EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002725-72-02/F Helsinki, 16 November 2012

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

For Cobalt(2+) propionate, CAS No 1560-69-6 (EC No 216-333-1), 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 cobalt(2+) propionate, CAS No 1560-69-6 (EC No 216-333-1), submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 6 September 2012, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 28 November 2011.

On 24 April 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 25 May 2012 ECHA received comments from the Registrant. On 26 July 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received. On basis of the comments, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 6 September 2012 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.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

a. Composition of the substance (Annex VI, section 2.3): Any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance, as specified under section III.1)(a) below;
b. The description of the analytical methods for the identification of the substance (Annex VI, 2.3.7.) as specified under section III.1)(c) below.

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 **18 February 2013**.

If the submitted information does not enable ECHA to establish and verify the identity of the registered substance (including any composition actually covered by the registration) and the validity for the inclusion of a composition in the dossier, the registration will not be considered valid.

III. Statement of reasons

Based on the examination of the technical dossier (targeted on substance identity endpoints), 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 100 to 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and Annexes VI 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 Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

(a) Composition of the substance (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 corner stone of all the REACH obligations.

ECHA notes that the Registrant adopted a registration approach consisting in registering the constituents of multi-constituent substances rather than the substance themselves.

According to the Guidance on substance identification under REACH[1] (referred to thereinafter as the Guidance), a multi-constituent substance should be registered and identified as such in its registration dossier. As a deviation from that approach, individual constituents can be registered when the following conditions are all met:

- there is no reduction in information requirements;

[1] http://echa.europa.eu/web/guest/regulations/reach/substance-identity

- there is sufficient existing data to justify the approach of registering the individual constituents i.e. the approach should normally not instigate additional (vertebrate animal) testing compared to the standard approach;
- registering the individual constituents leads to a more efficient situation (i.e. avoiding numerous registrations of substances which are composed of the same constituents);
- the information on the composition of the individual reaction masses is given.

However, ECHA observes that the compositions specified in the dossier do not all refer to substances for which such a registration approach applies.

More specifically, the Registrant indicated that the registration, which refers to the mono-constituent substance "cobalt(2+) dipropanoate", also covers the "cobalt(2+) dipropanoate" constituent present in substances identified as "Reaction mass of cobalt neodecanoate and cobalt propionate" and "[redacted]".
ECHA points out that the substance identified by the Registrant as "Reaction mass of cobalt neodecanoate and cobalt propionate" does not refer to a well-defined multi-constituent substance. In particular, neodecanoate corresponds to a carboxylate having an indefinite alkyl chain. It implies that the complete structure of cobalt neodecanoate is indefinite and covers a large number of constituents. The substance named by the Registrant as "Reaction mass of cobalt neodecanoate and cobalt propionate" is therefore regarded as a UVCB substance under REACH. As the approach for the registration of constituents rather than substances does not apply to UVCB substances, ECHA concludes that the "cobalt(2+) dipropanoate" constituent present in the composition of the UVCB substance named "Reaction mass of cobalt neodecanoate and cobalt propionate" can not be covered by this registration. The UVCB substance shall be registered as such.

The Registrant explained, in their comments to the draft decision, that the neodecanoate structure was established to be well defined based on the information that the "neodecanoic acid" precursor has been registered as a mono-constituent substance by their supplier. The Registrant also specified that it was not possible for them to obtain compositional information of the supplied "neodecanoic acid".
ECHA further clarifies that "neodecanoate" does not relate to any nomenclature to systematically name a defined chemical structure. The precursor "neodecanoic acid" is known to designate C10 trialkylacetic acids and is composed of a large number of isomers and therefore a multitude of constituents. ECHA notes that the registrant specified, in the IUPAC name field and molecular and structural information of the reference substance for "neodecanoic acid, cobalt salt", the well-defined structure "cobalt(2+) bis(2-ethyl-2,5-dimethylhexanoate)". However, for the same reason as to why "2-ethyl-2,5-dimethylhexanoic acid" (CAS number 24353-79-5) refers to a different substance than "neodecanoic acid" (CAS number 26896-20-8), "cobalt(2+) bis(2-ethyl-2,5-dimethylhexanoate)" shall not be regarded the same as cobalt bis(neodecanoate). ECHA also underlines that the knowledge of the structural information associated with the "neodecanoate" building block of the substance is essential for establishing the registration obligations under REACH.

The Registrant is therefore requested to remove from IUCLID section 1.2 of the dossier the composition for the UVCB substance "Reaction mass of cobalt neodecanoate and cobalt propionate". The Registrant shall also ensure to delete any reference to the manufacturing and use of this UVCB substance made in IUCLID section 3 of the dossier.

In light of these considerations, the Registrant shall also evaluate the applicability of the provision for covering the multi-constituent substance by registering its individual

constituents in the case of the other substance included in the registration dossier: "[redacted]". In particular, the Registrant shall consider if the condition "registering the individual constituents leads to a more efficient situation" is still fulfilled. If the Registrant concludes that registering constituents of multi-constituent substances requires him to submit more registrations than the registrations required for the substances that are manufactured/imported, he shall remove from the registration dossier any information regarding the substance "[redacted]" and proceed with the registration of the substance. ECHA also draws the attention to the Registrant that the manufacturing process of "[redacted]" specified in the dossier indicates that this substance corresponds to the mixed cobalt salts with [redacted] and propanoic acid. It implies that this substance includes not only the cobalt(2+) dipropanoate and cobalt [redacted] constituents but also the mixed salt "cobalt(2+) propanoate [redacted]" constituent. ECHA notes that the Registrant acknowledged, in their comments, the existence of mixed cobalt salts in the substance referred to as "Reaction mass of cobalt neodecanoate and cobalt propionate". As the general manufacturing process is the same for these two substances, ECHA understands that the mixed salt "cobalt(2+) propanoate [redacted]" should also be present in the substance referred to as "[redacted]". ECHA underlines that mixed salts remain constituents of the registered substance and have to be registered individually as any other constituent of the multi-constituent substances concerned by such registration strategy.

If the Registrant concludes that all the conditions set in the Guidance for registering constituents of multi-constituent substances apply, the registrant shall specify the reasons as to why the four conditions mentioned hereinabove in this communication for making use of such deviation are considered to be fulfilled. This information should be provided in the Description field of the reference substance in IUCLID section 1.1. Only then, the Registrant shall report the chemical composition of each well-defined substance for which the contribution of cobalt dipropionate is covered by the registration. The compositional information shall include information on the chemical identity of each individual constituent (including main constituent and impurity present at ≥ 1 % (w/w) or contributing to the PBT assessment or classification) or so that it refers to one specific chemical structure. Information on the concentration level of each constituent (including minimum, maximum and typical concentration) shall also be provided.

Further technical details on how to report the composition of 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.

(c) Description of the analytical methods (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not include the description of an appropriate method for the quantification of cobalt ion. The Registrant only provided the results of a method for the quantification of the cobalt counter-ion based on a complexiметric titration analysis that is not specific for cobalt.

The Registrant is accordingly requested to provide the description of an analytical method that is specific for the quantification of the cobalt ion present in the substance. The description shall be sufficient for the method to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4.

IV. 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.

[redacted]

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