~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001558-68-04/F Helsinki
Decision date: 27 July 2011

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

For HFO-1234ze/ [redacted] (EC Nr. 471-480-0); 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 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation) the European Chemicals Agency (ECHA) has performed a compliance check of the registration dossier for **HFO-1234ze/ [redacted] (EC Nr. 471-480-0)** submitted by [redacted] (Registrant), latest submission number [redacted], for >1000 tonnes per year.

The compliance check was initiated on 13 September 2010.

On 23 November 2010 ECHA sent a draft decision to the Registrant for comments. On 1 December 2010, ECHA held an informal telephone conference with the Registrant. On 17 December 2010, the Registrant provided comments on the draft decision, and on 21 January 2011, the Registrant provided an updated dossier. ECHA has considered the information received and amended the draft decision accordingly.

On 17 March 2011, ECHA notified the Member State Competent Authorities of its draft decision and invited them to provide proposals for amendment.

After receiving proposals for amendment from Member State Competent Authorities, ECHA forwarded the proposals for amendment to the Registrant on 20 April 2011 and decided to amend its draft decision.

On 2 May 2011, the draft decision was referred to the Member State Committee.

On 18 May 2011, the Registrant provided comments on the proposed amendments.

The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 25-27 May 2011, the Member State Committee modified the amended draft decision and a unanimous agreement of the Member State Committee on the modified and amended draft decision was reached on 27 May 2011.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, Section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

   a. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.).
   b. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

2) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi) and (vii), 12(1)(e) and Article 13(3) as well as Annexes VII-X of the REACH Regulation the Registrant shall submit the information using the test method as indicated on

   a. Two-generation reproductive toxicity study (Annex X, 8.7.3.; EU Method B.35). As described in section 1.5.8.1 of B.35, the heart shall be considered as a target organ, and be subject to histopathological examination.

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 **27 January 2014 - 30 months from the date of the decision**.

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 and 13 and with Annexes VI, IX and 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 substance identity

Pursuant to Article 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, Section 2 lists information requirements that shall be sufficient to identify the registered substance.

a. The registered dossier provided a gas chromatogram, but the submitted chromatogram does not contain a quantification of the individual peaks observed, and therefore it is not possible to confirm the composition of the substance. The chromatogram should include a quantification of the main constituent and impurities, and this should correspond to the information in section 1.2 of the IUCLID dossier. The chromatogram provided does not show the full profile of the peaks, and has an interruption in the axes. It is not possible therefore to be sure that the peaks are mono-constituent, or whether there are additional peaks, and accordingly, the chromatogram is not satisfactory. The Registrant should provide a complete, full-scale chromatogram. The information provided is not sufficient to meet the information required by Annex VI, 2.3.6. of the REACH Regulation. Thus there is an information gap.
b. It is not possible to establish from the information provided how the results of the chromatogram yield the composition of the registered substance. Specifically, the Registrant should provide the calculations that have been carried out to derive the composition of the substance. The information provided is not sufficient to meet the information required by Annex VI, 2.3.7. Thus there is an information gap.

Hence, the Registrant is requested to submit the missing information.

2) Missing information related to endpoints

a. Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi) and (vii), 12(1)(e), and Annex X, Section 8.7.3., the Registrant is required to provide information on the reproductive toxicity of the registered substance:
    - Two-generation reproductive toxicity study (Annex X, 8.7.3.) in the rat, by inhalation

    The Registrant waived the study, stating that the study is "scientifically unjustified". However, no argument for adaptation of the information requirement of Annex X, 8.7.3. was made that satisfies the requirements of either the column 2 provisions of Annex X, 8.7.3., or Annex XI. Therefore the adaptation of the testing requirement is not valid, and there is an information deficit for Annex X, 8.7.3.

    The Registrant is accordingly requested to submit the information using the test method: Two-generation reproductive toxicity study in the rat, by inhalation (method B.35 of Regulation (EC) No 440/2008 or OECD 416). ECHA notes that pre-existing studies, or dose-ranging studies, may be useful for determining the appropriate exposure concentrations. The results of repeated-dose toxicity testing show that the heart is a target organ. As described in section 1.5.8.1 of method B.35, the heart shall be considered as a target organ, and be subject to histopathological examination. The Registrant is requested to update the dossier with the relevant information.

At this stage, ECHA cannot determine whether the prenatal developmental toxicity endpoint is compliant. Depending on the outcome of the two-generation reproductive study, it will be determined whether further information on the pre-natal developmental end point is required.

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 1907/2008 as adapted to the 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 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.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs