European Chemicals Agency

Decision number: CCH-D-0000001202-91-03/F Helsinki, 12 October 2010

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

[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 for [redacted] submitted [redacted] (the "Registrant"), latest submission [redacted] for 1 – 10 tonnes per year.

The compliance check was initiated on 14 January 2010.

On 24 June 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.

By 26 July 2010 ECHA did not receive any comments from the Registrant.

On 27 August 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 26 September 2010 ECHA did not receive any proposals for amendments from the 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), 10(a)(vi), 12(1)(a) and (b) and 13(1) as well as Annexes VII and XI of the REACH Regulation, the Registrant is requested to submit study summaries for the endpoints listed below. The study summaries should cover the following endpoints for [redacted], the hydrolysis products of the registered substance:

- Skin irritation or skin corrosion (Annex VII, 8.1.)
- Eye irritation (Annex VII, 8.2.)
- Skin sensitisation (Annex VII, 8.3.)
- Mutagenicity (Annex VII, 8.4.1.)
- Acute toxicity (Annex VII, 8.5.1.)
- Short-term toxicity testing on invertebrates (Annex VII, 9.1.1)
- Growth inhibition study aquatic plants (Annex VII, 9.1.2)

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 **6 months from date of 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 as well as Annexes VII and XI 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)(a) and (b) of the REACH Regulation, a registration for a substance produced in quantities of 1 – 10 tonnes per year shall contain all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the information specified in Annex VII of the REACH Regulation.

The technical dossier submitted by the Registrant contains adaptations to the standard information requirements ('data waivers') for the following endpoints:

- Skin irritation or skin corrosion (Annex VII, 8.1.)
- Eye irritation (Annex VII, 8.2.)
- Skin sensitisation (Annex VII, 8.3)
- Mutagenicity (Annex VII, 8.4.1)
- Acute toxicity (Annex VII, 8.5.1.)
- Short-term toxicity testing on invertebrates (Annex VII, 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, 9.1.2.)

The Registrant suggests to adapt the standard testing regime for the above endpoints on the following three basis:

- Qualitative or Quantitative structure-activity relationship ((Q)SAR),

- Testing not technically possible, and
- Testing does not appear scientifically necessary.

With regard to the suggested adaptation of the studies on the basis of results obtained from (Q)SAR models, general rules under Annex XI, 1.3 allow adaptation of the standard testing by making use of (Q)SAR if the following conditions are met: (i) results are derived from a (Q)SAR model whose scientific validity has been established, (ii) the substance falls within the applicability domain of the (Q)SAR model, (iii) results are adequate for the purpose of classification and labelling and/or risk assessment, and (iv) adequate and reliable documentation of the applied method is provided.

Information on skin irritation or skin corrosion, eye irritation, skin sensitisation and mutagenicity was originated from DEREK for Windows predictions. Contrary to (iv) above, the Registrant has not provided adequate and reliable documentation of the method. In addition, the DEREK for Windows model is not sufficient to rule out skin irritation/corrosion because the model only contains alerts for the potential presence of irritation/corrosion.

Information for short-term toxicity testing on invertebrates and growth inhibition study aquatic plants was originated from EPI Suite v. 3.2 predictions. Contrary to (i) above, the Registrant has not provided justification for the use of the model, i.e. scientific validity of the model and the applicability domain of the model have not been provided. Additionally, adequate and reliable documentation of the applied method has not been provided ((iv) above).

Therefore, the conditions for adaptations as set out in Annex XI, 1.3 are not met and the suggested adaptation on the basis of the (Q)SAR modelling cannot be accepted.

The second adaptation argument submitted by the Registrant is based on rapid hydrolysis of the registered substance [redacted]. The Registrant therefore suggests to omit the testing for the above endpoints because it is not technically possible to perform these tests.

The adaptation presented in the dossier is also based on the grounds that testing does not appear scientifically necessary (Annex XI, Section 1) because the hydrolysis products have been evaluated under other regulatory programmes. More particularly, [redacted] has been evaluated under the EU Biocides Programme, and [redacted] under OECD HPV Programme. The Registrant claims that the data from the hydrolysis products can be used for read-across to the registered substance.

ECHA concludes that it is technically not possible within the meaning of Annex XI, Section 2 to test the parent compound (the registered substance) due to the rapid hydrolysis. However, the missing information requirements could be met by providing the appropriate information on the hydrolysis products. A mere reference to other chemical assessment programmes is not sufficient to meet this obligation. The Registrant has not indeed submitted any study summaries or other data concerning the hydrolysis products that would on the basis of Annex XI support the adaptation of the standard information requirements for the registered substance for the endpoints listed.

According to Annex XI, Section 1.2 (weight of evidence), "*There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion*". In all cases *'adequate and reliable documentation shall be provided'*. The information

on the two hydrolysis products, i.e. [redacted] and read-across from this information to the parent (registered) compound, could be considered as information from two single sources which combined are regarded as sufficient to fulfil the information requirement. Guidance on the weight of evidence reporting is available at http://echa.europa.eu/doc/publications/practical_guides/pg_report_weight_of_evidence.pdf

Accordingly, in order to support the weight of evidence approach in line Article 13(1) and Annex XI, Section 1.2 to fulfil the missing information endpoints, the Registrant is requested to submit study summaries for [redacted], the hydrolysis products of the registered substance, for the above endpoints as basis for meeting the information requirements.

## 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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]

Geert Dancet
Executive Director