EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114328311-63-01/F Helsinki, 25 April 2016

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

For calcium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate, CAS No 5281-04-9 (EC No 226-109-5), 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 calcium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate, CAS No 5281-04-9 (EC No 226-109-5), submitted by [redacted] (Registrant).

ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes I and VII to X was done on the lead registrant dossier of this joint submission.

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 03 March 2016, 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 12 November 2013.

On 8 January 2014 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 6 February 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 18 March 2015 the Registrant updated his registration with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended.

On 3 March 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, 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), 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:

1. Description of the analytical methods (Annex VI, 2.3.7.)

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 **01 August 2016**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein does not comply with the requirements of Article 10 of the REACH Regulation and 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.

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.

1. Description of the analytical methods (Annex VI, section 2.3.7.)

ECHA notes that the Registrant has not provided sufficient information on the analytical methods used to determine the composition of the registered substance, as required by Annex VI, Section 2.3.7. of the REACH Regulation.

More specifically, the dossier submitted by the Registrant does not include the description of a method suitable to analyse the composition and confirm the results reported in Section 1.2 of the registration dossier. Additionally ECHA observes that the Registrant did not include the description of an appropriate method for the quantification of the calcium ion.

In line with Annex VI, 2.3.7, the Registrant is accordingly requested to provide the description of an analytical method that is specific for the quantification of the calcium ion present in the substance. The description shall be sufficient for the method to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4. The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

ECHA observed that the registrant has included the following text in report [redacted] attached to section 1.4; "[redacted]" In this respect, ECHA notes that some organic pigments are known to be manufactured/imported as nanomaterial forms (compositions that meet the EU recommendation on the definition of nanomaterials[1] in terms of primary particle size and/or specific surface area).

To ensure a high level of protection of human health and the environment, the REACH Regulation imposes the determination of hazards and risk, taking into consideration the forms of the substances concerned. This includes more specifically nanomaterial forms of substances, which may trigger specific hazardous properties and risks, as already highlighted by various institutions, including the European Parliament.[2]

In fact, the current scientific knowledge establishes that the risks of nanomaterial forms of substances would require separate assessment. Indeed, the specific risks of nanomaterial forms are not founded on mere hypotheses that have not been scientifically confirmed. These risks have actually been fully demonstrated by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).[3] The fact that there is still some degree of scientific uncertainty as to the existence or extent of such risks does not, by itself, discharge registrants from characterising nanomaterial forms in order to carry out their duties under the REACH Regulation. Based on the above, the Registrant is compelled to scientifically assess the potentially adverse effects of nanomaterial forms.

Furthermore, it is self evident that in order to determine the hazardous properties and the appropriate risk management measures for substances in different forms, it is necessary to characterise the substance in terms of its physical form, in particular regarding nanomaterial forms, before determining the corresponding hazards and assessing the exposure of humans and the environment and the associated risk management measures. The characterisation of nanomaterial forms of the substance is a pre-requisite to the determination of all the hazardous properties and appropriate risk management measures concerning the registered substance. Therefore, it is essential that suitable information on nanomaterial forms is submitted, especially in order to identify precisely whether the registered substance includes nanomaterial forms.

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[1] Commission Recommendation on the Definition of Nanomaterials of 20 October 2011, 2011/696/EU, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

[2] "*Whereas nanomaterials [...] potentially present significant new risks due to their minute size, such as increased reactivity and mobility, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species*". Recital D of European Parliament Resolution of 24 April 2009 on Regulatory aspects of nanomaterials.

[3] "*There is sufficient evidence that there can be a change in some properties of the material at the nanoscale which is, for instance, due to the increase in surface-to-volume ratio. These nanospecific properties raise concerns over their potential to cause harm to humans and the environment. The chemical reactivity of nanoparticles often relates to the surface area. Consequently, the chemical reactivity per mass dose increases for smaller particles of the same type. This effect may or may not be associated with an increase in biological activity or toxicity*". SCENIHR, Opinion of 8 December 2010 on *Scientific Basis for the Definition of the Term «nanomaterial »*, page 31.

Consequently, where the Registrant intends to cover nanomaterial forms, information on their respective composition and size range will need to be included in section 1 of the dossier (description of the substance in section 1.1 and relevant nanomaterial forms reported as a composition in section 1.2 and sufficient analytical data for the nanomaterial forms included in section 1.4). Information on how this can be technically done is available in "Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH" available on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals. In addition, the registrant shall make sure that the respective particle sizes covered by this registration are also reported in Section 4.5 of the joint IUCLID dossier information (i.e. in the form of particle size distribution).

Similarly, the Registrant shall note that where it intends to cover chemically surface treated nanomaterial forms, information on these nanomaterial forms in terms of their respective composition and size ranges will also need to be provided. In this respect, the Registrant shall note that the FAQ available on the ECHA website concerning the exemption from registration obligations for chemically surface treated substances[4] is not applicable to high surface area particulates such as nanomaterial forms, as the question tackled by this FAQ only relates to "macroscopic particles" of low specific surface area.

In the absence of suitable information, ECHA cannot be in a position to determine whether the registration covers nanomaterial forms of the substance. Only the Registrant of the substance knows the relevant forms under which the substance is manufactured or imported.

ECHA highlights that failure to report sufficient information on relevant nanomaterial forms in the dossier, whether surface treated or not, may result in these nanomaterial forms not being covered by this registration.

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[5] by Guilhem de Seze, Head of Unit, Evaluation E1

[4] Q&A pair [38] "Do I have to register chemically surface treated substances?" available at http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/topic/reach

[5] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.