European Chemicals Agency

Decision number: CCH-D-0000001268-73-03/F Helsinki, 17 December 2010

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

Substance chromium triacetate, EC No. 213-909-4, CAS 1066-30-4, 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 (the REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation, ECHA has performed a compliance check of the registration dossier for **Chromium triacetate (EC No. 213-909-4)** submitted by [redacted] (the "Registrant"), latest submission number [redacted], for 10-100 tonnes per year.

The present compliance check was initiated on 09 March 2010.

On 30 April 2010 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. The registrant did not provide any comments on the draft decision.

On 11 June 2010 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.

By 11 July 2010 ECHA did not receive any proposals for amendments from the competent authorities of the Member States.

This compliance check decision has been targeted on the substance identity and 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), 41(3) and 10(a)(ii) as well as Annex I and Annex VI, Section 2.1. and Section 2.2. of the REACH Regulation, the Registrant shall

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

eliminate the following inconsistencies in the substance name and molecular formula in order to univocally identify the substance that has been registered:

a. Concerning the molecular and structural formula information the registration can only cover chromium triacetate (CAS 1066-30-4, EC 213-909-4) but not acetic acid, chromium salt, basic (CAS 39430-51-8, EC 254-447-3), which is a different substance. Therefore the registrant shall eliminate the text in the remarks field of the IUCLID reference substance dataset, which indicates the intention to register "acetic acid, chromium salt, basic" under CAS 1066-30-4 and EC 213-909-4.
b. The chemical name (Chromium triacetate, basic) and molecular formula (Cr3(OH)2(CH3COO)7 xH2O) given in the substance composition field of IUCLID section 1.2. refers to a different substance and shall be made consistent with those provided in section 1.1. (Chromium triacetate and C2H4O2.1/3Cr).
c. The substance considered in the chemical safety report shall be made consistent with the substance referred to in the technical dossier.

2. Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, Sections 2.3.5., 2.3.6. and 2.3.7. of the REACH Regulation, the Registrant shall provide:
   a. The IR spectrum for the registered substance (chromium triacetate).
   b. The UV/Vis spectrum for the registered substance (chromium triacetate).
   c. An integrated H-NMR recorded from 0-15 ppm, containing also information on the recording conditions and/or a mass spectrum.
   d. Analytical information to confirm the quantitative and qualitative composition of the registered substance.
   e. Description of the analytical methods used or the appropriate bibliographical references for the identification of the registered substance.

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 **6 months from the date of the decision**.

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 in accordance with **Article 6** of the REACH Regulation, does not comply with the requirements of Articles **10, and with Annexes I and VI** thereof. Consequently, the Registrant is requested to submit the information required above that is needed to bring the registration into compliance with the relevant information requirements.

1) Eliminate inconsistency in the substance name and molecular formulae

According to Annex VI section 2, information should be provided that is sufficient to enable each substance to be identified. The provided information does not allow the registered substance to be univocally identified, because in the three sections below the registrant refers to different substances:

a. The reference substance refers to chromium triacetate (EC number 213-909-4, CAS number 1066-30-4). However, in the remarks field of the reference substance dataset the registrant explains that he intends to register Acetic acid, chromium salt, basic (EC number 254-447-3, CAS number 39430-51-8). EC number 254-447-3 is unspecified, no structural formula is available, and in theory could contain various forms of chromium acetates and/or various oxidation states of chromium could be possible as well. For these reasons, under the REACH Regulation, the substance

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

with EC number 254-447-3 cannot be regarded as identical to EC 213-909-4, the registration of chromium triacetate (EC number 213-909-4) could not be regarded as covering any possible substance that can be referred as EC number 254-447-3, and the registrant shall correct the text in the remarks field accordingly.

b. In IUCLID section 1.1, Identification, both molecular ($C_2H_4O_2$.1/3Cr) and structural formulae are provided and are corresponding with the provided chemical name in the reference substance dataset, hence 'Chromium triacetate'. However, in the IUCLID section 1.2 – Composition - the name is given as: 'Chromium triacetate, basic' and described as: $Cr_3(OH)_2(CH_3COO)_7$ xH_2O, blue-green powder in the substance composition field. Although the latter substance it is also a chromium(3+) acetate, it is a different substance than chromium (3+) triacetate. The substance with the molecular formula $Cr_3(OH)_2(CH_3COO)_7$ xH_2O, refers to 'Hepta(acetate-*O*)dihydroxychromium hydrate' (possible IUPAC name) or Chromium, hepta(acetato-*kO*)dihydroxy-, hydrate (possible CAS name). For the reasons mentioned above, the registrant is requested to eliminate any inconsistency and refer to chromium triacetate with the molecular formula $C_2H_4O_2$.1/3Cr. However, if the registrant wants to cover also chromium triacetate hydrate(s) (see point (c.2) below), then this information should be included in the remarks field and detailed information regarding the individual chromium triacetate hydrate(s) should be given in the related information field (i.e. Related CAS information).

