~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001261-87-04/F Helsinki, 20 December 2010

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

Substance S194055, EC No. 445-470-1, Registration Number: [redacted]

Addressee: [redacted]

I. Procedure

Pursuant to Article 41(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), the European Chemicals Agency (ECHA) has performed a compliance check of the registration dossier for **S194055, (EC No. 445-470-1)** submitted by [redacted] (the "Registrant"), latest submission number [redacted], for [redacted] per year.

Following the tonnage band update to [redacted] per year for a substance that was previously notified pursuant to Directive 67/548/EEC, the Registrant is according to Article 24(2) of the REACH Regulation obliged to submit the additional required information corresponding to the reached tonnage threshold, as well as to all lower tonnage thresholds, in accordance with Articles 10 and 12 of the REACH Regulation.

The present compliance check was initiated on 18 January 2010.

The draft decision on the basis of the compliance check was sent to the Registrant for comments on 12 April 20010. ECHA has taken the comments provided by the Registrant on 11 May 2010 into account and has amended the statement of reasons of this draft decision accordingly.

On 11 June 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 11 July 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.

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II. Information required

ECHA has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of the REACH Regulation.

1. Pursuant to Articles 41(1)(a), 41(3), [redacted] and 13(1) as well as Annex VIII, Section 8.7.1. of the REACH Regulation, the Registrant shall submit information on reproductive/developmental toxicity using the test method of screening for one species, guideline OECD 421 or 422.

2. Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii), 3(28) and 111 of, as well as Sections 1.1.4. and 3.1.5. of Annex I to the REACH Regulation, the Registrant shall provide in the IUCLID format a robust study summary of the following studies provided under the following provisions of the REACH Regulation and IUCLID sections:
   - Annex VII, Section 9.2.1.1 (IUCLID Section 5.2.1): study named[1] *Biodegradation in water screening tests SNIF#001-5.2.11-02*
   - Annex VIII, Section 9.3.1 (IUCLID Section 5.4.1): study named *Adsorption / desorption, SNIF#001-5.3.10-02*
   - Annex VIII, Section 9.1.3 (IUCLID Section 6.1.1): study named *Short-term toxicity to fish, SNIF#001-5.1.01-01*
   - Annex VII, Section 9.1.1 (IUCLID Section 6.1.3): study named *Short-term toxicity to aquatic invertebrates, SNIF#001-5.1.02-01*
   - Annex VIII, Section 9.1.4 (IUCLID Section 6.1.7): study named *Toxicity to microorganisms, SNIF#001-5.1.06-01*
   - Annex VII, Section 8.4.1 (IUCLID Section 7.6.1) study named *Genetic toxicity in vitro, SNIF#001-4.3.10-01*
   - Annex VIII, Section 8.4.2 (IUCLID Section 7.6.1). A robust study summary is requested at least for the study that was used to draw the conclusions on the endpoint, i.e. either *Genetic toxicity in vitro, SNIF#001-4.3.21-01* or *Genetic toxicity in vitro.004*
   - Annex VIII, Section 8.4.3 (IUCLID Section 7.6.1). study named *Genetic toxicity in vitro 003*

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 **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, 13 and 111 and with Annexes I, VI to VIII and XI** thereof. Consequently, the Registrant is requested to submit the information required above that is needed to bring the registration into compliance with the relevant information requirements.

[1] This is the name of the study in IUCLID. When the study was migrated from a previous SNIF file, a name was automatically generated with the code SNIF#.

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1) Missing information on screening for reproductive/developmental toxicity

Pursuant to Article [redacted] of the REACH Regulation, a registration for a substance manufactured or imported in quantities of [redacted] per year shall contain as a minimum the information specified in Annexes VII [redacted] of the REACH Regulation.

A screening study for reproductive/developmental toxicity, one species (OECD 421 or 422) is a standard piece of information required for registrations in the [redacted] range pursuant to Annex VIII, column 1 of Section 8.7.1.

The Registrant has omitted the screening study in question with a reference to exposure based waiving according to Annex XI, Section 3.

According to Article 13(1) of and Section 3 of Annex XI to the REACH Regulation (as amended by Commission Regulation (EC) No 134/2009), testing in accordance with Section 8.7. of Annex VIII may be omitted based on a thorough and rigorous exposure assessment, provided that any one of the three criteria of Section 3 of Annex XI are met and that adequate justification and documentation are submitted.

> The first criterion (3.2(a)) requires "absence of or no significant exposure in all scenarios of the manufacture and all identified uses". Moreover, relevant PNECs or DNELs are to be derived and exposure results are to be well below the derived PNECs or DNELs.
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> The second criterion (3.2(b)) requires "throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f)".
>
> The third criterion (3.2(c)) sets out conditions which have to be fulfilled for a substance incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means.

In the registration dossier, the Registrant has not indicated, which of these criteria he is using for waiving the testing for reproductive/developmental toxicity. Instead, the Registrant has included in the dossier an exposure assessment by which he claims that a relevant human exposure can be excluded.

ECHA has analysed the exposure scenarios and risk characterisation contained in the registration dossier and makes the following observations:

- Strictly controlled conditions as set out in Article 18(4)(a) to (f) are not demonstrated and therefore criterion 3.2(b) for exposure-based waiving is not satisfied. In particular, conditions (a), (c) and (f) set out in Article 18(4) do not appear to be fulfilled for the consumer use of [redacted] (exposure scenario 2). This is because it has not been shown that the substance is rigorously contained by technical means during its whole lifecycle (condition a), is not handled by trained and authorised personnel only (condition c), and substance-handling procedures are not well documented and strictly supervised by the site operator (condition f).

- In addition to the main observation above, estimated exposure levels are beyond insignificant and therefore either criteria for 3.2 (a) and 3.2(b) for exposure-based waiving are not satisfied. This is because

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- An indication of significant exposure can be observed in Table 86 concerning the risk characterisation of long-term systemic effects for workers. From the reported exposure values it appears that the average yearly exposure to dermal route accounts for 9 % of DNEL, and the average yearly exposure to combined inhalation and dermal routes account for 10 % of DNEL.
- Insignificant exposure for consumer use has not been demonstrated. In the exposure scenario for consumer use (ES4), a sub-scenario of accidental oral exposure of small children is described. This exposure scenario has not been covered in the risk characterisation (oral exposure of consumers is not considered under section 10.4.1.1.1 of the chemical safety report, as required by Annex I, Section 10.2.1.2). It has only been addressed in the exposure section, where the exposure is compared with the NOAEL (divided by one assessment factor, 10), whereas the evaluation of exposure requires a comparison with the appropriate DNEL (Annex I, Section 6.3) in the risk characterisation section.

- The third criteria (3.2(c)) concerns the substance incorporated in an article. [redacted] not an article within the meaning of Article 3(3) of the REACH Regulation, and the substance is not permanently embedded in it, this criterion does not apply to this case.

For these reasons, ECHA concluded that the justification provided by the Registrant for waiving the concerned test does not fulfill the criteria set out in Annex XI, Section 3.

The Registrant received the draft decision for comments on 12 April 2010 and provided the following comments on 11 May 2010, in brief:

- The study was omitted on the basis of criterion 3.2(a) of Section 3 of Annex XI.
- The Registrant agrees to provide the reproductive/developmental study as requested by ECHA. The Registrant believes that exposure monitoring data could demonstrate that human exposure is very low. However, the performance of a reproductive/developmental screening study appears the most appropriate way of confirming that there is no risk, because of a number of complications in obtaining exposure data.
- Concerning the consumer exposure, the Registrant states that he will update the child oral exposure scenario so that more realistically reflects accidental/incidental child exposure and meets the requirements of Annex I, Section 6.3. In addition, the risk characterisation will be completed with inclusion of this scenario.

ECHA acknowledges the intention of the Registrant to perform a reproduction / developmental screening toxicity study in compliance with the REACH Regulation. ECHA specifies that the refinement of the exposure assessment would be not sufficient to fulfill the criterion 3.2(a) of section 3 of Annex XI for the reproductive/developmental toxicity, because a relevant and appropriate DNEL to be compared with exposure is not available.

Therefore, **the Registrant is requested to provide information on reproductive/developmental toxicity using the test method of screening for one species, guideline OECD 421 or 422.**

2) Lack of robust study summaries

According to Articles 10(a)(vii) and 111 and Sections 1.1.4 and 3.1.5 of Annex I to the REACH Regulation, a technical dossier that is in the IUCLID format shall include robust study summaries of all key data used in the human health and environmental hazard assessment. Under Article 3(28), the robust study summary shall include a "detailed

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summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report".

The Registrant has not reported in the IUCLID format robust study summaries within the meaning of Article 3(28) of the REACH Regulation for the following studies provided under the following provisions of the REACH Regulation and IUCLID sections:

- Ready biodegradability (Annex VII, Section 9.2.1.1; IUCLID Section 5.2.1). In particular, details of the inoculum, the description of test conditions (e.g. temperature, pH) and indications of the fulfilment of validity criteria are missing;
- Adsorption/desorption (Annex VIII Section 9.3.1; IUCLID Section 5.4.1). Details on the operating conditions, the reference substances and indications of the fulfilment of validity criteria are missing;
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3; IUCLID Section 6.1.1). In particular, details of test conditions (e.g. dissolved oxygen, pH, temperature), details of the test design and indications of the fulfilment of validity criteria are missing;
- Short term toxicity testing on invertebrates (Annex VII, Section 9.1.1; IUCLID Section 6.1.3). In particular, details of test conditions (e.g. dissolved oxygen, pH, test temperature), of the test design (e.g. number of replicates), the report of observations in the controls and the treatment groups (e.g. number and percentage of daphnids that were immobilised or showed any adverse effect), and indications of the fulfilment of validity criteria are missing;
- Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4; IUCLID Section 6.1.7). In particular, details of the test system (e.g. concentration of the activated sludge), of the test conditions (e.g. temperature) and indications of the fulfilment of validity criteria are missing;
- Mutagenicity, *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1; IUCLID Section 7.6.1). In particular, positive control is not specified and information on frequency of the revertant colonies per dose is missing;
- Mutagenicity, *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2; IUCLID Section 7.6.1). A robust study summary is requested at least for the study that was used to draw the conclusions on the endpoint, i.e. either *Genetic toxicity in vitro, SNIF#001-4.3.21-01* or *Genetic toxicity in vitro.004.* In particular, information on percentages of cells with structural chromosome aberrations per dose is missing;
  and
- Mutagenicity, *in vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3; IUCLID Section 7.6.1). In particular, mutant frequency per test concentration is missing.

Therefore, **the Registrant is required to provide robust study summaries of all studies listed above in the IUCLID format**. Further guidance can be found in the *Information requirements Manual 1 Requirements for Robust Study Summary* published on the website at: http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf.

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:

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"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 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 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]

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