Decision number: CCH-D-2114308955-43-01/F Helsinki, 27 November 2015

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

**For Slimes and Sludges, blast furnace and steelmaking, CAS No 65996-73-8 (EC No 266-006-2), 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 Slimes and Sludges, blast furnace and steelmaking, CAS No 65996-73-8 (EC No 266-006-2), 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. 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 4 November 2013.

On 10 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 15 August 2014 ECHA received comments from the Registrant on the draft decision.

On 26 August 2014 the Registrant updated his registration dossier with the submission number [redacted].

ECHA received comments from the Registrant on the draft decision, concerning the information requirements of Annex VI and IX, Sections 8.6.2., 8.7.2. and 8.7.3. (Also, ECHA received comments from the Registrant, concerning the information requirements of Annex VI. However, as there was no Annex VI information requirements in the draft decision, ECHA Secretariat has not considered these specific comments). The compliance check requirement to submit information of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has been removed from this draft decision due to legislative amendments to the REACH Regulation regarding Annex X, Section 8.7.3. In light of this, ECHA Secretariat did not consider further the Registrant's comments and update concerning the information requirement of Annex X, Section 8.7.3. However, ECHA Secretariat did consider further the Registrant's comments concerning the information requirements of Annex IX, Sections 8.6.2. and 8.7.2. and the Registrant's update. On the basis of all this information and change of scope (based on Section 8.7.3) , Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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.

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

On 17 July 2015 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 amended the draft decision.

By 17 August 2015, 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 on the proposals for amendment of the Registrant 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 was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

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)(vi) and/or (vii), 12(1)(e), 13 and Annexes IX, 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), inhalation route (Annex IX, 8.6.2.; test method: OECD 413) 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 **4 December 2017**. [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)(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.

a. Sub-chronic toxicity study (90-day), inhalation 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 sought to adapt this information requirement. The justification of the adaptation given by the Registrant in IUCLID section 7.5.1. (Repeated dose toxicity: oral) is that the test substance is *"predominantely composed of slightly soluble oxides"* and that *"the largest part are iron oxides"*. The Registrant supposes that *"major toxicity is caused by iron and its compounds"*. Furthermore, according to the Registrant systemic exposure via skin contact is deemed insignificant and systemic exposure via other routes is limited by a variety of factors (e.g. iron absorption strictly regulated, binding of iron to transferrin, ferritin and haemosiderin). The Registrant estimates that the ingested amount of iron after 8 hours of exposure will be not higher than 50 mg and that due to a lack of significant systemic exposure, testing of metallic iron for sub-chronic toxicity is not appropriate. According to the Registrant's comments oral uptake is very unlikely and "the occasional intake can sometimes occur due to inattention or accident but a systematic long-term intake of large quantities of the substance via food or drink can be omitted".

The Registrant's justification for adaptation in IUCLID sections 7.5.2. (Repeated dose toxicity: inhalation) is that "dust formation at the workplace is not probable (the substance is water suspension, insoluble and not inhalable)" and that the registered substance "is formed as water suspension and during further handling and transportation is wet".

The Registrant's justification for adaptation in IUCLID section 7.5.3. (Repeated dose toxicity: dermal) is that intake of the test substance through intact skin barrier is negligible. The Registrant also provides in the updated dossier results from an OECD Guideline 428 study (Skin Absorption: In Vitro Method) to demonstrate that "the elements contained in the test substance do not significantly penetrate into the deeper skin layers and receptor fluid, thus excluding the possibility of systemic exposure."

In their comments,the Registrant makes reference to the adaptation possibility of Annex IX, 8.6.2., column 2, indent 4 of the REACH Regulation. According to that provision a sub-chronic toxicity study (90 days) does not need to be conducted if the following cumulative conditions are met: (i) the substance is unreactive, insoluble and not inhalable and (ii) there is no evidence of absorption and (iii) no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure.

However, ECHA notes that in the current case the cumulative conditions for adaptation of Annex IX, 8.6.2., column 2, indent 4 are not met:

(i) Unreactive, insoluble and not inhalable substance:
In their comments the Registrant states that the registered substance is manufactured and used wet, as water suspension. In section 3.1 of the updated IUCLID dossier (technological process) it is stated that the "substance is in the form of suspension in water. Average content of water is [redacted] %". However, in sections 4.1 and 4.5 of the updated IUCLID dossier (appearance/physical state/colour and particle size distribution) the substance is still described as black powder with a median particle size of 3.43 µm and a "diameter on cumulative [redacted] % 0.59 µm". Further, the adaptations in IUCLID sections 4.21 (dissociation constant) and 4.22 (viscosity) refer to a solid substance.

(ii) No evidence of absorption:
There is evidence of absorption after oral exposure as shown by the results of the 28 day repeated dose toxicity study.

(iii) No evidence of toxicity in a 28-day 'limit test':
There is evidence of toxicity in the 28 day repeated dose toxicity study (NOAEL 400 mg per kg body weight, based on haematological, clinical chemistry and histopathological findings; further dose-dependent decreased liver weights and indication for hepatocellular damage at the high dose).

Therefore, since the cumulative conditions of an adaptation in Column 2 of Annex IX, 8.6.2. are not met, 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.

As already addressed above, the substance is described by the Registrant as being used wet, as water suspension. However, the physico-chemical properties of the substance as given in the IUCLID dossier indicate that the registered substance is a dust of inhalable and respirable size and of low water solubility, thus having accumulation potential in the lungs. The significant routes of human exposure are dermal and by inhalation, and the pattern of exposure is continuous/frequent as described in the generic exposure potential in IUCLID section 3.7.3. The uses described in the IUCLID dossier are i.a. production of briquettes and pellets, which, by their nature, once formed and dried, are dusty, and cement production.

