ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003825-69-02/F Helsinki, 14 August 2013

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

For 2-[(2-methoxy-4-nitrophenyl)diazenyl]-N-(2-methoxyphenyl)-3-oxobutanamide, CAS 6358-31-2 (EC No. 228-768-4), 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 **2-[(2-methoxy-4-nitrophenyl)diazenyl]-N-(2-methoxyphenyl)-3-oxobutanamide, CAS 6358-31-2 (EC No. 228-768-4)** submitted by [redacted] (Registrant), latest submission number [redacted], for 100 – 1000 tonnes per year.

The compliance check was initiated on 24 March 2011.

On 20 March 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. That draft decision was based on submission number [redacted]

On 19 April 2012 ECHA received comments from the Registrant. On 20 April 2012 the Registrant updated his registration dossier (submission number [redacted]).

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 20 June 2013 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.

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

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II. Information required

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

(a) High-pressure liquid chromatogram or gas chromatogram (Annex VI, 2.3.6.),as specified in section III.1.(a) below; and
(b) The description of the analytical methods (Annex VI, 2.3.7.); as specified in section III.1.(b) below.

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 **14 February 2014.**

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant does not comply with the requirements of Article 10 and Annex VI of the REACH Regulation. 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. The information given shall be sufficient to enable the substance to be identified. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance:

(a) High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.).

ECHA notes that the registration does not contain a high-pressure liquid chromatogram or gas chromatogram which is required according to Annex VI, 2.3.6. of the REACH Regulation in order to confirm the composition of the substance. The Registrant has stated in section 1.4 of the IUCLID dossier that the method used for the quantitative analysis of the substance is high-performance liquid chromatography (HPLC), however, this chromatogram cannot be found in the registration dossier. Without such information, the composition of the registered substance cannot be confirmed.

In response to ECHA's draft decision the Registrant updated the IUCLID dossier on 18 April 2012. The information requested, however, has been only partially included in an analytical report attached in section 1.4 of the IUCLID dossier. Such analytical report shows the result of an HPLC analysis, including the concentration values of the impurities detected. The actual chromatogram, however, has not been provided.

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Therefore, the Registrant is requested to submit a high performance liquid chromatogram. As for the reporting of the chromatographic data in the registration dossier, a chromatogram should be attached in IUCLID section 1.4 – Analytical information.

(b) The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

ECHA observes that the registration dossier does not contain sufficient information on the analytical methods used to identify the registered substance, qualitatively and quantitatively, as required by Annex VI, 2.3.7 of the REACH Regulation.

For the qualitative identification a description and the results of the analytical method used to identify unambiguously the structure of the main constituent is required. In the present case, the mass spectrum (MS) that has been provided by the Registrant could not confirm the identity of the substance. In fact an explanation on the origin of the adduct ions observed in the spectrum and a fragmentation pattern with its relative interpretation are missing from the analytical report provided. This information is necessary to derive the structural formula of the main constituent and thereby to confirm the identity of the substance.

For the above reasons, the qualitative identification of the substance is insufficient to identify the substance. Therefore, for the qualitative identification the Registrant is requested to submit a description and the results of the analytical method used to identify unambiguously the structure of the main constituent. The Registrant shall provide an explanation on the origin of the adduct ions observed in the mass spectrum (MS) spectrum and a fragmentation pattern with its relative interpretation. In the alternative, the Registrant may provide a Nuclear Magnetic Spectrum enabling the unambiguous identification of the substance.

For the quantitative identification and to confirm the composition of the substance, a description of the method(s) or the appropriate bibliographical references used to quantify the main constituent and impurities present in the substance is required.

In the present case, ECHA notes that, in the update dossier submitted in response to ECHA's draft decision, the Registrant provided the result of a chromatographic method used for quantifying impurities present in the substance. In addition, the Registrant stated in the update dossier "determination of impurities = indirect determination of pigment purity". ECHA understands that this means that the purity of the substance is indirectly determined on the basis of the quantification of the impurities.

ECHA underlines that a quantification of the main constituent performed on a calculation of the concentration of the impurities would be based on the assumption that all the impurities present in the substance are clearly quantified. ECHA considers that the information given is not sufficient to verify that the purity reported by the Registrant is representative of the substance actually manufactured.

ECHA expects that the quantification of the main constituent is performed by means of a direct analytical method if there is no specific reason that would not allow the analysis to be carried out.

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In addition, ECHA notes that in the IUCLID dossier the Registrant has indicated that pigments show low solubility. This fact may lead into the impossibility to carry out a direct analysis of the substance. However, for substances, such as the registered substance, ECHA would not expect that solubilisation of the substance in any solvent including highly polar solvents would be a limiting factor for performing the analysis. Unless the Registrant provides scientific proof that a direct analysis of the main constituent cannot be carried out the description of a direct quantification method of the main constituent and results thereof shall be provided.

For the above reasons, the quantitative identification of the substance presented by the Registrant is insufficient to identify the substance. For the quantitative identification and to confirm the composition of the substance, a description of the method(s) and results thereof used to quantify the main constituent by means of a direct analysis shall be provided.

This information shall be sufficient to allow the qualitative and quantitative methods to be reproduced and shall therefore include details of the experimental protocol followed, the calculation used and the result obtained. As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4.

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]
Jukka Malm
Director of Regulatory Affairs