ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000001760-79-05/F Helsinki, 28 February 2012

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

For (1-METHYLETHYLIDENE)DI-4,1-PHENYLENETETRAPHENYL DIPHOSPHATE, CAS No 5945-33-5 (EC No 425-220-8), 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 the testing proposal set out in the registration dossier for (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate, CAS No 5945-33-5 (EC No 425-220-8) submitted by [redacted] (Registrant), latest submission number [redacted] for 1000 tonnes per year or more.

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 X:

Annex X, 8.7.3. Two-generation reproductive toxicity study.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 3 January 2011.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 5 April 2011 until 20 May 2011. ECHA received the following comment from third parties:

> The results from the "combined subchronic repeated dose study with one generation and teratogenicity study" with a read-across substance triphenyl phosphate (TPP) have been submitted to avoid the performance of a two-generation reproductive toxicity study with the registered substance.

ECHA examined the testing proposal and the information received from third parties and prepared a draft decision in accordance with Article 40(3) of the REACH Regulation.

On 1 July 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.

By 1 August 2011 the Registrant did not provide to ECHA any comments on the draft decision.

On 2 September 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, one Competent Authority of the Member States submitted a proposal for amendment to the draft decision. ECHA reviewed the proposal for amendment received and did not modify the draft decision.

On 5 October 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 on those proposals for amendment within 30 days of the receipt of the notification. The Registrant did not provide any comments on the proposal for amendment.

On 17 October 2011, the draft decision was referred to the Member State Committee.

After discussion in the Member State Committee meeting on 7-9 December 2011, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the modified draft decision was reached on 8 December 2011.

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)(d) of the REACH Regulation, the testing proposal submitted as part of the registration dossier to fulfil the information requirements set out in Annex X for performing the:

Two-generation reproductive toxicity study (Annex X, 8.7.3., EU Method B. 35)

is rejected.

III. Statement of reasons

The decision of ECHA is based on the fact that the above mentioned test has already been requested by the Competent Authority of [redacted] from another registrant [redacted] (previous registrant) under the national legislation implementing Directive 67/548/EEC. Decisions by Member State Competent Authorities are deemed to be ECHA decisions pursuant to Article 135(1) of the REACH Regulation. The previous registrant had notified the substance following the national provisions implementing Directive 67/548/EEC and the notification is regarded a registration under the REACH Regulation in accordance with Article 24(1) thereof. The decision of the [redacted] Competent Authority is effective and enforceable.

Given that the previous registrant had already been required to perform the test referred to in Section II and given that Article 25(1) of the REACH Regulation provides for avoidance of unnecessary testing on vertebrate animals, there is no need to request a second test for the same substance at this moment. Instead, the Registrant will need to take full account of the obligation to agree on sharing information and costs with the previous registrant once the

requested data has been generated and is available. In that case, ECHA will inform the Registrant accordingly and both the Registrant and the previous registrant will pursuant to Article 27 need to make every effort to reach an agreement on the sharing of the information requested, ensuring that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

As stated above, ECHA may initiate a compliance check on the registration dossier at hand in order to receive the standard information required for substances registered for 1000 tonnes or more per year. In particular, ECHA may check whether the Registrant has complied with Annex X, 8.7.3. of the REACH Regulation.

With regard to the two-generation reproductive toxicity study, a third party comment was received during public consultation. The information of the reprotoxic potential of a related substance, triphenyl phosphate (TPP), which was tested in a "combined subchronic repeated dose study with one generation and teratogenicity study" has been submitted, stating that no reproductive toxicity of the read-across substance TPP has been noted.

The third party comment refers to a "combined subchronic repeated dose study with one generation and teratogenicity study" to cover the testing proposal for a two-generation reproductive toxicity study which is required under Annex X, section 8.7.3. of the REACH Regulation. The publication submitted by the third party describes in fact a combined subchronic repeated dose study and a teratogenicity study, since the dams were terminated on day 20 of gestation, after which numbers of corpora lutea were examined in the ovaries, number and status of fetuses were confirmed and implantation sites were recorded in uteri, and visceral and skeletal malformations of the fetuses were examined.

The study in question does not address peri- and postnatal effects as described in the endpoint specific standard study (EU test method B.35: two-generation reproduction toxicity study).

Based on the observations listed above ECHA concludes that without prejudice to the rejection of the testing proposal for other reasons as described above, the study by third parties cannot be accepted as it does not cover the endpoint subject to testing proposal (two-generation reproduction toxicity study).

IV. 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 adapted

to the 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.

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.

[redacted]
Jukka Malm
Director of Regulatory Affairs