European Chemicals Agency

Decision number: **CCH-D-0000001318-76-03/F** Helsinki, 8 March 2011

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

For Ethylhexyltriazone (Tris(2-ethylhexyl)-4,4',4"-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate) CAS 88122-99-0 (EC Nr. 402-070-1), 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 (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for **Ethylhexyltriazone (Tris(2-ethylhexyl)-4,4',4"-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate) CAS 88122-99-0 (EC Nr. 402-070-1)** submitted by [redacted] (the "Registrant"), latest submission number [redacted] for 10-100 tonnes per year.

The compliance check was initiated on 21 May 2010.

On 14 July 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.

On 2 August 2010 the Registrant provided to ECHA comments on the draft decision. The Registrant indicated his intention to gain access to the required data and subsequently update the dossier. ECHA did not amend the draft decision.

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On 29 October 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 28 November 2010 ECHA did not receive any proposals for amendments from Competent Authorities of the Member States.

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 Annex VIII of the REACH Regulation the Registrant shall submit the information using the test method as indicated on

- **Mutagenicity (Annex VIII, 8.4.3.; EU 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 **12 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(a)(vi), 12(1)(c) and with Annex VIII 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)(c) of the REACH Regulation, a registration for a substance produced in quantities of 10-100 tonnes per year shall contain as a minimum the information specified in Annexes VII and VIII of the REACH Regulation.

The technical dossier provided no information for the endpoint described in Annex VIII, 8.4.3 *in vitro* gene mutation study in mammalian cells, if a negative result in Annex VII, Section 8.4.1 and Annex VIII, Section 8.4.2'. The information provided in the technical dossier showed negative findings for both the *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1.) and the *in vitro* micronucleus study (Annex VIII, Section 8.4.2) so that the condition for requesting the *in vitro* gene mutation study in mammalian cells is fulfilled.

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*

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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.

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]

Jukka Malm
Director of Regulatory Affairs

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