~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001321-89-06/F Helsinki, 08 July 2011

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

For 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole- 1,4-dione (c.i.pigment Red 254), CAS 84632-65-5 (EC No. 401-540-3), 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 dossier for **3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole- 1,4-dione (c.i.pigment Red 254), CAS 84632-65-5 (EC No. 401-540-3)**, submitted by [redacted] (Registrant), latest submission number [redacted], for 100-1000 tonnes per year.

The Registrant notified the substance pursuant to the [redacted] legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) to the [redacted] 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 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 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 26 April 2010.

ECHA drafted a decision in accordance with Article 41 of the REACH Regulation. On 13 August 2010, ECHA notified the Registrant of its draft decision and invited him to provide comments.

The Registrant provided comments on the draft decision to ECHA on 9 September 2010. Since the Registrant did not update the dossier along his comments, ECHA decided not to amend the draft decision.

On 7 January 2011, ECHA notified the Member State Competent Authorities of its draft decision and invited them to provide proposals for amendment.

After receiving a proposal for amendment from one Member State Competent Authority, ECHA forwarded the proposal for amendment to the Registrant on 11 February 2011 and decided not to amend the draft decision.

On 21 February 2011, the draft decision was referred to the Member State Committee.

On 4 March 2011, the Registrant provided comments addressing other issues, but not the proposed amendments.

The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 March 2011 in a written procedure launched on 21 March 2011.

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

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and Annexes VIII - IX of the REACH Regulation, the Registrant shall submit the information using the test method as indicated below.

a) A pre-natal developmental toxicity study, (Annex IX, 8.7.2. of REACH and Annex VIII Level 1 of Directive 67/548/EEC), one species, oral (EU test method B.31 or OECD 414)
b) An *in vitro* gene mutation study on mammalian cells, (Annex VIII, 8.4.3. of REACH and Annex VIII Level 1 of Directive 67/548/EEC, EU test method B.17)

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 09 July 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 13 and with Annexes VIII and IX 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.

Since the next tonnage threshold has not yet been breached, the registration at hand does not have to comply with all of the information requirements of all relevant tonnage band levels of the REACH Regulation (Article 24(1) of the REACH Regulation). It rather 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. A comparison of the information requirements of the REACH Regulation and Directive 67/548/EEC is provided for the relevant endpoints to explain the information request.

The technical dossier provided did not contain any information for the endpoints mentioned above under Section II. a) to b).

IV. General instruction on the update of dossiers of previously notified substances

Pursuant to Article 111 of the REACH Regulation, the requested information should be submitted to ECHA in the form if an IUCLID dossier update. You can find the instruction on the submission of the dossier update in the Question and Answer document for the registrants of previous notified substances published on the ECHA website on the following link: http://echa.europa.eu/doc/reachit/prev_not_sub_registrants_qa.pdf. In addition we also advise you to consult the Data Submission Manual No 5, Annex 4, "Minimum information required for updating a registration under previous directive", in the section "Other updates", available at: http://echa.europa.eu/reachit/registration-it_en.asp.

The reference documents include information on possible alternative means that can be used in place of robust study summaries i.e. that under certain circumstances study summaries can be sufficient when submitting a dossier update.

V. 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 1907/2006 as adapted to the technical progress 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.

VI. 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]

Jukka Malm
Director of Regulatory Affairs