

Decision number: CCH-D-0000002643-76-02/F

Helsinki, 15 October 2013

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For 67828-72-2_master_strontium 4-[(4-chloro-5-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (1:1), CAS 67828-72-2 (EC No 267-291-6), 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 the ECHA has performed a compliance check of the registration dossier for 67828-72-2_master_strontium 4-[(4-chloro-5-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (1:1), CAS 67828-72-2 (EC No 267-291-6) submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 1-10 tonnes per year.

The compliance check was initiated on 24 May 2011.

On 14 November 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 14 December 2011 the Registrant provided to ECHA comments on the draft decision.

On 31 May 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received. On the basis of the comments and the update of the registration dossier received, Section II (including the deadline given to update the registration dossier with information requested) was amended. The Statement of Reasons (Section III) was changed accordingly. On 20 June 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

- 1) Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vi), 12(1)(a), 13 and Annexes VII and XI of the REACH Regulation the Registrant shall submit the information on the registered substance using the test method as indicated on:
 - a. Flammability (Annex VII, 7.10.; UN test method N.1. section 33.2.1);
 - b. Self-ignition temperature (Annex VII, 7.12.; UN test method N.4 part III, sub section 33.3.1.6).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **15 April 2014**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1 to 10 tonnes per year in accordance with **Article 6 and 11(2)** of the REACH Regulation, does not comply with the requirements of Articles **10 and with Annexes VII and XI** thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10(a)(vi), 12(1)(a) and Annex III(b) of the REACH Regulation, a registration for a substance produced in quantities of 1 – 10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

The technical dossier provided information originating from other substances than the registered substance on the following endpoints:

- Flammability (Annex VII, 7.10.);
- Self-ignition temperature (Annex VII, 7.12.);

a) Flammability (Annex VII, 7.10.)

The results of experimental studies with calcium 4-[(5-chloro-4-methyl-2-sulfonatophenyl)diazenyl]-3-hydroxy-2-naphthoate and with strontium 3-hydroxy-4-[(4-methyl-2-sulfonatophenyl)diazenyl]-2-naphthoate on flammability are provided in the registration dossier.

On 31st May 2012 the Registrant submitted an updated registration dossier providing results of two additional flammability studies on substances other than

the registered substance and the two following waiving justifications based on section 1 of Annex XI:

"In accordance with section 1 of REACH Annex XI, the study does not need to be performed as based on chemical structure pyrophoric properties are not to be expected";

"In accordance with section 1 of REACH Annex XI, the study does not need to be performed as based on chemical structure water reactivity is not to be expected".

ECHA notes that the justification for adaptation of the standard information requirement for pyrophoricity and water reactivity is acceptable. However while it is accepted that the presence of halogens when covalently bound to carbon generally decreases flammability potential, in ECHA's opinion the requirement to perform flammability testing on the registered substance remains.

A possible classification as a flammable solid should be considered for all solid organic substances (Article 8.2 of CLP). Furthermore, according to Article 10(a)(iv) and Annex VI, section 4 of REACH, the registration dossier must contain the hazard classification of the substance together with the reasons why no classification is given, e.g. based on data from the tests carried out. As such, testing in accordance with the UN-MTC (UN test method N.1. section 33.2.1) as required by the CLP Regulation should be performed for the registered substance and reported in the registration dossier.

A read-across approach is not applicable since structure alone may not be sufficient to predict the presence or absence of a flammable hazard (ECHA Guidance R. 7.1.10.3). Additional parameters such as physical condition, particle size, density and crystal structure may influence the test result.

Thus, the Registrant is requested to submit the information on flammability of the substance using the test methods as indicated above. The tests must be performed on the registered substance (strontium 4-[(4-chloro-5-methyl-2-sulfonatophenyl)azo]-3-hydroxy-2-naphthoate).

b) Self-ignition temperature (Annex VII, 7.12.)

The results of experimental studies with strontium 4-[(5-chloro-4-methyl-2-sulfonatophenyl)diazonyl]-3-hydroxy-2-naphthoate and strontium 3-hydroxy-4-[(4-methyl-2-sulfonatophenyl)diazonyl]-2-naphthoate on self-ignition temperature are provided in the registration dossier. In the update of the registration dossier the Registrant submitted results of four additional auto flammability studies on substances other than the registered substance.

ECHA notes that a read-across approach to predict self-ignition is not applicable as structure alone is not sufficient to predict the presence or absence of a self heating hazard since self-heating strongly depends on particle shape, size, heat conductivity, bulk density and other parameters (ECHA Guidance R. 7.1.10.7). According to Article 10(a)(iv) and Annex VI, section 4 of REACH, the registration dossier must contain the hazard classification of the substance together with the reasons why no classification is given e.g. based on data from the tests carried out.

As such, testing in accordance with the UN-MTC (UN test method N.4 part III, sub section 33.3.1.6) as required by the CLP Regulation should be performed for the registered substance and reported in the registration dossier.

Thus, the Registrant is requested to submit the information on self-ignition temperature of the substance using the test methods as indicated above. The tests must be performed on the registered substance (strontium 4-[(4-chloro-5-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate).

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

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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