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **28 August 2014.**

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement. The scope of the present decision is the *in* vitro gene mutation study in bacteria (Annex VII, 8.4.1. of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1) of the REACH Regulation, any registration for a substance shall contain this information.

The technical dossier did not contain an *in vitro* gene mutation study in bacteria nor an adaptation argument to the standard information requirement that forms the scope of the present decision.

Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant was requested to submit the information for this endpoint using the abovementioned test method on the registered substance.

Following the draft decision the registrant commented that "As a good laboratory practice (GLP) gene mutation assay in Chinese Hamster V79 cells in vitro (V79/HPRT) (OECD476) is already available and as no alerts were noted in this test, we consider that it is not necessary to perform an in vitro gene mutation study in bacteria (OECD471)."

However, as specified in Annex VIII, Column 2, 8.4. "Appropriate *in vivo* mutagenicity studies shall be considered in case of a positive result **in any** of the genotoxicity studies in Annex VII or VIII.". Thus, the Ames test is an important regulatory trigger for further *in vivo* genotoxicity studies that cannot be waived on the basis of another available *in vitro* study in mammalian cells. Therefore, the section II of the draft decision has not been amended.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the 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 carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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]

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