ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114298783-31-01/F Helsinki, 3 June 2015

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

For Ceramic materials and wares, chemicals (Galaxite), CAS No 66402-68-4 (EC No 266-340-9), 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 "Ceramic materials and wares, chemicals" (Galaxite), CAS No 66402-68-4 (EC No 266-340-9), submitted by Veitsch-Radex GmbH & CO (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 8.6.2. and 8.7.2. 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 100-1000 tonnes per year. This decision does not take into account any updates submitted after 30 October 2014, 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 15 May 2014.

On 15 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. The draft decision was based on submission number [redacted].

Within 30 days, ECHA did not receive comments from the Registrant on the draft decision.

On 30 October 2014 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 5 December 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment and modified Section III (Statement of reasons) of the draft decision whilst Section II (Information required) was not amended.

On 15 December 2014 ECHA referred the draft decision to the Member State Committee.

By 5 January 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

After discussion in the Member State Committee meeting on 3-5 February 2015, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting wasreached on 4 February 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(d), 13 and Annex IX 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. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats; and
2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route.

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.

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 **12 June 2017**. The timeline has been set to allow for sequential testing as appropriate.

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 requirement.

1. Sub-chronic toxicity study (90-day):

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the substance subject to the present decision to meet this information requirement.

The Registrant has proposed to adapt the information requirement of sub-chronic toxicity (Annex IX, Section 8.6.2. of the REACH Regulation).

In the justification of this proposed adaptation the Registrant *inter alia* claims that neither an oral, nor an inhalation study needs to be conducted due to the chemical inertness and unreactive nature of the registered substance.

However, ECHA notes that neither column 2 of Annex IX, Section 8.6.2. nor the general rules for adaptation in Annex XI (such as Section 1 of Annex XI, which the Registrant refers to) include the possibility to adapt the standard information requirement on the basis of the argument made by the Registrant.

The justification of the Registrant most closely relates to the adaptation possibility of Annex IX, 8.6.2. Column 2, last indent of the first paragraph, according to which no sub-chronic toxicity study needs to be conducted if "the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure."

According to the Registrant, the solubility of galaxite is below 0.03 mg/L. The determined accessibility of galaxite in lung is below 1%. The Registrant has claimed that absorption of the substance subject to the present decision "is not expected". Data on low bioaccessility (below 1%) has been provided to substantiate that claim. The main constituents of galaxite ($MnAl_2O_4$) are aluminium and manganese. According to the *in vitro* bioavailability studies, aluminium determinations were below the limit of detection, while managanese showed minor resorption in the gastro-intestinal tract.

ECHA notes that while the Registrant has provided data which shows low solubility and low bioaccessibility of the substance subject to this decision, the Registrant has not demonstrated that the cumulative conditions of the adaptation possibility in Annex IX, 8.6.2. Column 2 are fulfilled. In this respect, ECHA, notes that no 28-day study record/data on the substance subject to the present decision was provided in the registration dossier. Moreover, evidence of limited human exposure, which is not an obligatory element of this adaptation but may support it, has not been given.

One Member State proposal for amendment indicates that the general rules for adaptations as descripted in Section 1.2 of Annex XI (Weight of evidence) could justify the acceptance of the adaptation of the 90-d study and the PNDT if presented in a proper way, in particular with reference to the following:

- The solubility of the substance is proven to be low,
- The bioavailability of the metal-ions is proven to be extremely low, i.e. the potential uptake of aluminium and manganese from the registered substance would result in levels 40 and 25 times lower than the normal serum concentration, respectively, and
- Body burden at levels of 1/25th or 1/40th of the normal serum levels (of aluminium and manganese) will not result in toxicological effects (normal serum fluctuations will be of the same order of magnitude).

In their comments to the proposals for amendment the Registrant agreed with the possibility of a Weight of evidence adaptation and provided further justification for it. In particular the Registrant refers to a 28-day inhalation toxicity study made with a read-across substance "spinel", which consists of aluminium and manganese oxides, similarly with the registered substances. Within the read-across justification included in the original dossier submission, the Registrant has provided data on chemical similarity between source and target substance of the read-across, data on category definition and membership, read-across hypothesis, relevant physico-chemical and toxicokinetic information, and a data matrix. ECHA considers this read-across plausible and therefore, the data on the source substance of the read-across could be used as an element in the Weight of Evidence approach. The effect seen in that study are due to deposition of the substance and overloading respiratory tract with the dust of the substance, and no specific toxicity was observed. The Registrant furthermore refers to an in vitro cytotoxicity study which suggests that the toxicity of the registered substance is low.

ECHA acknowledges that the information given in the Regsitrant's comments and also included in the original dossier submission is relevant and could be used in a WoE approach to adapt the information requirement.

However, in the original dossier submission, a justification of the WoE adaptation, based on the above and other adequate and reliable documentation was not provided. ECHA would like to point out that, as specified in the chapter I "Procedure" above, this decision does not take into account any updates submitted after 30 October 2014.

Therefore, since the Registrant has not provided adequate reasoning to support the fulfilment of the criteria pursuant of an adaptation according to Column 2 of Annex IX, 8.6.2. or according to Annex XI, 1.2, the adaptation of the information requirement suggested by the Registrant cannot be accepted. Consequently there is an information gap and it is necessary to provide information for Annex IX, Section 8.6.2.

