EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005779-56-01/F Helsinki, 24 November 2014

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

For pentaerithrityl tetranitrate, CAS No 78-11-5 (EC No 201-084-3), 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 pentaerithrityl tetranitrate, CAS No 78-11-5 (EC No 201-084-3), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 9.2.1.1 and Annex VIII, Section 8.4.3. 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 6 March 2014, 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 5 June 2013.

On 31 October 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.

By 2 December 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 6 March 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

1. Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes VII and XI of the REACH Regulation the Registrant shall submit the following information using one of the indicated test methods and the registered substance subject to the present decision:

   Ready biodegradability (Annex VII, 9.2.1.1.; test method: CO2 evolution test, OECD 301B).
   or
   Ready biodegradability (Annex VII, 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD 310).
   or
   Ready biodegradability (Annex VII, 9.2.1.1.; test method: MITI test (I), OECD 301C).
   or
   Ready biodegradability (Annex VII, 9.2.1.1.; test method: Closed bottle test, OECD 301D).
   or
   Ready biodegradability (Annex VII, 9.2.1.1.; test method: Manometric respirometry test, OECD 301F).
   or
   Ready biodegradability (Annex VII, 9.2.1.1.; test method: DOC die-away test, OECD 301A).
   or
   Ready biodegradability (Annex VII, 9.2.1.1.; test method: Modified OECD screening test, OECD 301E).

2. Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e) and Annex VIII 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 mammalian cells (Annex VIII, 8.4.3.; test method: EU B.17/OECD 476).

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 **1 December 2015**.

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 requirements. The scope of the present decision is the ready biodegradability (Annex VII, 9.2.1.1. of the REACH Regulation) and *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3. of the REACH Regulation).

1. Ready biodegradability

Pursuant to Articles 10(a)(vii) and 12(1)(a) of the REACH Regulation, the endpoint 'ready biodegradability' (Annex VII, 9.2.1.1.) is a standard information requirement for registration for a substance produced or imported in quantities of one tonne or more per year. Column 2 of Section 9.2.1.1 of Annex VII further states that the study does not need to be conducted if the substance is inorganic. The registrant may also seek to adapt the information requirement according to general rules for adaptation laid down in Annex XI, including weight of evidence (Section 1.2).

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) Adequate and reliable documentation of the study is provided.

In the present case, the technical dossier contains two study records taken from the reviewed scientific articles (Appl Environ Microbiol 62: 637-642 and 1214-1219). The two reported studies do not follow any standard test guideline, they are both assessed as reliability score 4 and they are used in the Weight of Evidence assessment. In the first study the degradation of the substance was measured after 100 hour incubation with the pure culture isolated from a mixture of sewage, soil and natural water. In the second study the degradation was measured after 100-hour incubation in the presence of pure culture isolated from natural soil. In both studies the concentration of the parent compound was reported to be decreased 99-100 % after the incubation and based on the results the substance was concluded to be readily biodegradable.

ECHA considers that the information provided in the registration dossier is not appropriate to conclude that the registered substance is readily biodegradable. The information in the technical dossier section 5.2.1 is not based on any of the standard ready biodegradability test guidelines. Furthermore, the documentation in this technical dossier section is not adequate to enable the assessment of the adequacy of the provided data to demonstrate the ready biodegradability. Since adequate and reliable documentation of the studies is not provided it is not possible to assess if the data are adequate for demonstrating ready biodegradability and thus adequate for the purpose of classification and labelling and risk assessment. Therefore, the conditions 1 and 4 of the section 1.1.2 of Annex XI of the REACH Regulation are not met.

Since there is no other data presented to support the weight of evidence approach in line with Annex XI, Section 1.2 of the REACH Regulation, ECHA concludes that the criteria for it are not met.

ECHA therefore considers that the information provided on this endpoint is not adequate to conclude on ready biodegradability. The technical dossier does not either contain acceptable adaptation in accordance with Column 2 of Section 9.2.1.1 of Annex VII or Annex XI for this standard information requirement.

Regarding the test method, depending on the substance profile, the Registrant may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA Guidance on information requirements and chemical safety assessment, Volume 5 Chapter R7b (November 2012) and in the paragraph below. The test guidelines include the description of their applicability domain.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to perform one of the following tests with the registered substance subject to the present decision:

Ready biodegradability (Annex VII, 9.2.1.1.; test method: CO_2 evolution test, OECD 301B).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Ready biodegradability – CO_2 in sealed vessels (headspace test), OECD 310).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: MITI test (I), OECD 301C).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Closed bottle test, OECD 301D).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Manometric respirometry test, OECD 301F).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: DOC die-away test, OECD 301A).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Modified OECD screening test, OECD 301E).

2. Mutagenicity, *in vitro* gene mutation study in mammalian cells

In accordance with Articles 10(a)(vii), 12(1)(e) and with Annex VIII, section 8.4.3. of the REACH Regulation, an *in vitro* gene mutation study in mammalian cells is required if there is a negative result in the *in vitro* studies specified under Annex VII, section 8.4.1. and Annex VIII, section 8.4.2. Column 2 of Section 8.4.3 of Annex VIII provides that the study does not usually need to be conducted if adequate data from a reliable *in vivo* mammalial gene mutation test are available. The registrant may also seek to adapt the information requirement according to general rules for adaptation laid down in Annex XI.

In the present case, the registration dossier reports negative results for the both *in vitro* studies. Therefore the REACH Regulation requires that information on *in vitro* gene mutation in mammalian cells (Annex VIII, 8.4.3.) is provided in the dossier. The Registrant has neither provided this standard information nor adapted the requirement in line with column 2 of Annex VIII, 8.4.3 or Annex XI. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: EU B.17./OECD 476).

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. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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.

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