ECHA therefore considers that exposure via inhalation is a likely route of human exposure and testing by the inhalation route is most appropriate.

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.

According to the test method OECD 413 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Sub-chronic inhalation toxicity: 90-day study (test method: OECD 413) in rats.

b. 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 sought to adapt this information requirement and has justified the proposal for adaptation with a reference to Annex IX, section 8.7. column two, specifying that
- *"the results of a 28-day oral toxicity study, performed in the rat and presented in the Registration Dossier, indicate mild toxicity at the Limit Dose Level of 1000 mg/kg body weight and day"*,
- *the "effects observed in the study (perturbations in erythrocyte parameters, changes in clinical chemistry parameters indicative of mild hepatotoxicity, effects on spleen weight, histopathological evidence of liver toxicity and significant local irritation of the gastrointestinal tract) are entirely consistent with iron toxicity"*,
- the *"substance contains a number of inorganic components which are non-volatile"*,
- the *"exposure to the substance Slimes and Sludges is likely to be predominantly via the dermal route; however the bioavailability of its components will be very low following dermal exposure"*.

The Registrant therefore proposes a waiver for this endpoint *"based on the predictable and low inherent toxicity of the substance and the low level of systemic absorption"* and notes that *"the available evidence indicates that the toxicity of the substance is due to its high iron content; there is known to be no risk of developmental toxicity from exposure to iron. As can be seen in registration dossier section 7.1 on toxicokinetics and 7.2 on acute toxicity shows that the substance is of low toxicological activity and on the test results and according to the EC criteria for classification and labelling requirements for dangerous substances and preparations the test substance Slimes and Sludges, blast furnace and steelmaking did not fall into any of quoted categories of toxicity both oral and inhalation."*

Furthermore, according to the Registrant, systemic exposure via skin contact is deemed insignificant and systemic exposure via other routes is limited by a variety of factors (e.g. iron absorption strictly regulated, binding of iron to transferrin, ferritin and haemosiderin). The Registrant estimates that the ingested amount of iron after 8 hours of exposure will be not higher than 50 mg and that due to a lack of significant systemic exposure, testing of metallic iron for developmental toxicity is not appropriate.

ECHA notes, firstly, that a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD 422) does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations.

Secondly, according to Annex IX, 8.7., Column 2, third indent, the study does not need to be conducted if the following cumulative conditions are met: (i) the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), (ii) 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 (iii) there is no or no significant human exposure.

However, ECHA notes that in the current case the cumulative conditions for adaptation of Annex X, 8.7., column 2 are not met. Specifically, the first criterion is not met, because clear toxic effects were noted both in the repeated dose 28-day oral toxicity study (OECD 407) and in the reproduction/developmental toxicity screening test (OECD 421) performed with the registered substance. The NOAEL was 400 mg per kg body weight and day in both studies. Also, the second criterion is not met as there is evidence of absorption (as stated by the Registrant and as shown by the results of the 28 day toxicity study). Furthermore, the third criterion is not met as there is human exposure to be expected from the uses , which are described in the IUCLID dossier i.a. as production of briquettes and pellets and cement production.

Therefore, since the cumulative conditions of an adaptation in Column 2 of Annex IX, 8.7. are not met, 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.

In their comments, the Registrant states that it would be appropriate to perform a two generation reproductive toxicity study (B.35) and based on its results it would be decided if there would be a necessity for a pre-natal developmental toxicity study (B.31). In addition, a possible read-across adaptation for a pre-natal developmental toxicity study performed on a similar substance was indicated

In the updated dossier the Registrant has added an additional adaptation for data waiving for this endpoint, with the justification "Preparing of Read-across and waiting for test results of Two-generation reproductive toxicity (OECD 416/EU B-35)".

ECHA understands that the Registrant in their adaptation only suggests possibilities to adapt the information requirement, but that the Registrant does not further propose or justify a tiered testing strategy or a read-across approach:

With regard to a possible preparation of a read-across approach indicated by the Registrant ECHA notes that the Registrant has not provided any relevant documentation. ECHA cannot assess a read-across approach without any documentation and can therefore not accept this adaptation. For a read across to be acceptable there needs to be a clear and robust justification for the proposed approach. The Registrant is reminded to refer to REACH guidance on this topic, in particular to "Practical Guide 6 How to report read-across and categories" http://echa.europa.eu/documents/10162/13655/pg_report_readacross_en.pdf.

With regard to the intention of possibly performing a tiered testing ECHA notes that the Registrant has also not provided any justification or explanation how they would use the results of a two-generation reproductive toxicity study to decide on the necessity for performing a pre-natal developmental toxicity study, which is a standard information requirement according to REACH Annex IX, 8.7.2. ECHA therefore also cannot accept this adaptation.

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.

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 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.

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 testing is necessary to fulfill this information requirement, 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 no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

c. Note for consideration by the Registrant

ECHA has observed some level of inconsistencies in the Registration dossier concerning the form and composition of the registered substance. The Registrant should consider examining these inconsistencies to provide clarity to the registration dossier.

d. Deadline for submitting the required 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 requested another study (Two-generation reproductive toxicity study (Annex X, 8.7.3.; test method: EU B.35./OECD 416) in rats, oral route; or Extended one-generation reproductive toxicity study in rats, oral route (test method: OECD 443) including the extension of Cohort 1 B to mate the F1 animals to

produce the F2 generation which shall be kept until weaning). As this study 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 IUCLID5 dossier 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. 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.

Authorised[2] by Guilhem De Seze, Head of Unit, Evaluation, E1

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