In the light of the properties of the substance and the information provided on the uses and potential human exposure, ECHA considers that testing by the oral route is most appropriate. According to the test method EU B.26./OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, in the absence of a justified adaptation and pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information on sub-chronic toxicity (90-day) in rats, oral route (EU B.26./OECD 408) (Annex IX, Section 8.6.2.) using the registered substance.

2. Pre-natal developmental toxicity study:

A pre-natal developmental toxicity study is a standard information requirement as laid down in Annex IX, section 8.7.2. 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 proposed to adapt the information requirement for pre-natal developmental toxicity (Annex IX, Section 8.7.2. of the REACH Regulation).

In the justification of this proposed adaptation the Registrant *inter alia* claims that the study does not need to be conducted due to the chemical inertness and unreactive nature of the registered substance.

The justification of the adaptation given by the Registrant is that "according to section 1 of REACH Annex XI, testing for developmental toxicity does not need to be conducted if testing does not appear scientifically necessary". Furthermore, according to the Registrant, "Aluminium and manganese are firmly bound in the Galaxite lattice such that they do not have a relevant solubility which is a precondition for bioavailability. This was confirmed by solubility tests in physiological media (lung surfactant and digestive tract)." The Registrant also refers to inertness of the galaxite.

The determined bioaccessibility of galaxite in lung is below 1%. The Registrant has claimed that absorption of the substance subject to the present decision "is not expected". Data on low bioaccessility (below 1%) has been provided to substantiate that claim. The main constituents of galaxite (MnAl2O4) are alumium and manganese. According to the *in vitro* bioavailability studies, aluminium determinations were below the limit of detection, while managanese showed minor resorption in the gastro-intestinal tract. Furthermore, the Registrant has compared the calculated body burdens of aluminium and manganese and compared those with their normal serum concentrations and concluded that the potential uptake of these metals from the registered substance would result in levels 40 and 25 times lower than the normal serum concentration, respectively.

However, ECHA notes that neither Column 2 of Annex IX, 8.7. nor the general rules for adaptation of Annex XI include the above criteria to adapt this information requirement.

Indeed, ECHA notes that the justification of the Registrant most closely relates to the adaptation possibility of Annex IX, 8.7 Column 2 according to which no reproductive toxicity studies need to be conducted if the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.

However, while the Registrant has provided data which show low solubility and low bioaccessibility of the substance subject to this decision, the Registrant has not demonstrated that the cumulative conditions of the adaptation possibility of Annex IX, 8.7 Column 2 are fulfilled. In this respect, ECHA notes that no systemic toxicity test on the substance subject to the present decision has been provided. Moreover, evidence of no or no significant human exposure has not been given.

One Member State proposal for amendment indicates that the general rules for adaptations as descripted in Annex XI. Section 1.2 of Annex XI (Weight of evidence) could justify the acceptance of the adaptation of the 90-d study and the PNDT if presented in a proper way, in particular with reference to the following:

- The solubility of the substance is proven to be low,
- The bioavailability of the metal-ions is proven to be extremely low, i.e. the potential uptake of aluminium and manganese from the registered substance would result in levels 40 and 25 times lower than the normal serum concentration, respectively, and

- Body burden at levels of 1/25th or 1/40th of the normal serum levels (of aluminium and manganese) will not result in toxicological effects (normal serum fluctuations will be of the same order of magnitude).

In their comments to the proposals for amendment the Registrant agreed with the possibility of a Weight of evidence adaptation and provided further justification for it. In particular the Registrant refers to a 28-day inhalation toxicity study made with a read-across substance "spinel", which consists of aluminium and manganese oxides, similarly with the registered substances. Within the read-across justification included in the original dossier submission, the Registrant has provided data on chemical similarity between source and target substance of the read-across, data on category definition and membership, read-across hypothesis, relevant physico-chemical and toxicokinetic information, and a data matrix. ECHA considers this read-across plausible and therefore, the data on the source substance of the read-across could be used as an element in the Weight of Evidence approach. The effect seen in that study are due to deposition of the substance and overloading respiratory tract with the dust of the substance, and no specific toxicity was observed. The Registrant furthermore refers to an in vitro cytotoxicity study, which suggests that the toxicity of the registered substance is low.

ECHA acknowledges that the information given in the Regsitrant's comments and also included in the original dossier submission is relevant and could be used in a WoE approach to adapt the information requirement.

However, in the original dossier submission, a justification of the WoE adaptation, based on the above and other adequate and reliable documentation was not provided. ECHA would like to point out that, as specified in the chapter I "Procedure" above, this decision does not take into account any updates submitted after 4 September 2014.

Therefore, since the Registrant has not provided adequate reasoning to support the fulfilment of the criteria pursuant of an adaptation according to in Column 2 of Annex IX, 8.7.2. or according to Annex XI, 1.2 are met, the adaptation of the information requirement suggested by the Registrant cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information on pre-natal developmental toxicity (Annex IX, 8.7.2.) in rat or rabbit, oral route, using test method EU B.31/OECD 414 on the registered substance.

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 relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

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.

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