~~CONFIDENTIAL~~

Decision number: CCH-D-0000001317-78-04/F Helsinki, 18 March 2011

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

Substance: Zinn(II)-methansulfonat, CAS: [redacted] (EC No. 401-640-7),
Registration number: [redacted]

[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 **Zinn(II)-methansulfonat**, CAS [redacted] (EC No. 401-640-7) submitted by [redacted] (the Registrant), latest submission number [redacted] for [redacted]

The Registrant has 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 German Competent Authority in accordance with Articles 7 and 15 of Directive 67/548/EEC. The notification number allocated was [redacted]

On 15 March 2006, the Registrant notified the Competent Authority that the notification [redacted] reached [redacted] The national Competent Authority did not finalise its assessment on the testing programme to fulfil the higher tier testing requirements set out in Annex VIII, level 1 of Directive 67/548/EEC before the relevant Article 135 of the REACH Regulation entered into force on 1 August 2008. Thus, the dossier may miss some legally required information. Article 24(1) of the REACH Regulation provides that the notification [redacted] is regarded as a registration and ECHA has assigned a registration number.

ECHA invited the Registrant by letter of 27 August 2009 to submit testing proposals if necessary to bring the registration into compliance with the information requirements of the REACH Regulation. However, no testing proposal has been received by the date of this decision.

The compliance check was initiated on 17 February 2010.

The draft decision was notified to the Registrant on 11 August 2010. By 10 September 2010 ECHA did not receive any comments from the Registrant on the draft decision.

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. Subsequently, Competent Authorities of the Member States submitted proposals for amendment on the draft decision.

On 1 December 2010 ECHA notified the Registrant of the proposals for amendment of the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposed amendments within 30 days of the receipt of the notification.

ECHA has reviewed the proposals for amendment received and has modified the draft decision accordingly.

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

On 22 December the Registrant sent a registered mail to ECHA informing about its plan for updating the dossier, in a joint submission for the information requirements up to [redacted] and in a second step for the next tonnage band.

The Member State Committee took the information received from the Registrant into account. After discussion in the Member State Committee meeting on 1-3 February 2011, a unanimous agreement of the Member State Committee on the amended draft decision was reached on 3 February 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), 10(a)(vi) and (vii), 12(1)(d) as well as Annexes VII to IX of the REACH Regulation, the Registrant shall submit information on:

a. Activated sludge respiration inhibition testing, EU test method C.11 (OECD 209)
b. Assessment of the toxicokinetic behaviour to the extent that can be derived from the relevant available information
c. Long-term toxicity testing on *Daphnia magna*, EU test method C.20 (OECD 211)
d. Long-term toxicity testing on fish. OECD Guideline 210 or EU test method C.15 (OECD Guideline 212) or EU test method C.14 (OECD Guideline 215)
e. Subchronic toxicity, tested for the most appropriate route of administration, having regard to the likely route of human exposure, i.e. EU test method B.26 (OECD 408) or B.28 (OECD 411) or B.29 (OECD 413)
f. Developmental toxicity, EU test method B.31 (OECD Guideline 414)

As explained in the cover letter, the information above is partially, and possibly entirely, available by other registrants of the same substance, therefore the Registrant of the dossier under consideration should make every effort to agree on data sharing before generating new comparable information.

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 12 months from the date 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 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 with Annexes VII - IX thereof. The registration dossier that was migrated from the structured notification interchange format (SNIF) into IUCLID does not contain relevant information on endpoints that is obligatory for this tonnage band. 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 registration is not a tonnage band update, it does not have to comply with all 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 in other cases than tonnage band updates and originating from a previous notification needs to comply with the information requirements of the REACH Regulation limited by information requirements pursuant to Directive 67/548/EEC, depending on which regulatory framework requires less information. The information requested is thus covered by both the REACH Regulation and Directive 67/548/EEC.

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

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 of an IUCLID dossier update. You can find instructions on the submission of the dossier update in the Question and Answers 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.

These 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 1907/2008 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.

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,

Jukka Malm

Director of Regulatory Affairs