ECHA
European Chemicals Agency

Decision number: TPE-D-0000001732-78-03/F Helsinki, 7 November 2011

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

For Sodium phosphinate, CAS 7681-53-0 (EC No. 231-669-9), 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 **Sodium phosphinate, CAS No 7681-53-0 (EC No 231-669-9)** 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:

> Annex IX, 8.7.2: Pre-natal developmental toxicity study in rat by the oral route and according to the EU test Method B.31/OECD test guideline 414.

The examination of the testing proposal was initiated on 13 July 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 26 January 2011 until 14 March 2011. ECHA received the following comments from third parties:

- Consideration of existing toxicological data;
- *In vitro* test methods which are validated or at the pre-validation stage;
- Exposure;
- Clarification on conduction of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.

On 15/07/2011 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.

The Registrant did not provide 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, 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 test using the indicated test method while taking full account of the obligation to agree on sharing of information and costs with other registrants:

Pre-natal developmental toxicity study (Annex IX, 8.7.2, EU Method B 31) in rat by the oral route.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **7 November 2012** 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.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance and the scientific information submitted by third parties.

a) Examination of testing proposal

A pre-natal developmental toxicity study for a first species is a standard information requirement under Annex IX, 8.7.2. As 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, it follows that there is an information gap and that it is necessary to generate the data for this endpoint.

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 was not sufficient to fulfil this information requirement.

Therefore, pursuant to Article 40(3) (a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Pre-natal developmental toxicity study in rats, oral route (method B.31 of Regulation (EC) No 440/2008; OECD test guideline 414).

b) Response to third party information on the testing proposal

It was proposed by third parties that, before further animal testing would be carried out to meet the information requirements, consideration should be given to the following alternative testing strategies:

1. Results of the existing 28-day or 90-day study (OECD Guideline 407 or 408) and other toxicological data;
2. *In-vitro*-testing methods which are validated or at the pre-validation stage;
3. Exposure considerations;
4. Clarification on conduction of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.

The third party has proposed a strategy for ECHA to consider before further tests on animals are requested. However, third parties were invited, as specified by Article 40(2) to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy cannot be regarded as such information or studies, ECHA concludes that this is not a sufficient basis for rejecting the Testing Proposal.

Additionally, ECHA draws your attention to the following:

- For *in vitro* tests (embryonic stem cell test, the limb bud micromass culture and the whole embryo culture), ECHA notes the Guidance on information requirements and chemical safety assessment R.7, chapter R.7.6, which states these tests have limited value in a regulatory context. ECHA notes that the mentioned *in vitro* tests only cover some of the reproductive toxicity endpoints, modes of action and mechanisms covered by the *in vivo* pre-natal developmental toxicity tests and therefore cannot be used as stand alone replacement tests. Furthermore, these alternative methods are not part of the information requirements laid down in Annex VII to X of REACH and can therefore not be requested by ECHA in the context of a testing proposal examination. ECHA outlines that it is the Registrant's responsibility to establish the weight of evidence justification demonstrating that the data set provided by the use of the proposed tests is sufficient to meet the information requirements when submitting and/or updating its registration dossier.

- The communication issued by ECHA on 15 September 2009 and referred to by the third party provided clarifications on the minimum of information expected for a dossier to be considered complete and outlined that additional information could be necessary to comply with the REACH Regulation and to ensure safe use. In the present case, the information requirements from column 1 of the Annexes VII, VIII, IX and X are cumulative and apply to this dossier. The results from the combined 28-day repeated dose toxicity study with the reproduction/developmental toxicity screening test included in the registration

dossier do fulfil the standard information requirements stated under Annex VIII, 8.6.1 and 8.7.1. According to Annex VIII, 8.7.1 column 2, the screening study for reproductive/developmental toxicity does not need to be conducted if a pre-natal developmental toxicity study or a two-generation reproductive toxicity is available. Since none of these studies is available, the information requirement of stated in Annex VIII, 8.7.1 was fulfilled by conducting a reproduction/developmental toxicity screening test using the registered substance and according to the OECD test guideline 422.

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 as adapted to technical progress 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.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs