EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003999-52-02/F Helsinki, 10 October 2013

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

For 2-ethylhexyl 4-methoxycinnamate, CAS No 5466-77-3 (EC No 226-775-7), 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 for 2-ethylhexyl 4-methoxycinnamate , CAS No 5466-77-3 (EC No 226-775-7) submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, section 2 of the REACH Regulation.

This decision is based on the registration 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 submitted after 01 August 2013, 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 from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 4 April 2013.

On 26 April 2013 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 27 May 2013 ECHA received comments from the Registrant.

On 20 June 2013 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments and the update received.

On basis of the comments and the updated dossier, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 1 August 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

II. Information required

A. Information in the technical dossier related to the identity of the substance

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

- Name or other identifiers of the substance (Annex VI, 2.1), as specified under section III.A.1 below;

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **10 January 2014**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

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.

Name or other identifiers of the substance (Annex VI, Section 2.1.)

The name and other identifiers, as required by Annex VI, section 2.1. of the REACH Regulation, are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the cornerstone of all the REACH obligations.

ECHA notes that the Registrant identified the registered substance as a mono-constituent substance. In line with the "Guidance for identification and naming of substances under REACH and CLP" (Version: 1.2, March 2012), mono-constituent substances are well-defined substances in which one constituent is present at a concentration ≥ 80% (w/w) (referred to thereinafter as "main constituent"). A mono-constituent substance is named after the name of its main constituent. ECHA observes that the Registrant did not provide appropriate information on the name of the substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the Registrant assigned EC and CAS entries and IUPAC name corresponding to "2-ethylhexyl 3-(4-methoxyphenyl)acrylate" to the registered substance. ECHA observes that such name and identifiers refer to a multi-constituent substance consisting of four main constituents: the cis- and trans-isomers of 2-ethylhexyl 3-(4-methoxyphenyl)acrylate, where the cis- and trans-isomers both

furthermore include the R- and S-stereoisomers.

However,following the Registrant's dossier update, ECHA underlines that in IUCLID section 1.2 the Registrant indicated "trans - Isomer, [redacted] R- and [redacted] S- 2-ethylhexyl 4-methoxycinnamate" in the remarks field of the main constituent 2-ethylhexyl 3-(4-methoxyphenyl)acrylate. Furthermore, the cis-isomer is indicated as an impurity. This compositional information is in contradiction with the EC and CAS entries used to identify the registered substance and would indicate that the registered substance is predominantly composed of the trans-2-ethylhexyl 3-(4-methoxyphenyl)acrylate. In addition, in section 1.4 the Registrant has attached GC analysis results (attachment "OMC GC chromatogram and method.pdf"), which specify the main peak with area% of [redacted] as "E-OMC, MCX", and one of the minor peaks with area% of [redacted] as "Z-OMC,CIS", indicating the peaks correspond to the trans- (E) and cis- (Z) isomers, respectively. This information indicates that the substance consists predominantly of the trans-isomer as specified in section 1.2 of the IUCLID dossier.

In response to ECHA's draft decision, the Registrant commented that the CAS No 5466-77-3 has been assigned to the original substance *2-ethylhexyl 3-(4-methoxyphenyl) acrylate* based on a patent filed in the 1960s, and that the entry "*does not reflect a specific ratio regarding cis/trans isomers nor R- and S- stereoisomers of the substance*". The Registrant noted that the CAS entry 5466-77-3 has been reported to define the corresponding EINECS entry 226-775-7. The Registrant comments also that "*since decades [the company] has been placing the same quality on the European market...*" and "*...it always has consisted of more than 80% of the trans isomer...*" The Registrant did not amend the information in the updated dossier as required under this issue.

