~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001409-73-04/F Helsinki,
Decision date: 27 July 2011

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

For Polysantol, CAS [redacted] (EC No 411-580-3); 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 (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 **Polysantol [(+/-) trans-3,3-dimethyl-5-(2,2,3-trimethyl-cyclopent-3-en-1-yl)pent-4-en-2-ol], CAS [redacted] (EC No 411-580-3)**, submitted by [redacted] (Registrant), latest submission number [redacted], for [redacted].

The compliance check was initiated on 16 July 2010.

On 15 November 2010 ECHA sent a draft decision to the Registrant for comments. By 16 December 2010, the Registrant did not provide any comments on the draft decision.

On 18 February 2011, ECHA notified the Member State Competent Authorities 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.

After receiving a proposal for amendment from one Member State Competent Authority, ECHA forwarded the proposal for amendment to the Registrant on 23 March 2011 and decided to amend the draft decision.

On 4 April 2011, the draft decision was referred to the Member State Committee.

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The Registrant did not provide any comments on the proposed amendment.

The amended draft decision was made available to the Member State Committee for agreement seeking in written procedure on 28 April 2011.

A unanimous agreement of the Member State Committee on the draft decision was reached on 10 May 2011 in a written procedure launched on 28 April 2011.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(a) and 13 as well as Annex VII of the REACH Regulation, the Registrant shall submit the following information using the test method as indicated below

- *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. one *E. coli WP2* strain or *S. typhimurium TA102*, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

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 **27 July 2012 - 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, 12 and 13 and Annex VII** 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.

Missing information related to mutagenicity

Pursuant to Articles 10(a)(vi), 12(1)(a) and(b) of the REACH Regulation, a registration for a substance manufactured or imported in quantities of 1-10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

ECHA notes that for the endpoint 8.4.1 of Annex VII, *in vitro* gene mutation study in bacteria, the Registrant provided data from an *in vitro* gene mutation study in bacteria performed in 1992 or before according to OECD Test Guideline (TG) 471 in force at that time and in accordance with the OECD good laboratory practice (GLP) principles. This data was provided to the Registrant by ECHA pursuant to Article 25(3) of the

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REACH Regulation as a response to the inquiry submitted by the Registrant pursuant to Article 26 of the REACH Regulation.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA. Other tests may be used if the conditions of Annex XI are met.

In the present case, the test submitted was carried out according to GLP and to OECD TG 471. However, since the test was conducted, significant changes have been made to OECD 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

The version of the EU Test Method B.13/14/OECD TG 471 in force since 1997 introduces the need for performing the test in at least 5 strains of bacteria whereas the OECD TG 471 in force in 1992 only required testing in a minimum of 4 bacterial strains. The required 5th bacterial strain, i.e. *Escherichia coli WP2* strains or *S. typhimurium TA102*, has the potential to detect certain types of mutagens, such as cross-linking agents or oxidising mutagens, which the 4 bacterial strains recommended in the former version of the OECD TG 471 may not detect.

Consequently, the Registrant is required to complete the data set on mutagenicity by performing an *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. one *E. coli WP2* strain or *S. typhimurium TA102*, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

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 1907/2006 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.

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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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