Decision number: CCH-D-2114306071-69-01/F Helsinki, 30 July 2015

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

For Reaction mass of Fumes, silica and diiron trioxide, CAS No NS (EC No 909-981-8), 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 Reaction mass of Fumes, silica and diiron trioxide, CAS No NS (EC No 909-981-8), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of Annex VII and VIII, Sections 8.4.1., 8.4.2. and 8.4.3. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

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 after the deadline for updating (13 March 2015) communicated to the Registrant by ECHA on 4 February 2015.

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 22 May 2014.

On 14 July 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 8 August 2014 ECHA received comments from the Registrant on the draft decision.

On 12 March 2015 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 11 June 2015 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

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes VII and VIII of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: EU B.13/14 / OECD 471);
2. *In vitro* cytogenicity study in mammalian cells (Annex VIII, 8.4.2., test method: EU B.10/OECD 473) or *in vitro* micronucleus study (Annex VIII, 8.4.2.; test method: OECD 487);
3. *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.; test method: EU B.17/OECD 476), provided that there is a negative result in the studies requested under 1. and 2.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

Deadline for submitting the required information:

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **8 August 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

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.

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)

An "*in vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of an *in vitro* gene mutation study in bacteria in the dossier that would meet the information requirement of Annex VII, Section 8.4.1. Instead, the Registrant updated the dossier and completed the adaptation of the information requirement of Annex VII, Section 8.4.1. by introducing a read-across approach and supporting data as described below.

The original justification of the adaptation given by the Registrant in the registration dossier was that according to Section 1 of REACH Annex XI, testing for genetic toxicity is scientifically not relevant for this substance since this pigment can be considered as chemically inert. However, ECHA notes that this adaptation does not meet the general rules for adaptation of Annex XI, Section 1., which the Registrant refers to because none of the specific adaptation possibilities in this Section includes the possibility to adapt the standard information requirement on the basis of the argument made by the Registrant, as explained in more detail below. Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

In its comments to the draft decision, the Registrant wished to extend the adaptation argumentation and to demonstrate that the substance is "unreactive and insoluble" in the light of the available information on the poor bioaccessibility of the substance. Furthermore, the Registrant seeks to generate additional data to demonstrate the lack of bioavailability (i) by introducing a testing strategy involving 28-day oral repeated dose toxicity study, a toxicokinetic mass balance study, and a blood kinetic study and ii) by making a reference to genotoxicity data of the (released) individual metal constituents, to confirm that the conditions for an adaptation of the data requirements for reasons for technical and scientific feasibility are fulfilled.

Consequently, the Registrant updated the registration dossier by completing the data waiving justifications by introducing a read-across approach and providing supporting data generated with iron and silica compounds, respectively. In particular, the Registrant specified in the data waiving justifications (for *in vitro* clastogenicity and *in vitro* gene mutation) that the assessment of the genotoxic potential of minor amounts of Fe and Si being released of the registered substance, under various tested conditions described, "can instead be easily read across from available data on iron salts and silica."

Firstly, as already outlined above, ECHA notes that the argument of inertness/insolubility/bioaccessibility/reactivity of the registered substance does not constitute an argument for adaptation of the standard test regime according to Column 2 of Annex VII and Annex VIII 8.4. or Annex XI, Section 1. Furthermore, based on the information in the technical dossier highlighted by the Registrant in his comments, the limited solubility of the substance does not prevent *in vitro* testing for mutagenicity and the OECD test guidelines 471, 473, 487 and 476 provide recommendations for test substance preparations of solid materials.

Secondly, ECHA notes that in its updated adaptation argumentation the Registrant makes a reference to Annex XI, section 1. Based on the argumentation provided, ECHA understands

that the Registrant proposes to adapt the standard information requirement by applying Annex XI, Section 1.5. Grouping of substances and read-across approach. According to Annex XI, section 1.5. of the REACH Regulation, "application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach)." Contary to Annex XI, Section 1.5., the Registrant fails to demonstrate the absence of possible genotoxic properties of the registered substance in its crystalline form. The Registrant also fails to establish the structural similarity and the subsequent possibility to predict properties of the registered substance and its Si-containing and Fe-containing dissolution products on basis of the substances used to generate the data referred to. Therefore, in the light of the current information, the proposed read-across cannot be accepted.

ECHA acknowledges the Registrant's intention to further support his adaptation by generating data from a repeated dose toxicity study, a toxicokinetic mass balance study, and a blood kinetic study. ECHA notes these data are not in the updated dossier and so is unable to assess these data.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD 471).

2. *In vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, Section 8.4.2.)

An "*in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of an *in vitro* gene mutation study in mammalian cells in the dossier that would meet the information requirement of Annex VIII, Section 8.4.2. Instead, the Registrant updated the dossier and compleed the adaptation of the information requirement of Annex VIII, Section 8.4.2 by introducing a read-across approach and supporting data as described under the Section III, issue 1 of this decision.

The original justification of the adaptation given by the Registrant in the registration dossier was that according to Section 1 of REACH Annex XI, testing for genetic toxicity is scientifically not relevant for this substance since this pigment can be considered as chemically inert. However, ECHA notes that this adaption meets neither the requirements of column 2 of Annex VIII, Section 8.4.2 nor the general rules for adaptation in Annex XI, Section 1. which the Registrant refers to because these adaptations do not include the possibility to adapt the standard information requirement on the basis of the argument

made by the Registrant, as explained in more detail above, under Section III.1 of this decision. Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* cytogenicity study in mammalian cells (test method: EU B.10./OECD 473) or *in vitro* mammalian cell micronucleus study (test method: OECD 487).

3. *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained. ECHA notes that the registration dossier contains no information for both of these information requirements.

The Registrant has not provided any study record of an *in vitro* gene mutation study in mammalian cells in the dossier that would meet the information requirement of Annex VIII, Section 8.4.3. Instead, the Registrant updated the dossier and completed the adaptation of the information requirement of Annex VIII, Section 8.4.3. by introducing a read-across approach and supporting data as described under the Section III, issue 1 of this decision.

The original justification of the adaptation given by the Registrant in the registration dossier was that according to Section 1 of REACH Annex XI, testing for genetic toxicity is scientifically not relevant for this substance since this pigment can be considered as chemically inert. However, ECHA notes that this adaptation meets neither the requirements of column 2 of Annex VIII, Section 8.4.3 nor the general rules for adaptation in Annex XI, Section 1. which the Registrant refers to because these adaptations do not include the possibility to adapt the standard information requirement on the basis of the argument made by the Registrant, as explained in more detail above, under Section III.1 of this decision. Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject

to the present decision: *In vitro* mammalian cell gene mutation test (test method: EU B.17./OECD 476) provided that both studies requested under 1. and 2. have negative results.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation . The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. 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[1] by Leena Ylä-Mononen, Director of Evaluation

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