~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001250-90-04/F Helsinki, 16 June 2011

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

For HS 3520R-N and HS 3520R-N2, CAS 18241-31-1, (EC Nr. 406-470-7), registration numbe[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 **HS 3520R-N** and **HS 3520R-N2**, CAS 18241-31-1, (EC Nr. 406-470-7) submitted by [redacted] (the "Registrant"), latest submission number [redacted]

The Registrant 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 Article 7 of Directive 67/548/EEC. The notification number allocated was [redacted]

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

The national competent authority did not finalise its assessment of the testing programme before the relevant Article 135 of the REACH Regulation entered into force on 1 August 2008. Thus, the dossier may not include some relevant legally required information. For that reason, ECHA has invited the Registrant by letter of 27 August 2009 to update the dossier and submit testing proposals if necessary to bring the registration into compliance with the information requirements of the REACH Regulation. An updated dossier was received on 4 January 2010 without an inclusion of any testing proposals.

The compliance check was initiated on 28 January 2010.

On 4 October 2010 the draft decision was sent to the Registrant for comments. The Registrant did not provide any comments on the draft decision.

On 7 January 2011, ECHA notified the Member State Competent Authorities of its draft decision and invited them to provide proposals for amendment.

After receiving proposals for amendment from Member State Competent Authorities, ECHA forwarded the proposals for amendment to the Registrant on 17 February 2011 and did not amend its draft decision.

On 21 February 2011, the draft decision was referred to the Member State Committee.

On 18 March 2011, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 13-14 April 2011, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the modified draft decision was reached on 14 April 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), [redacted] of the REACH Regulation, the Registrant shall submit the information using the test method as indicated below.

1. Sub-chronic toxicity (90 day; Annex IX, 8.6.2. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC), rat, oral (EU test method B.26; OECD 408)
2. Prenatal developmental toxicity (Annex IX, 8.7.2. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC), rat, oral (EU test method B.31; OECD 414)
3. Bioaccumulation in aquatic species (Annex IX, 9.3.2. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC), fish (test method OECD 305), unless valid justification for adaptation of this information requirement as set out in section III.3 below is provided
4. Short-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC), earthworms (test method OECD 207)
5. Short-term toxicity to plants (Annex IX, 9.4.3. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) (test method OECD 208)

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 18 months from date of draft 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 Annex IX 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.

Since the registration is not a tonnage band update, it does not have to comply with all of 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 originating from a previous notification and in cases other than a tonnage band update needs to comply with the information requirements of the REACH Regulation limited by the scope of information requirements pursuant to Directive 67/548/EEC, depending on which regulatory framework requires less information. The information requested is covered by both the REACH Regulation and Directive 67/548/EEC.

The technical dossier provided did not contain information for the endpoint on the following endpoints:

1. Sub-chronic toxicity

Sub-chronic toxicity (90-day) is an information requirement both under the REACH Regulation (Annex IX, 8.6.2) and under Directive 67/548/EC (Annex VIII, level 1). The latter indicates that "Sub-chronic and / or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Annex VII (i.e. the 28-day study) or other relevant information demonstrate the need for further appropriate investigation.

The effects which would indicate the need for such a study could include for example:
(a) serious or irreversible lesions;
(b) a very low or absence of a "no effect" level;
(c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous."

However, the full study report obtained by the German competent authority who has previously examined the dossier, revealed limitations in the 28-day study, namely no immunotoxic and neurotoxic parameters have been investigated. Furthermore, in the oral 28-day study on rats test substance-related effects were noted at dose levels of ≥250 mg/kg bw/d. In detail, at the dose level of 250 mg/kg bw/d (male rats), histopathological changes in the kidney were observed. At the highest dose (1000 mg/kg bw/d) microcytic anaemia, severely reduced kidney function and a slight liver change possibly cholestatic in nature were observed. Thus, it cannot be excluded that, as a result of a repeated daily dose of the test substance, detrimental toxic effects in the critical dose range may develop for part of the expected life span (sub-chronic exposure, a prolonged period of the animal's life span covering post-weaning maturation and growth well into adulthood).

Against the relevant criteria above, ECHA does not consider that the omission of this endpoint is acceptable and the Registrant is requested to submit the missing information on sub-chronic toxicity of the registered substance via the oral route in the rat.

