ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002044-86-04/F Helsinki, 5 April 2012

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

For [redacted], CAS No [redacted] (EC No [redacted]), 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 the ECHA has performed a compliance check of the registration dossier for [redacted] submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 28 February 2011.

On 2 May 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.

On 1 June 2011 the Registrant provided to ECHA comments on the draft decision, and on 2 September 2011 the Registrant updated the dossier.

ECHA took into account the information received and amended the draft decision accordingly.

On 4 November 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 submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided to modify the draft decision.

On 8 December 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 within 30 days of the receipt of the notification.

On 19 December 2011 the draft decision was referred to the Member State Committee.

On 9 January 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 6-10 February 2012, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 8 February 2012.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vii) and 12(1)(e) as well as Annexes IX-X of the REACH Regulation, the Registrant shall submit the information using the test method as indicated below:

   a. Sub-chronic toxicity (90-day) in the rat via the oral route (Annex IX, 8.6.2; EU Method B.26 or OECD test guideline 408); and
   b. Developmental toxicity study in the rabbit via the oral route (Annex X, 8.7.2.; EU Method B.31 or OECD test guideline 414).

Pursuant to Article 41(4) of the REACH Regulation, the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by 5 April 2014.

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

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12, 13 and 14, as well as with Annexes I and IX-X thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Missing information related to endpoints

Pursuant to Articles 10(a)(vii) and 12(1)(e) of the REACH Regulation, a registration for a substance produced in quantities of above 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII and VIII and testing proposals for the provision of information specified in Annexes IX and X to the REACH Regulation.

   a. Sub-chronic toxicity (90-day) (Annex IX, 8.6.2)

ECHA notes that the Registrant has provided a 28-day oral repeated dose toxicity study as the key study, as well as several support studies of various durations. The dossier contained an oral 35-day study carried out in 1960 without any histopathology, 6 studies of reliability 3-4 with very limited information, with either unknown number of animal, unknown duration, unspecified organ weights, no information on study design, parameters investigated and even results. There is also a 21-day rabbit study, a 120-day dietary study in the rat that investigated only immunotoxicity and a 90-day oral study in the rat with a minimal abstract presented in the place of the Robust Study Summary (RSS). ECHA states

that most of these studies were conducted by using outdated testing protocols and were either too short to cover the 90-day duration or involved only selected parameters (e.g. immunotoxicity, neurotoxicity) compared to the full range of parameters in the 90-day repeated dosed toxicity study. For example, kidney and liver have not been investigated in a study with appropriate length (at least 90-days).
In response to ECHA's draft decision, the Registrant submitted additional data on sub-acute and sub-chronic toxicity and argued that Annex XI 1.1.2 conditions for waiving the information requirement are met. For the reasoning presented above, ECHA concludes that the additional information both on its own and in a combined weight-of-evidence approach, as defined in Annex XI, 1.2 to the REACH Regulation, does not meet the criteria set out in Annex IX, Column 2, 8.6.2 and Annex XI, sections 1.1.2 and 3.2.

The Registrant is therefore requested to submit information on a sub-chronic toxicity (90-day study) in the rat via the oral route by using the EU test method B.26 or OECD test guideline 408.

b. Pre-natal developmental toxicity study in another species than rat by oral route (Annex X, 8.7.2)

Annex IX, section 8.7.2 describes the information requirement for a pre-natal developmental toxicity study, with the following column 2 provision: "The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data." Annex X, section 8.7.2 has a separate, and additional, column 1 information requirement for "Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (OECD 414)." Both information requirements are subject to all appropriate column 2 or Annex XI data adaptations.

ECHA observes that in the technical dossier, the Registrant has provided data on developmental toxicity, and no adverse effects on prenatal development were observed in a study on the first species. However, there is no information provided for the pre-natal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement. Therefore there is an information gap.

In response to ECHA's draft decision, the Registrant expressed his view that a developmental toxicity study in a second species (e.g. rabbit) would not be a standard information requirement for substances manufactured or imported in quantities of 1000 tons or more. ECHA concludes that the justification does not meet the criteria set out in Annexes IX and X (8.7.2), and Annex XI. Moreover, as outlined above, it follows from the information in Annexes IX and X, 8.7.2 that a first species test is to be conducted at a tonnage band of 100 to 1000 tonnes per year and where deemed necessary already at this level, a second species test may be necessary. The second species test then becomes a default requirement at a tonnage band of 1000 tonnes or more. Otherwise there would be no need to restate as information requirement for this study at Annex X level. Accordingly, the Registrant is requested to submit information on a developmental toxicity study for a second species, namely in the rabbit via the oral route by using EU Method B.31 or OECD test guideline 414.

2) Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a 2-generation reproductive toxicity study in order to comply with the information requirement set out in Annex X, 8.7.3. As it was ultimately decided not to address in this decision any potential deficiencies with respect to the compliance of the dossier with the standard information requirement set out in Annex X, 8.7.3., ECHA considers that a reasonable time period for providing the remaining required information in the form of an updated IUCLID5 dossier is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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 ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 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.

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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