EUROPEAN CHEMICALS AGENCY

Helsinki, 06/09/2012

Final decision: CCH-D-0000002678-63-02/F

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

For Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol (List No 904-153-2), 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 dossier for Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol (List No 904-153-2) by [redacted] (Registrant).

This decision is based on the registration dossier 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 after 19 July 2012, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 9 March 2012.

On 05 June 2012 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 05 July 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 07 June 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received and did not amend the draft decision.

On 19 July 2012 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), 41(3) and 10(a)(ii) as well as Annex VI , sections 2 and 3 of the REACH Regulation the Registrant shall submit for the registered substance:

a. Composition of the substance (Annex VI Section 2.3 of the REACH Regulation) as specified below in section III, 1) a.
b. Information on manufacture and use(s) of the substance(s) (Annex VI Section 3.2 of the REACH Regulation) as specified below in section III, 1) b.

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 6 November 2012**.

The determination of the identity of the registered substance pursued by the present decision is a pre-requisite to the evaluation of testing proposals submitted in the registration dossier. As a result, the present decision does not prejudice any future decision of ECHA concerning testing proposals contained in the dossier, irrespective of Article 43(2) of the REACH Regulation.

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 for the purpose of registration within the applicable tonnage band of over 1000 tonnes per year in accordance with **Article 6** of the REACH Regulation, does not comply with the requirements of Article **10 and with Annex VI** 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.

Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, Sections 2 and 3 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance and on its manufacture and uses. Annex VI, Sections 2 and 3 list information requirements that shall be sufficient to identify the registered substance subject to the present decision.

a. Composition of the substance (Annex VI Section 2.3 of the REACH Regulation)

The substance composition corresponds to the chemical representation of what the substance consists of and it is a crucial parameter in its identification.

ECHA notes that the Registrant identified the registered substance as a multi-constituent substance. In line with the Guidance for identification and naming of substances under the REACH Regulation and the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances (CLP Regulation), multi-constituent substances are well-defined substances in which more than one constituent is present at a concentration ≥10% (w/w) and <80% (w/w) (referred to hereinafter as "main constituent"). Multi-constituent substances are named as the reaction mass of the main constituents.

ECHA observes that the name provided for the registered substance is "Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol". This name refers to a multi-constituent substance including three main constituents present at concentration ≥10% (w/w) and <80% (w/w).

The compositional information indicated in the IUCLID dataset of the registered substance indicates that more than one substance is covered by this registration. More specifically, the Registrant included wide concentration ranges for the three main constituents reported in the IUCLID dossier. In particular the concentration ranges of 2-ethylpropane-1,3-diol and propylidynetrimethanol vary from [redacted] and from [redacted] respectively. Such wide concentration ranges are not appropriate for the registered well defined substance as they would imply that the following three substances could actually be covered by the composition information provided:

1) Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol;

2) Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol;

3) Reaction mass of 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol.

ECHA points out that for well-defined substances such as the registered substance the composition shall be known, does not present large variability and is predictable.

The Registrant is therefore required to report the composition information referring to the registered multi-constituent substance: "Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol". Any information referring to other substances shall be excluded from the composition information.

Any substance with a different composition than the one of the multi-constituent substance covered by the registration subject to this decision has to be registered separately.

Regarding how to report the composition of the registered substance in IUCLID, the Registrant shall revise the information provided on the concentration ranges of the main constituents in Section 1.2 of the IUCLID dossier. The information provided shall be consistent with the name given for the registered substance.

Further technical details on how to report the composition of multi-constituent substances in IUCLID are available in paragraph 2.2.1.2 of the Data Submission Manual 18 on the ECHA website.

The Registrant is reminded that, in line with paragraph 4.3 of the Guidance for identification and naming of substances under REACH and CLP, the following applies to multi-constituent substances, including the registered substance:

- All main constituents shall be identified and reported individually; and
- All the impurities present at ≥ 1 % shall be identified and reported individually; and
- All the impurities relevant for the classification and/or PBT assessment shall be identified and reported individually.

For each constituent, including the main constituents and any impurity, the typical, minimum and maximum concentration level shall be specified. The registrant shall comply with these requirements.

b. Description of the technological process used in the manufacture (Annex VI Section 3.2 of the REACH Regulation)

ECHA observes that the Registrant specified in section 3.1 of the IUCLID dossier that the registered substance is a "[redacted]".

This description would indicate that two possible by-products are referred to in the manufacturing process description. It is not clear to which by-product the registered substance refers to.

ECHA observes that in line with Articles 3(1) and 3(2) of the REACH Regulation the blending of two isolated by-products derived from two different manufacturing processes in the absence of chemical reaction would be considered as the production of a mixture.
The Registrant shall note that separate considerations shall be made for the registration obligations of these two by-products and that different substances contained in a mixture have to be registered separately.

The Registrant is therefore requested to provide a clear description of the technological process used. The Registrant shall report in the IUCLID dossier only information on the manufacturing process referring to the registered substance: Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol.

Regarding how to report the description of the manufacturing process, the information shall be included in the Description field in IUCLID section 3.1.

IV. 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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