~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001306-81-04/F Helsinki, 22 March 2011

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

For Pigment Additive 1799u [redacted] *CAS* [redacted] (EC Nr. 404-170-0), registration numbe[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 **Pigment Additive 1799u [redacted] CAS [redacted] (EC Nr. 404-170-0)** submitted by [redacted] the Registrant), latest submission number [redacted]

The Registrant notified the substance pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the Netherlands competent authority in accordance with Article 7 of Directive 67/548/EEC. The notification number allocated was [redacted]

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

The national competent authority did not finalise its assessment of the testing programme before the relevant Article 135 of the REACH Regulation entered into force on 1 August 2008. Thus, the dossier may not include some relevant legally required information. For that reason, ECHA has invited the Registrant by letter of 27 August 2009 to update the dossier and submit testing proposals if necessary to bring the registration into compliance with the information requirements of the REACH Regulation. However, no testing proposal or updated dossier has been received by the date of this decision.

The compliance check was initiated on 13 April 2010.

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The draft decision was notified to the Registrant on 14 July 2010. By 13 August 2010 ECHA did not receive any comments from the Registrant on the draft decision.

On 29 October 2010, ECHA notified the Member State Competent Authorities of its draft decision and invited them to provide proposals for amendment.

After receiving proposals for amendment from Member State Competent Authorities, ECHA forwarded the proposals for amendment to the Registrant on 1 December 2010 and did not amend its draft decision.

On 13 December 2010, the draft decision was referred to the Member State Committee.

The Registrant did not provide any comments on the proposals for amendment.

After discussions in the Member State Committee meeting on 1-3 February 2011, the draft decision was modified by the Member State Committee and a unanimous agreement of the Member State Committee on the modified draft decision was reached on 3 February 2011.

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

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi) and (vii), [redacted] of the REACH Regulation, the Registrant shall submit the information using the test method as indicated below.

- Pre-natal developmental toxicity (Annex IX, 8.7.2. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC), one species, oral (EU test method B.31 or OECD guideline 414);
- Long-term toxicity to invertebrates (Annex IX, 9.4.1. column 2 REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) earthworm reproduction test (such as OECD 222) or, if the Registrant considers otherwise, short-term toxicity to invertebrates (Annex IX, 9.4.1. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) earthworm acute toxicity test (EU Method C.8);
- Long-term toxicity on plants (Annex IX, 9.4.3. column 2 REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) (such as ISO standard 22030) or, if the Registrant considers otherwise, short-term toxicity on plants (Annex IX, 9.4.3. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) seedling emergence and seedling growth test (such as OECD 208/ ISO standard 11269-2)

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 **12 months from the date of the decision, i.e. on 22 March 2012.**

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant in course of the earlier notification and now subject to the requirements of the REACH Regulation, does not comply with the requirements of Articles **10, 12 and** [redacted] 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.

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Since the registration is not a tonnage band update, it does not have to comply with all of the information requirements of all relevant tonnage band levels of the REACH Regulation (Article 24(2) of the REACH Regulation). Rather it follows from this Article that a registration originating from a previous notification and in cases other than a tonnage band update needs to comply with the information requirements of the REACH Regulation limited by the scope of information requirements pursuant to Directive 67/548/EEC, depending on which regulatory framework requires less information. The information requested is covered by both the REACH Regulation and Directive 67/548/EEC.

The technical dossier provided did not contain information for the endpoints on:

- Pre-natal developmental toxicity (requirement of Annex IX, 8.7.2. of REACH and of Annex VIII Level 1 of Directive 67/548/EEC)
- Effects on terrestrial organisms (requirement of Annex IX, 9.4. of REACH and of Annex VIII Level 1 of Directive 67/548/EEC)

A pre-natal developmental toxicity study is a requirement of both Annex IX, 8.7.2. of the REACH Regulation and Annex VIII Level 1 of Dir. 67/548/EEC. The Registrant is accordingly requested to perform such a study (one species, oral route) according to OECD 414 or EU Method B.31.

Tests on terrestrial organisms and in particular on invertebrates (e.g. earthworms) and on higher plants are requirements of both Annex IX, 9.4. of the REACH Regulation and Annex VIII Level 1 of Directive 67/548/EEC. Column 1 of Annex IX, 9.4. of REACH specifies short-term tests as the standard information requirement. However, column 2 of that Annex specifies that long-term toxicity testing shall be considered by the registrant instead of short-term if the substance has a high potential to adsorb to soil. It should be noted that the substance is highly adsorptive, and so long-term tests should be preferred as the condition of column 2 is met. Therefore, on this basis ECHA considers that the Registrant should perform the (long-term) earthworm reproduction test (such as OECD 222) and the long-term toxicity on plants (such as ISO standard 22030) to meet the requirements set out in Annex IX 9.4.1 and 9.4.3 of the REACH Regulation respectively. If the Registrant does not consider long-term testing appropriate the Registrant is required to perform instead a (short-term) earthworm acute toxicity test (EU Method C.8) and a short-term toxicity on plants - seedling emergence and seedling growth test (such as OECD 208/ ISO standard 11269-2) to meet the requirements set out in Annex IX 9.4.1 and 9.4.3 of the REACH Regulation respectively.

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

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(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.

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,

Jukka Malm
Director of Regulatory Affairs

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