EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288754-34-01/F Helsinki, 12 December 2014

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

For Slags, silicomanganese-manufg., CAS No 69012-33-5 (EC No 273-733-9), 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 Slags, silicomanganese-manufg., CAS No 69012-33-5 (EC No 273-733-9, submitted by [redacted] (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.

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 12 June 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 3 July 2013.

On 25 July 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. That draft decision was based on submission number [redacted].

On 26 August 2013 ECHA received comments from the Registrant on the draft decision. On 13 August 2013 the Registrant updated his registration dossier with 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 12 June 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 18 July 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 received and did not amend the draft decision.

The draft decision was split into two draft decision documents: one relating to the request for a two-generation reproductive toxicity study and one relating to the request for a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study. The present decision relates solely to compliance checks for a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study. The other compliance check requirement of a two-generation reproductive toxicity study (Annex X, 8.7.3.; test method: EU B.35./OECD 416; OECD 443) in rats, oral route is addressed in a separate decision although all endpoints were initially addressed together in the same draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments of the Registrant on the proposals for amendment into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision relating to a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study was reached on 1 September 2014 in a written procedure launched on 21 August 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)(e), 13 and Annexes IX and X 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;

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route;

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 **19 December 2016**. The timeline has been set to allow for sequential testing as appropriate.

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.

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)(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 IX and X of the REACH Regulation.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.)

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 registered substance to meet this information requirement.

The Registrant has not provided any study record of a sub-chronic repeated dose toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

The Registrant provided comments to the draft decision and updated the registration dossier (submission number [redacted]).

ECHA notes that in the updated dossier the Registrant indicated an adaptation according to Annex XI, Section 1, but does not further specify the adaptation. ECHA understands that the Registrant intends to adapt according to weight of evidence (Annex XI, Section 1.2.). To make use of this adaptation, the Registrant needs to document that "there is sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property".

Absorption
The Registrant has provided further information on "Evidence for absence of absorption" indicating that the registered substance is very poorly soluble in water but is rendered more soluble in gastric juice.

ECHA acknowledges that the oral absorption is expected to be low. However, ECHA notes that the substance is a substance of unknown or variable composition, complex reaction products or biological materials (UVCB). The Registrant has calculated the release of the different compounds from 100 g of the registered substance in 1.5 L gastric juice and compared the released doses with European Tolerated Daily Intake (TDI) or Tolerated Weekly Intakes (TWIs) or estimated background dietary values. The estimated values were exceeded for manganese (32 versus 9 mg/day), aluminium (6.9 versus 1.5 mg/kg bw/week) and barium 0.3 versus 0.2 mg/kg bw/day). Therefore, ECHA does not agree with the Registrants conclusion of "absence of absorption".

Workplace handling
ECHA notes that the Registrant did not derive any derived no effect level (DNEL) with the justification of absence of absorption and that it is highly unlikely that the substance exhibits any toxicological effects in long-term studies. Hence, the Registrant did not provide an exposure assessment and a risk characterisation. Therefore, it is not documented that appropriate risk management measure are in place.

ECHA acknowledges that due to the information on particle size distribution in the technical IUCLID dossier (inhalable particles sizes less than 100 µm below 0.1% and 3.5%), the potential for inhalation exposure is low; therefore the inhalation route was considered as being not the most appropriate route for testing. Hence, according to ECHA Guidance document R.7.5.4.3 (Version 2.4, February 2014), ECHA considers the oral route as most appropriate route of administration for the sub-chronic toxicity study (90-day) in rats to identify the potential systemic toxicity of the substance after repeated exposure.

Available data
In the technical IUCLID dossier, the Registrant has provided information on acute toxicity, skin and eye irritation, sensitisation and genetic toxicity. However, the Registrant did not provide any information on repeated dose toxicity of the registered substance or of any constituent of the registered UVCB substance. Therefore, it cannot be concluded that the registered substance has no potential for toxicity after sub-acute or sub-chronic exposure.

Animal welfare
The Registrant argued that the required studies would involve several hundred test animals which are unnecessary based on the substance characteristics and in particular on the absence of absorption. However, ECHA notes that the studies are information requirements of REACH and the Registrant did not provide sufficient information to adapt these information requirements. Consequently, the Registrant cannot use this argument to avoid generating new information.

Conclusion
As outlined in Annex XI, Section 1.2., weight of evidence requires evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from single source alone is regarded insufficient to support this notion.

ECHA understands that the Registrant intends to justify that the substance has no sub-chronic toxicity. However, ECHA notes that the Registrant did not provide sufficient information to conclude that the substance has not such a particular dangerous property: the substance is a UVCB with individual components some of these of known toxicity. Even if oral absorption might be low, oral absorption is to be expected to occur and might even exceed European Values for Tolerated Daily or Weekly Intakes values. In addition, no short-term repeated dose toxicity study is available to support the assumption that the substance has no particular dangerous property for sub-chronic toxicity. Therefore, ECHA concludes that the provided justification is not sufficient to assume that the registered substance - Slags, silicomanganese-manufg. - has no dangerous property with regard to sub-chronic toxicity (90 days).

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.

In light of the properties of the substance (very poorly water soluble solid of non-inhalable size), 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 rodent species. ECHA considers this species as being appropriate

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.)

A "Pre-natal developmental toxicity study" for a first species 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 not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

The Registrant provided comments to the draft decision and updated the registration.

The Registrant provided a similar justification as for the sub-chronic toxicity study (90 days). ECHA refers to the considerations given for the sub-chronic toxicity study (90-days) above Section III, 1. In addition, ECHA notes that the Registrant did not provide any information on pre-natal developmental toxicity.

As outlined in Annex XI, Section 1.2., weight of evidence requires evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from single source alone is regarded insufficient to support this notion.

ECHA understands that the Registrant intends to justify that the substance has no pre-natal developmental toxicity. However, ECHA notes that the Registrant did not provide sufficient information to conclude that the substance has not such a particular dangerous property: the substance is a UVCB with individual components some of these of known toxicity including developmental toxicity. Even if oral absorption might be low, oral absorption is to be expected to occur and might even exceed European Values for Tolerated Daily or Weekly Intakes values. In addition, no pre-natal developmental toxicity study or any other developmental toxicity study is available to support the assumption that the substance has no particular dangerous property for pre-natal developmental toxicity. Therefore, ECHA concludes that the provided justification is not sufficient to assume that the registered substance - Slags, silicomanganese-manufg. - has no dangerous property with regard to pre-natal developmental toxicity.

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.

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.

In their comments to the proposals for amendment by Member State Competent Authorities the Registrant agreed that a step-wise approach shall be used. ECHA points out that the present decision and the deadline given to submit the requested information allow sequential testing and adequate consideration of the results of the sub-chronic toxicity study before it has to be decided whether the further studies (EU B.31./OECD 414 and EU B.35./OECD 416) may be omitted.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that the conditions for these adaptations are not fulfilled, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that the conditions for these adaptations can be fulfilled, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2. of the REACH Regulation.

3. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also addressed a two-generation reproductive toxicity study (Annex X, 8.7.3.). As this endpoint is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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.

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://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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