EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114330983-46-01/F Helsinki, 03 May 2016

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

For sodium dithionite, EC No 231-890-0 (CAS No 7775-14-6), 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 sodium dithionite, EC No 231-890-0 (CAS No 7775-14-6), submitted by [redacted] (Registrant).

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 date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 26 June 2015.

ECHA notified the draft decision to the Registrant and invited them to provide comments. ECHA noted that the Registrant's comments were sent with one day after the end of the commenting period. Exceptionally, ECHA decided to take these comment into account because of the short period after the prescribed deadline, and they are reflected in the Statement of Reasons (Section III).

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according 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, Section 2.3.)
2. Spectral data (Annex VI, Section 2.3.5)
3. Description of the analytical methods (Annex VI, Section 2.3.7.).

B. Information in the technical dossier derived from the application of Annexes VII to XI

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

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210).

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.

C. 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 **10 May 2017** 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.

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, Section 2.3.)

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

In that respect, according to chapters 4.2 and 8.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, the Registrant shall note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and <80% for multi-constituent substance) shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.
- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In addition, pursuant to article 3(1) of the REACH Regulation and as explained in chapter 4.2 of the guidance, additives are agents intentionally added to preserve the substance stability and are, therefore, considered as part of the substance composition. Annex VI, section 2.3.4 of the REACH Regulation requires sufficient information on the nature and order of magnitude of any additive used in the substance. An agent added to fulfil any other function must be removed from the substance composition.

The Registrant has identified the substance as the well-defined mono-constituent substance "sodium dithionite" and has only specified:

- the typical concentration and the lower value for the concentrantration range for the main constituent,
- the typical concentrations.

However the Registrant did not provide information on the concentration ranges for all other constituents (impurities and additives), as listed in section 1.2.

In addition, sodium carbonate has been reported as an additive in section 1.2 of IUCLID. However, the stabilizing function is not specified and it seems not applicable as the dry substance is stable without addition of sodium carbonate. The function reported for this additive is "buffer", therefore sodium carbonate shall not be considered as a stabilizer under the meaning of Article 3(1) of the REACH Regulation.

ECHA, therefore, concludes that the compositional information of the registered substance has not been provided to the required level of details. The missing information on the lower and upper limits of the concentration ranges for the constituents, additive and impurities of the substance is fundamental to understand the variability in the composition of the registered substance for the purpose of determining substance identity and substance sameness. Moreover, the stabilizing function of sodium carbonate is not specified and the function "buffer" reported in the "remark" field is not acceptable under the meaning of Article 3(1) of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct composition of the registered substance as specifically explained above including all identified constituents and impurities, with their typical concentrations and concentration ranges. The concentration ranges must be representative for the substance as manufactured or imported by the registrant. The Registrant is also requested to provide sufficient information on the nature and order of magnitude of any additive used in the substance. However, if the specified additive does not fulfill the definition of stabilizer under REACH, it shall be removed from the substance and not included in the mass balance. The Registrant shall ensure that the information is consistent throughout the dossier.

In his comments to the draft decision, the Registrant has agreed to the request and provided some justification for the role of sodium carbonate as stabiliser which can be considered as sufficient. The Registrant also declared his intention to update his registration dossier.

Regarding how to report the concentration range values for all the identified constituents of the registered substance in IUCLID, the following applies: the Registrant shall report the concentration range values of the main constituent, of each impurity and of additives (necessary to preserve the stability of the substance) by providing their lower and upper limit, as % (w/w), each under the respective "concentration range" field in section 1.2. The concentration ranges provided and the typical concentrations must be representative for the substance as manufactured. Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

Regarding how to report additives in IUCLID, the following applies: if the additive meets the definition of stabilizer, it must be included under the additives section in IUCLID and the function "stabilizer" must be selected. If the additive does not meet the definition of stabilizer, it shall be removed from the composition.

2. Spectral data (Annex VI, Section 2.3.5).

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement. The REACH Regulation requires Ultraviolet and Visible (UV/VIS), Infrared (IR), and Nuclear Magnetic Resonance (NMR) or Mass spectrum (MS) to be submitted to identify a substance. For inorganic substances X-Ray Diffraction (XRD) or an X-Ray Fluorescence (XRF) or Atomic Absorption Spectroscopy (AAS) analysis may be more suitable.

However ECHA notes that spectral data have not been provided in the dossier.

This information is necessary and scientifically relevant for the identification of the registered substance. In particular, as the substance is an inorganic salt, an XRD spectrum of the substance provides a diffraction pattern that allows the identification of the substance and of its phases. Other spectral data as IR can further support the substance identification.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: an XRD spectrum, as specifically explained above, in order to allow the unequivocal identification of the substance. Alternative spectral data that would equally allow an adequate identification of the substance may be sumitted if a scientific justification is provided. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the spectral data in the registration dossier, it must be included in Section 1.4 of IUCLID.

3. Description of the analytical methods (Annex VI, Section 2.3.7).

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement. A description of the analytical methods used for the identification and quantification of the subtance shall be provided at a level of details which allows the methods to be reproduced.

ECHA notes that the analytical information included in section 1.4 contains only a description of the titration method used to quantify the ion "dithionite" and the description of a method to determine the elemental carbon content, potentially used to extrapolate the sodium carbonate content. In addition, no actual results obtained specifically on the registered substance and related calculations are reported and therefore it is not clear how the composition of the substance as reported in section 1.2 was derived.

ECHA therefore considers that the Registrant has not included sufficient data that would enable the composition of the substance to be verified. ECHA also considers essential for the unequivocal identification and quantification of the substance that the experimental results of the quantitative methods applied are provided, together with the calculation used to derive the composition of the substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct description of the analytical methods used to identify and quantify the registered substance as specifically explained above, including the experimental results and calculations applied to quantify the main constituent, the impurities and additives of the registered substance. In the description of the titration method, the Registrant shall include the experimental results obtained when applying the given experimental protocol to the substance. For the XRD method the Registrant shall include the details of sample/standard preparation, voltage, current, X-ray source. Moreover, the refinement method shall also be given if a quantitative XRD is provided. The Registrant shall ensure that the information is consistent throughout the dossier.

In his comments to the draft decision, the Registrant has agreed to the request and declared his intention to update his registration dossier to include the missing information with the next dossier update.

The analytical methods used for identification and quantification of the substance data, including the description of the analytical methods and the actual results of analysis, shall be reported in Section 1.4 of IUCLID.

B. Information in the technical dossier derived from the application of Annexes VII to XI

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.

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement. Column 2 of Annex IX, Section 9.1. specifies that long-term aquatic toxicity testing shall be proposed by the Registrant if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

In order to fulfil this information requirement, the registrant has provided a study with the analogue substance sodium sulphite according to OECD 210 technical guideline, giving the justification that 'dithionite rapidly decomposes into sulphite and sulphate under aerobic environmental conditions, these data are useful for assessing chronic toxicity of dithionite'. ECHA considers that this justification is the basis whereby the Registrant proposes that the properties of the registered substance may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met". According to Annex XI, Section 1.5., there needs to be structural similarity among the substances within a group or category and furthermore, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). Furthermore, Annex XI, Section 1.5 lists several additional requirements, including that adequate and reliable documentation of the applied method is to be provided.

ECHA considers that the read-across argumentation has several problems. Firstly, although sodium sulphite may be one of the breakdown products of sodium dithionite in water, there are other potential hydrolysis products which have not been considered by the registrant, such as sulphate and thiosulphate. The Registrant has not explained, for this endpoint, why information for sulphite can be used to predict the properties of other breakdown products. Additionally, the Registrant has not provided a basis, for this endpoint, whereby the sulphite can be used to predict the properties of the parent substance (as opposed to breakdown products). Secondly, the available results show that the proposed analogue substance has different properties from the registered substance, in contradiction to the Registrant's hypothesis. Specifically, the NOEC value derived from the long-term fish OECD 210 study on sodium sulphite (>316 mg/L), is higher than the LC50 values from the short term fish toxicity study with the registered substance (62.3 mg/L). ECHA considers it unlikely that a short-term study for the same substance will yield a lower LC50 than the corresponding long-term study NOEC. Thus, ECHA considers that the justification provided does not constitute a reliable basis for making a prediction of the properties of the registered substance, and that the evidence in the dossier contradicts the Registrant's proposed hypothesis in his justification. Hence the read-across argumentation does not fulfil the criteria of Annex XI, Section 1.5, that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).

For the reasons explained above, the provided information on the suggested read-across did not meet the requirements of Annex XI, 1.5. of the REACH Regulation. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In his comments to the draft decision the Registrant disagreed with the request. The Registrant outlined how he could address the information requirement by stating that he can "*include available reliable acute data (fish) for the degradation products thiosulfate and sulphite and to reconsider the relevance of the report from* [redacted] *Report on the study of the acute toxicity resulting in LC50 = 62.3mg/L.*

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:
ECHA agrees with the registrant's comment that the result LC50 = 62.3mg/L of the '"*Report on the study* [redacted]', for the substance sodium dithionite can be considered of limited relevance as it is based on a deficiency (adequate oxygen saturation levels not maintatined throughout the test).

Furthermore ECHA notes that the additional acute data (fish) for the degradation products thiosulfate and sulphite together with the test reports seem very relevant to improve the read-across argumentation of the Registrant.

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 (after ECHA had sent the final decision).

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

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: Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

IV. Adequate identification of the composition of the tested material

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

In relation to the information required by the present decision, the sample of substance used for the new study 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 study 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 study 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 study 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 Ofelia Bercaru, Head of Unit, Evaluation E3

[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.