~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001424-81-05/F Helsinki, 8 July 2011

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

For Syringonitrile (4-hydroxy-3,5-dimethoxybenzonitrile) , CAS no. 72684-95-8; EC no. 700-251-2; 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 Syringonitrile, CAS no. 72684-95-8 EC no. 700-251-2 submitted by [redacted] (the "Registrant"), latest submission number [redacted] for 1 to 10 tonnes per year.

The compliance check was initiated on 26 May 2010.

On 5 January 2011 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.

By 4 February 2011 the registrant did not provide any comments on the draft decision to ECHA.

On 18 February 2011 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, one Competent Authority of the Member States submitted a proposal for amendment to the draft decision.

On 23 March 2011 ECHA notified the Registrant of the proposal for amendment to 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.

ECHA has reviewed the proposal for amendment received and has decided not to amend the draft decision.

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

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

After discussion in the Member State Committee meeting on 25-27 May 2011, a unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2011 and ECHA has taken the decision accordingly pursuant to Article 51(6) of the REACH Regulation.

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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), 10(a)(vi), 12(1)(a) and Annex VII Section 9.1.2 of the REACH Regulation the registrant shall submit for the registered substance:

Growth inhibition study aquatic plants (algae) test (EU test method C3).

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 **9 July 2012**.

III. Statement of reasons

The Algal Inhibition study contained in the registration dossier was found not in compliance with the test method, C3 - Algal Inhibition test, Regulation (EC) No 440/2008 regarding the following quality criterion:

'*The concentrations of the test substance shall be maintained to within 80 % of the initial concentrations throughout a time corresponding to the duration of the test. For substances which dissolve easily in the test medium, yielding stable solutions i.e. those which will not to any significant extent volatilise, degrade, hydrolyze or adsorb, the initial concentration can be taken as being equivalent to the nominal concentration. Evidence shall be presented that the concentrations have been maintained throughout the test and that the quality criteria have been satisfied.*
For substances that are:
(i) poorly soluble in the test medium, or
(ii) capable of forming stable emulsions or dispersions, or
(iii) not stable in aqueous solutions,
the initial concentration shall be taken as the concentration measured at the start of the test.

The concentration shall be determined after a period of equilibration. In any of these cases, further measurements must be made during the test to confirm the actual exposure concentrations or that the quality criteria have been met'.

No measurements were undertaken during the duration of the Algal Inhibition study, thus the above stated quality criterion cannot be verified. Therefore, the test is required to be repeated.

The short term toxicity to *Daphnia magna* study was also found not in compliance with the test method, C2 – Daphnia SP. Acute immobilisation test, Regulation (EC) No 440/2008, because no analysis was undertaken during the duration of the test.

A dose response relationship was observed in the Algal Inhibition study, indicating that Algae is the most sensitive species. Due to this observed fact, the registrant is only requested to repeat the C3 - Algal Inhibition test Regulation (EC) No 440/2008.

Adequate consideration of solubility is required prior to performing the study in order to avoid an inaccurate result. In this regard, it is recommended to review the water solubility currently indicated in the registration dossier due to the wide range of stated values i.e. 2 mg/L – 2 g/L.

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 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. The procedure is described in the Board of Appeal's "Preliminary instructions to Appellants" that can be found at the ECHA website. 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