ECHA highlights that the CAS and EINECS numbers are numerical identifiers which have been drawn up to meet the purpose of different regulatory regimes than REACH. EINECS was a prerequisite for the implementation of the 6th amendment of the Dangerous Substances Directive (Directive 67/548/EEC). It served the purpose of identifying all substances which could be considered as having been placed on the European market at a given point in time. The reporting rules for EINECS were tailored to meet the objective of that inventory. It was hence acceptable if some entries (reflected by one EINECS number) were defined broadly. Even with a broad definition the purpose of the legislation was met, as an operator or authority could easily identify whether his substance would fall into the "range" covered by an entry and thus was covered in the list.

The Chemical Abstract Service, on the other hand, when assigning CAS numbers, follows its own rules and is not bound by the substance definition under REACH. The numbers are also not tailor-made for use in a specific regulatory regime. It is thus normal that such numbers may be narrower or broader than the level of detail of the substance identification required under REACH.

However, the regulatory framework under REACH requires that substances are described as narrowly as possible to ensure that the risks are appropriately assessed and controlled. The identification of a substance under REACH has to be in line with the rules and principles that stem from the REACH Regulation and are described in more detail in the "Guidance for identification and naming of substances under REACH and CLP".

The "Guidance for Identification and naming of substances under REACH and CLP" clearly indicates in an example on p. 45 that generic EC entries without cis/trans specific information in the entry refer to mixtures of cis and trans isomers, and individual Z and E isomers are not covered by the registration of the isomeric mixture.

Furthermore, the EINECS reporting rules(Constructing EINECS: Basic documents – Reporting for EINECS Inventory, Commission of the European Communities, ISBN 92-825-2463-9, 92-825-2459-0) already emphasized that "*Care must be taken to ensure that the proper Chemical Abstracts Service Registry Number has been selected. It cannot be emphasized too strongly that CAS Registry Numbers are highly specific. Different positional isomers, stereochemical isomers, and salt forms have distinct CAS Registry Numbers. For example, the CAS Registry Number for trichloroethane (non specific) is 25323-89-1; the CAS Registry Number for the specific isomer 1, 1, 1-trichloroethane is 71-55-6; the CAS Registry Number for the specific isomer 1,1, 2-trichloroethane is 79-00-5. Be certain the CAS Registry Number you report exactly identifies the substance you wish to report for EINECS.*" This indicates that non specific CAS entries should not have been used when reporting specific substances to the EINECS inventory even though broad entries were possible.

Based on the compositional information, analytical information, and the Registrant's comments provided to the draft decision, ECHA concludes that the substance intended to be registered is the trans-isomer of 2-ethylhexyl 3-(4-methoxyphenyl)acrylate. Since the EINECS and CAS entries used by the Registrant do not specifically define the trans isomer, they cannot be used as identifiers for the substance under the REACH Regulation.

It follows that the registration dossier includes contradictory information on the identity of the registered substance. ECHA points out that, in accordance with the criteria for substance sameness specified in paragraph 5 of the Guidance for identification and naming of substances under REACH and CLP, well-defined substances with different main constituents shall be regarded as different substances under the REACH Regulation. ECHA therefore concludes that the provided CAS entry, chemical name and the composition specified in the dossier refer to different substances.

The Registrant is accordingly requested to provide a chemical name corresponding to the specific substance covered in this registration. The chemical name shall be generated on the basis of the main constituents actually present in the substance.

The Registrant shall also specify any available and appropriate CAS number and CAS name reflecting the identity of the main constituents of the substance. The Registrant shall delete from the registration any information referring to different substances than the substance which is the subject of this registration.

As for the reporting of the information in IUCLID, the chemical name shall be indicated in the "IUPAC name" field in IUCLID section 1.1. The appropriate CAS number and CAS name shall be reported under the "CAS information" header in IUCLID section 1.1. The CAS entry 5466-77-3 can be reported in the "Related CAS information" field in section 1.1. The Registrant is requested not to remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that EC entry in REACH-IT.

The Registrant shall ensure that the molecular and structural information specified in IUCLID section 1.1 and the composition indicated in IUCLID section 1.2 are consistent with the chemical name and CAS number and CAS name assigned to the registered substance.

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.

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Director of Regulatory Affairs