2. Pre-natal developmental toxicity

Pre-natal developmental toxicity is an information requirement both under the REACH Regulation (Annex IX, 8.7.2) and under Directive 67/548/EC (Annex VIII, level 1). The Registrant stated in the dossier that "in accordance with column 2 of REACH Annex IX, the pre-natal developmental toxicity study (required in section 8.7.2.) does not need to be conducted as a decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data". The 'first test' refers to the pre-natal developmental toxicity study required by column 1 that has not been performed. In that respect, column 2 does not provide an option to waive the pre-natal developmental toxicity study for one species at all. Rather it adds the obligation for a Registrant to consider a second similar test on a second species either on Annex IX level or the next higher level, i.e. Annex X level. Hence, the pre-natal developmental toxicity test is missing in the technical dossier and needs to be performed by the Registrant.

3. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is an information requirement both under the REACH Regulation (Annex IX, 9.3.2.) and under Directive 67/548/EC (Annex VIII, level 1). The Registrant uses a waiving statement to omit the information requirement stating that "direct or indirect exposure of aquatic environment unlikely". ECHA disagrees with the statement of the Registrant, as exposure of the aquatic compartment during the formulation of the substance into [redacted] is expected. During formulation and considering a worst case scenario, the Guidance Document table R.16-23 sets a default release rate of 2 percent from the formulation process to water. Additionally, aquatic exposure is not unlikely [redacted]

The second specific rule for adaptation of the information requirements (Annex IX, 9.3.2.) is a low potential for bioaccumulation, which has not been demonstrated by the Registrant in the technical dossier for either the registered substance or for any relevant hydrolysis products. In order for the Registrant to omit the information requirement based on the possibly low bioaccumulation potential of the hydrolysis products, these products need to be adequately identified. In line with the Guidance on Information requirements, it can be assumed that a hydrolysis half-life of less than 12 hours reduces the likelihood for bioaccumulation of the parent substance and a bioaccumulation test on the hydrolysis products may be more appropriate (R.7c, page 24).

Furthermore, the study setup should fulfil the validity criteria laid out in OECD 305 (Bioconcentration: Flow-through Fish Test), namely the concentration of the test substance in the chambers is maintained within ± 20% of the mean of the measured values during the uptake phase. Moreover, the test method (OECD 305) requires that reliable quantitative information on the rate of hydrolysis should be reported.

Unless low potential for bioaccumulation is demonstrated and fully justified, as discussed above, the Registrant is requested to submit the missing information on bioaccumulation in aquatic species in accordance with OECD 305.

4. Short-term toxicity to terrestrial invertebrates

Short-term toxicity to terrestrial invertebrates is an information requirement both under the REACH Regulation (Annex IX, 9.4.1.) and under Directive 67/548/EC (Annex VIII, level 1). The Registrant uses a waiving statement to omit the information requirement stating that "direct or indirect exposure of the terrestrial compartment is minimal". ECHA disagrees with the statement of the Registrant, as exposure of the soil compartment is likely: [redacted] where the diluted substance is adsorbed to sludge and may then be applied to agricultural soil. A simulation of the distribution of the substance in a municipal Sewage Treatment Plant using the model SimpleTreat 3.0 (debugged version, 3. Feb 1997) indicated that (together with the substance adsorbed at the paper fibres) about 32 percent of the diluted substance is not removed from the water phase and will enter surface water, whilst 49 percent of the diluted substance will be adsorbed at the sludge.

Additionally, the substance possesses significant potential for adsorption, as indicated by its log Koc value of 4. Therefore, ECHA does not accept the omission proposed by the Registrant and the Registrant is requested to submit the missing information on short-term toxicity to terrestrial invertebrates (earthworms).

5. Short-term toxicity to plants

Short-term toxicity to plants is an information requirement both under the REACH Regulation (Annex IX, 9.4.3.) and under Directive 67/548/EC (Annex VIII, level 1). The Registrant uses a waiving statement to omit the information requirement stating that "direct or indirect exposure of the terrestrial compartment is minimal". For the same reasons stated in section 4, ECHA does not accept the omission proposed by the Registrant and the Registrant is requested to submit the missing information on short-term toxicity to plants.

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. 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