European Chemicals Agency

Decision number: CCH-D-0000000419-73-05/F
Decision date: 2 July 2010

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

For [redacted] 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 [redacted] submitted by [redacted] (the "registrant"), latest submission number [redacted], for 1-10 tonnes per year.

The compliance check was initiated on 06 February 2009.

On 16 December 2009 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 18 January 2010 the registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and decided not to amend the decision.

On 25 February 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. Subsequently, competent authorities

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of the Member States submitted comments and proposals for amendments on the draft decision.

ECHA has reviewed the proposals for amendments received and decided not to amend the decision.

On 12 April 2010 ECHA referred the draft decision to the Member State Committee.

On 13 April 2010 ECHA notified the registrant of the comments and proposals for amendment of the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments within 30 days of the receipt of the notification.

On 13 May 2010 the registrant provided to ECHA comments on the proposals for amendment.

On 9 June 2010 the Member State Committee, taking into account the comments of the registrant, reached unanimous agreement on the draft decision of ECHA.

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), 10(vi) and 3(29), as well as Annexes VII-XI of the REACH Regulation the registrant shall submit for the registered substance:

For the mutagenicity endpoint, i.e. the *in vitro* gene mutation study in bacteria, the *in vitro* chromosome aberration test and the *in vivo* micronucleus test: updated study summaries for sections 7.6.1 and 7.6.2 of the IUCLID dossier, containing sufficient information to make an assessment of the relevance of the studies.

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 within **6 months of the date of adoption of this 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(vi) and 3(29), as well as Annexes VII-XI. 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.

There is missing information related to the genotoxicity endpoint (REACH Annex VII-X, 8.4.). Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance produced in quantities of 1-10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

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Mutagenicity (Annex VII-X, 8.4.)

REACH Annex VII requires the registrant to submit information on mutagenicity and any other relevant information that is available. The substance is reported to be negative in the *in vitro* gene mutation study in bacteria [redacted] However, from the study summary it is not fully clear whether 5 strains have been used as required by the OECD test guideline 471. According to the IUCLID dossier fields 'Species/strain' under method as well as results only four strains (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100) were included in the test.

The registrant states under 'conclusions' 'No substantial increase in revertant colony numbers of any of the five tested strains was observed...' However, no detailed test results are reported in the study summary. Further, the substance showed clastogenic effects in the *in vitro* chromosome aberration assay [redacted] that is reported as 'equivocal'. However, the results section in the IUCLID study summary does not allow verifying statements regarding dose-dependency and comparison with historical controls.

Based on the available information it is not possible to judge whether the clastogenicity observed in repeated experiments is relevant or not. The potential of the substance to induce clastogenic effects also in mammalian cells *in vivo* was further investigated in an *in vivo* micronucleus test. This test [redacted] is reported to be negative, but details on the test methods used to generate this information and corresponding results are lacking. For instance, the result section states 'negative' without reporting any of the parameters specified in the EU method B.12 (OECD TG 474), such as signs of toxicity, proportion of immature erythrocytes among total erythrocytes, number of micronucleated immature erythrocytes given separately for each animal, mean and standard deviation of micronucleated immature erythrocytes per group, dose response relationship, statistical analyses and method applied, concurrent and historical negative control data, concurrent positive control data. Based on this limited information ECHA cannot verify the statement that the test result is negative and that no further testing needs to be considered. Consequently, it is not sufficiently clear whether the substance has genotoxic properties *in vivo* or not.

In conclusion, ECHA was not provided with sufficient information to make an assessment of the relevance of the *genotoxicity* studies. This is the requirement to be fulfilled by a study summary submitted in the course of a registration dossier. You are therefore requested to provide an updated dossier with the study summary details on the mutagenicity endpoint (Annex VII-X, 8.4.) filled in for both *in vitro* [redacted] and the *in vivo* study [redacted]

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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.

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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found at the Board of Appeal website 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

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