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Helsinki, 22 September 2016

Addressee: [redacted]

Decision number: CCH-D-2114344289-42-01/F
Substance name: Reaction mass of tris(2-chloropropyl) phosphate and tris(2-chloro-1-methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester [...]
List number: 911-815-4
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08 February 2012
Registered tonnage band: over 1000 tonnes per year

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Name or other identifier of each substance (Annex VI, Section 2.1.) of the registered substance**
   - **Chemical name;**
2. **Composition of the substance (Annex VI, Section 2.3.)**
   - **Identification of the constituents;**
3. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2; test method: EU B.31/OECD TG 414) in rabbits, oral route with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **29 March 2018**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

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Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/guest/regulations/appeals.

Authorised[1] by, Ofelia Bercaru Head of Unit, Evaluation E3

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

1. Name or other identifier of the substance (Annex VI, Section 2.1.);

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Annex VI, section 2.1 of the REACH Regulation requires that the registration dossier contains adequate and sufficient information to enable each substance to be identified.

According to the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, a multi-constituent substance consists of several main constituents which are present at concentrations generally ≥ 10% and < 80% (w/w) and that the substance is named as a reaction mass of these main constituents. According to chapter 4.3 of the Guidance substances presenting a large number of constituents should, instead, be considered as UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin).

ECHA notes that you identified the registered substance as a well-defined multi-constituent substance. However, two of the constituents included in the name are present at concentrations < 10%.

Furthermore, the two other constituents that are indicated to be present ≥ 10% have multiple stereocenters which indicates that they represent several isomers and that both the identified constituents refer to a "constituent group". As a result, the number of the constituents is relatively large; therefore, the substance could be more appropriately identified as a UVCB substance (Substances of Unknown or Variable composition, Complex reaction products or Biological materials).

In the present dossier, you identified the registered substance as a well-defined multi-constituent substance "Reaction mass of tris(2-chloropropyl) phosphate and tris(2-chloro-1-methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester and Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester".

Based on the information given, two of the constituents listed in section 1.2 "[redacted]" and "[redacted]" are present in the substance at a concentration <10%. According to the Guidance, constituents present at a concentration <10%, are not regarded as main constituents in a multi-constituent substance and, therefore, should not appear in the name of the substance.

The two other constituents listed in section 1.2 "[redacted]" and "[redacted]" that are present in the substance at a concentration >10%, have both three stereocenters. Therefore, each of them represents a "group of constituents". Because "[redacted]" and "[redacted]" represent groups of constituents, the number of constituents present in the substance is relatively large, there is potential variability of the composition and the substance would be more appropriately identified as a UVCB substance instead of a multi-constituent substance.

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ECHA, therefore, concludes that the substance has not been appropriately identified and the chemical name indicated is not representative for the registered substance.

You are requested to clarify the identity of the substance and ensure that the information is consistent throughout the dossier.

In case you decide to identify the registered substance as a multi-constituent substance, the main constituents present at concentrations generally ≥ 10% and < 80% (w/w) need to be taken into account when naming the substance and the generic format used for naming multi-constituent substances is "Reaction mass of [IUPAC names of the main constituents]". Please note that a "main constituent" should refer to a single constituent present ≥ 10% – it is not sufficient that a "group of constituents" is present ≥ 10%.

In case you decide to identify the registered substance as a UVCB substance, the following applies:

a. The naming of the UVCB substances consists of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance.
b. The description of the manufacturing process shall cover the starting material used, ratio of the starting materials, steps and relevant process parameters.

As for the reporting of the information in IUCLID, the following applies:
You shall decide, first, whether the substance is to be identified as a multi-constituent substance or as a UVCB substance.
In case of a multi-constituent substance the substance is named as a "Reaction mass of [IUPAC names of the main constituents]" and this name is indicated in the IUPAC name field in IUCLID section 1.1. The main constituents shall be consistent with the constituents listed in IUCLID section 1.2 as "constituents".

In case of a UVCB substance the chemical name and the manufacturing process description shall be specified in the "IUPAC name" and "Description" field in IUCLID section 1.1, respectively. All constituents are to be listed under "constituents" as the terms "main constituents" and "impurities" are not regarded as relevant for UVCB substances.

Further technical details on how to include the name and report the composition of a multi-constituents substance or UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

As the EC identifier currently assigned to the registered substance does not fully correspond to the registered substance, you shall not, at this stage, remove or modify this EC entry for technical reasons, as the registration is linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, you shall however specify in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 911-815-4 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

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ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Under this compliance check, the process of adapting the identifier can however only be applied once ECHA is in a position to establish the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of this decision indicate that the process of adapting the identifier is relevant, ECHA will inform you in due time as to when this process shall be initiated. You should note that the application of the process of adapting the identifier is without prejudice to the requirements specified in this decision.

2. Composition of the substance (Annex VI, Section 2.3.);

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

ECHA notes that not all constituents listed in section 1.2 are unequivocally described.

In the present dossier, you have not indicated a IUPAC name for the second listed constituent (CAS number: [redacted], CAS name: [redacted]). Furthermore, the SMILES notation and the structural formula do not refer to the substance identified by the CAS entry, but to the fourth listed constituent (CAS number: [redacted], CAS name: [redacted]).

In the present dossier, you have not indicated a IUPAC name for the third listed constituent (CAS number: [redacted], CAS name: [redacted]. Furthermore, the structural formula does not refer to the substance the CAS entry and the SMILES notation identify.

ECHA therefore concludes that the constituents have not been appropriately identified.

Consequently, you are requested to review the information provided in section 1.2 and to ensure that information submitted on the constituents (or group of constituents) is consistent.

You shall ensure that each constituent is reported unequivocally. The IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.

For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.

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3. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material.

However, there is no information provided for a pre-natal developmental toxicity study in a second species.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out by using a rodent species (rats). According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbits as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbits) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7.2., column 2 and general adaptation possibilities of Annex XI.

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If the results of the test in the first species enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision, you requested either an extension of the timeline to 18 months for request number 3 of this decision, or an extension of the compliance check until March 2018. You sought to justify this request by informing ECHA that the registered substance is currently undergoing a comprehensive testing program by the U.S. National Toxicology Program ('NTP') and that this testing program is almost completed and the publication of the results is imminent. Depending on the results of the NTP testing program (e.g. if the substance is to be classified as a genotoxic carcinogen or the substance is a germ cell mutagen or has to be classified as toxic for reproduction Cat. 1A or 1B, H360D), the waiving arguments of Column 2 of Annex X 8.7.2 REACH may be fulfilled; or possibly waiving under Annex XI 1.2. REACH (weight of evidence) may be possible. In such case, the pre-natal developmental toxicity (PNDT) second species study (on rabbits) may not be required. Therefore, for animal welfare reasons, you requested to extend the deadline of the draft decision. ECHA has examined the information you provided and considered your request as acceptable. Therefore, ECHA has modified the deadline of the decision from 12 to 18 months.

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Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 12 February 2016.

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision and requested a prolongation of the deadline. ECHA took into account your comments and amended the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2017.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

3. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the substance composition manufactured or imported 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 test(s) 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 or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.