ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114328306-54-01/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 3 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.

By 7 February 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 3 March 2016 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. Composition of the substance (Annex VI, 2.3.)
2. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.)
3. Description of the analytical methods (Annex VI, section 2.3.7.)

**B. Information in the technical dossier related to the manufacture and use(s) of the substance**

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

4. Brief general description of the identified use(s) of the registered substance (Annex VI, section 3.5.).

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. Composition of the substance (Annex VI, 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

More specifically, in Section 1.2 of the registration dossier, the Registrant did not provide any indication of the minimum and maximum concentration required for the reported constituents. In line with Chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) - referred to as "the Guidance" thereinafter, the Registrant should note that, for each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

ECHA therefore concludes that the composition of the registered substance has not been provided to the required level of detail.

In line with Annex VI, Section 2.3., the Registrant is requested to include the concentration range values for the different constituents. The concentration range values are required to be representative for the registered substance as manufactured. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall indicate the composition of the registered substance in IUCLID Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

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]

[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.

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.

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 form(s) size ranges will also need to be provided. This is particularly relevant as in the description of the manufacturing process included in section 3.1, the role of [redacted] is not defined; "[redacted]".

[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.

Should [redacted] be a surface treating agent, the Registrant shall note that chemically surface treated nanomaterial forms of high specific surface area can only be covered by the registration if they have been reported in the dossier. 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.

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

ECHA notes that the registration dossier does not contain chromatographic data, which is required according to Annex VI, Section 2.3.6. of the REACH Regulation to support the indicated substance composition. The Registrant has also not included a robust scientific justifications for not providing all of the required information.

In line with Annex VI, 2.3.6, the Registrant is therefore requested to submit a high-pressure liquid chromatogram or gas chromatogram for the registered substance. The report from the chromatographic analysis, including a peak list with the corresponding retention time and peak area shall be also included. The Registrant shall ensure that the description of the analytical methods used for the recording of the chromatographic data is specified in the dossier, in line with the requirements under Annex VI section 2.3.7. This information shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. The Registrant shall ensure that the information provided in chromatographic analysis is in line with the composition reported in Section 1.2. If it is not technically possible or if it does not appear scientifically necessary to provide these chromatographic data, a scientifically based justification shall be given.

As for the reporting of the information in the dossier, the results of the chromatographic analysis, or a scientific justification for not including this data shall be attached in IUCLID section 1.4.

3. 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.

[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

More specifically, the dossier submitted by the Registrant does not include a description of a suitable method to analyse the composition and enable the results reported in Section 1.2 of the registration dossier to be verified. ECHA observes that the Registrant did not include the description of an appropriate method for the quantification of neither the organic ions present in the registered substance nor of the calcium ion. The elemental analysis that has been reported cannot be considered as an appropriate method for determining the quantitative composition of the registered substance on its own.

ECHA therefore concludes that the Registrant did not provide sufficient information on the description of the analytical methods used for quantification of the composition of the registered substance in terms of individual constituents present in the substance.

Accordingly, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide detailed description of the analytical method(s) used for identification and quantification of the registered substance including the constituents present. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

For chromatographic methods, the information shall include a legible print-out of the chromatogram as well as the report from the chromatographic analysis including the table of peak assignments that report the peak areas and corresponding amounts of each relevant constituent/group of constituents. In addition, the Registrant shall ensure that the composition reported in Section 1.2 is in line with the information provided in Section 1.4, which shall be sufficient to identify and quantify the substance.

As for the reporting of the additional analytical data in the dossier, the information should be attached in Section 1.4 of the IUCLID Dossier.

## B. Information in the technical dossier related to the manufacture and use(s) of the substance

4. Brief general description of the identified use(s) of the registered substance

Pursuant to Article 10(a)(iii) of the REACH Regulation the technical dossier shall contain information on the manufacture and use(s) of the substance as specified in Annex VI, Section 3 of the REACH Regulation.

Annex VI, Section 3.5. requires that each Registrant provides a brief general description of the identified use(s) of a registered substance.

The Registrant sought to adapt this standard information requirement by referring to Article 14(4) of the REACH Regulation. The registrant argues that, as he is not require to carry out an exposure assessment and risk characterisation for his substance in accordance with this article, he is not required to provide detailed information on the uses of the substance.

ECHA notes that Article 14 defines the requirements for the chemical safety asssessment to be carried out, but does not allow for an adaptation of the information requirement in Annex VI, section 3.5. According to section 3.5 of Annex VI, a description of the identified uses shall be included in the registration dossier. Therefore, the Registrant's justification for not providing the information cannot be accepted and the Registrant is requested to provide a brief general description of the identified use(s) of the registered substance and update the technical dossier accordingly. ECHA also notes that the information in the technical dossier and the Chemical Safety Report must be consistent and that the Registrant should ensure this in updating his registration.

Instructions on how to provide information on identified use(s) of a registered substance can be found in ECHA Guidance on information requirements and chemical safety assessment Part A: Introduction to the Guidance document, section A.2.4.1.2, pp. 18 and 19.

## 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

[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.