c. The Chemical Safety Assessment, Part B, substance identification (1.1) refers to four different substances:
   1. Chromium triacetate (EC number 213-909-4)
   2. Chromium (III)acetate hydrate (Chromium (III)acetate monohydrate: CAS number: 25013-82-5, Chromium (III)acetate trihydrate: CAS number: 5990-10-3 and Chromium (III)acetate hexahydrate, CAS number: 66851-10-3). These hydrates would be covered by the anhydrate (EC Number 213-909-4).
   3. Acetic acid, chromium salt, basic (EC number: 254-447-3)
   4. $Cr_3(OH)_2(CH_3COO)_7$ xH_2O (Hepta(acetate-*O*)dihydroxychromium hydrate, a CAS number does not seem to be available)

   According to Annex V section 6 of the REACH Regulation, the registration of chromium triacetate (EC Number 213-909-4) could also cover hydrated forms of chromium triacetate reported in the Chemical Safety Assessment, Part B (see point (c.2) above).
   As explained at point (a), Acetic acid, chromium salt, basic is unspecific and cannot be regarded as identical to chromium triacetate; for the reasons explained at point (b) $Cr_3(OH)_2(CH_3COO)_7$ xH_2O can not be regarded as identical to chromium triacetate.
   Therefore, the substance identity in the Chemical Safety Assessment shall be referred to chromium triacetate (EC Number 213-909-4) and its hydrates (see point (c.2)), if the registrants wishes to include these.

2) Provide further analytical data

According to Annex VI sections 2, 2.3.5. to 2.3.7. of the REACH Regulation, spectral and chromatographic information should be provided that are sufficient to identify the registered substance. The analytical information provided by the registrant does not allow the identification of the registered substance for the following reasons:

a. The provided Fourier transform infrared (FTIR) spectrum refers to 'Basic chromium acetate powder' and provides the chemical formula: $Cr_3(OH)_2(CH_3COO)_7$ xH_2O, therefore it does not refer to the registered substance. Moreover, bands in the FTIR

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

spectrum can be allocated to -C=O, CH2- CH3- and OH- groups, which would be for any metal acetate hydrate. Therefore the FTIR spectrum is not conclusive to identify the substance without any doubts. A IR spectrum for chromium triacetate shall be provided.

b. No ultra-violet visible (UV/Vis) spectrum was provided. The registrant indicated: "The method is not applicable for the analysis of chromium triacetate." As the substance contains acetate group(s) absorption is expected from the carbonyl groups around 220-290nm so that the statement provided by the registrant does not appear to be correct and no reasons have been stated why it is scientifically not necessary to give this information. A UV/VIS spectrum shall be provided.
c. Nuclear magnetic resonance (^{1}H-NMR and ^{13}C-NMR) spectra were submitted and confirm that the substance contains (an) acetate group(s). As the ^{1}H-NMR is not integrated, there is no possibility to verify how many acetate groups the substance consist of. The ^{13}C-NMR indicates the presence of aliphatic hydrocarbon (i.e. $-CH_3$) and a carbonyl group (i.e. C=O), which are expected for the substance. Therefore, an integrated ^{1}H-NMR recorded from 0-15ppm containing also information on the recording conditions (e.g. frequency, concentration, solvent, standard) and/or a mass spectrum for chromium triacetate shall be provided.
d. The information to be provided under points a, b and c is not sufficient as such to confirm the quantitative and qualitative composition of the substance chromium triacetate, therefore additional analytical information (e.g. atomic absorption spectroscopy, Karl Fisher titration) shall be provided to enable the substance to be identified.
e. The description of the analytical methods or the appropriate bibliographical references for the identification of the registered substance is missing. Thus, no methods can be reproduced. This information shall be provided to enable the substance to be identified.

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 reads:

> "*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

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 1907/2008 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

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.

Done at Helsinki,

[redacted]

Geert Dancet
Executive Director

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu