EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003794-66-04/F Helsinki, 13 December 2013

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

For 1,3,5-triazine-2,4,6-triamine phosphate, CAS No 41583-09-9 (EC No 255-449-7), 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 for 1,3,5-triazine-2,4,6-triamine phosphate, CAS No 41583-09-9 (EC No 255-449-7), submitted by [redacted] The scope of this compliance check is limited to the following standard information requirements relating to "Aquatic toxicity" and related environmental hazard assessment (Annex IX, 9.1.5. and 9.1.6., and Annex I, Section 3.3. of the REACH Regulation). ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration 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 submitted 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 registration at a later stage.

The compliance check was initiated on 17 May 2013.

On 28 June 2013 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 9 July ECHA received comments from the Registrant agreeing to ECHA's draft decision but requesting prolongation for the deadline given in Section II.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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) and (b), 41(3), 10(a)(vii), 12(1)(e), 13 as well as Annex IX of the REACH Regulation the Registrant is required to carry out the following studies using the indicated test methods and the registered substance subject to the present decision:

a. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
b. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210),

as specified further under Section III.

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I, 3.3. of the REACH Regulation the Registrant shall submit the following information:

c. Revised PNECs for the aquatic compartment on the basis of data from a. and b. above as it becomes available.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **13 June 2016**. The timeline has been set to allow for sequential testing as appropriate.

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

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 covers Annex IX, 9.1.5. and 9.1.6. as well as related environmental hazard assessment. In accordance with Articles 10(a)(vii), (b), 12(1) and 14(1) of the REACH Regulation, the registration is required to contain this information.

a. and b. Long-term aquatic toxicity testing on invertebrates and fish

According to column 1 of Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates and on fish is required to fulfil the standard information requirements.

The Registrant sought to fulfil these information requirements on aquatic long-term toxicity from the application of the following studies for Fish :

- Acute and subacute toxicity to rainbow trout study on juvenile fish,

- The influence of melamine on the egg-larval development of the fresh water fish *Jordanella floridae* study,

and for aquatic Invertebrates :

- The acute and chronic toxicity of melamine (2,4,6-triamino-triazine) to *Daphnia magna* using dutch proposed standards NEN 6501 and 6502.

ECHA notes that these studies were carried out on a proposed analogue substance.

Aquatic toxicity studies on Fish can be only regarded as long-term when the sensitive life-stages (juveniles, eggs, larvae) are exposed. For aquatic toxicity studies on Invertebrates at least two broods (depending on the species even more) need to be exposed so that the study can be considered as long-term.(ECHA Guidance on information requirements and chemical safety assessment, pages 25, 26 of Chapter R. 7B (version 1.2., November 2012)).

The submitted information does not suffice to fulfil the two endpoints in question:

- Annex IX, Section 9.1.6. – fish:
  Firstly, none of the submitted fish studies covers all sensitive life-stages (juveniles, eggs and larvae). With the available data, even a weight-of-evidence approach could not be applied.
- Annex IX, Section 9.1.5. – aquatic invertebrates: The acute and chronic toxicity studies do not cover two broods and can therefore not be recognised as long-term study. The Registrant also has not submitted a weight-of-evidence argument.

As the information provided would not even fulfil the information requirement for the analogue substance, ECHA stresses that at this stage it has not assessed the Registrant's justification for proposing a read-across from the analogue substance.

As the submitted information does not fulfil the information requirements, there are information gaps and it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with relevant information requirements.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5., pages 32-57, including Figure R.7.8-4 on page 56) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit information using the following test methods on the registered substance:

- Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
- Long-term toxicity testing on fish (Annex IX, 9.1.6.1; test method: Fish, early-life stage toxicity test, OECD 210). If based on the integrated testing strategy (described above) the Registrant comes to the conclusion that no further investigation of effects on fish is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, Section 9.1.6.

c. Revised PNECs for the aquatic compartment

Annex I, Section 3.3. of the REACH Regulation requires the Registrant to establish predicted no effect concentrations (PNEC(s)) for the registered substance, covering each environmental sphere, including the aquatic compartment.

ECHA notes that, the registration submitted by the Registrant contains PNECs for the aquatic compartment. ECHA notes furthermore that in the derivation of the aquatic PNECs the Registrant has applied as lowest an assessment factor (AF) of [redacted].

The footnote to Annex I, Section 3.3.1. provides information on the application of assessment factors to cover the uncertainty associated with the available data, indicating that an assessment factor of 1000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10 is applied to the lowest of three long-term NOEC values derived from species representing different trophic levels. This is further explained in the ECHA guidance Chapter R.10.

ECHA concludes that the Registrant's choice of an AF is not in line with the provisions of the footnote to Annex I, Section 3.3.1 and of ECHA Guidance chapter R.10, Section R.10.3.1.2 and – without full justification – not appropriate in accordance with Annex I, Section 3.3.1.In particular, while the information stemming from the studies submitted for fulfilling the information requirements of Annex IX, 9.1.5. and 9.1.6. is data that is available and shall be taken into consideration in the derivation of the PNEC, it does not justify the AF the Registrant has chosen, as these test methods even in a weight of evidence approach do not provide information on long-term toxicity (see subsections III. a. and b. above).

Consequently, the derived aquatic PNECs are invalid. The Registrant shall therefore provide revised aquatic PNECs derivation in line with the provisions of Annex I as indicated above, in particular by applying an appropriate and fully justified AF. They shall be kept updated, along with the whole Chemical Safety Report. In particular, when data becomes available from the study required under Section II.a and b. it shall be taken into consideration in an updated derivation of the aquatic PNECs.

Deadline for submitting the required information

In the draft decision, ECHA indicated that the Registrant should submit the required information to ECHA in an updated registration dossier within 18 months from the date of the final decision. In its comments, the Registrant requested to prolong the timeline from 18 to 36 months. The Registrant based its request on issues related to the laboratory capacity and on the time frame for the development of the analytical method.
ECHA accepts the Registrant's argument that a 9 months scheduling phase is necessary. However, the argument that further 9 months are needed to develop an anlytical method and pre-test was considered excessive. ECHA considers that 6 months in addition to the 9 months provided for scheduling purposes are sufficient.

Furthermore, ECHA agrees to the fact that sequential testing should be possible. On this basis, ECHA agrees to the 6 months period that the Registrant suggests for conducting the Daphnia test first. However, ECHA does not agree with the Registrant's additional suggestion to allow 12 further months for performing the Fish test as the analyticial set up should be already finalised and the experimental set-up from the Daphnia test can also be applied. ECHA considers 9 months adequate for performing consecutively the Fish test.

Therefore, ECHA acknowledges the Registrant's request to extend the deadline due to substance properties and issues with test laboratory facilities and agrees to extend the timeline from 18 months to 30 months.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants 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 relation to the information required by the present decision, 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 joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

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 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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