~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001410-90-05/F Helsinki
Decision date: 21 June 2011

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

For Magnesium hydroxide sulphate trihydrate, CAS [redacted] (EC No. 483-390-9), 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 Magnesium hydroxide sulphate trihydrate, CAS [redacted] (EC No. 483-390-9) submitted by [redacted] (the "Registrant"), latest submission number [redacted]

Following the tonnage band update to [redacted] per year for a previously notified substance, 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 compliance check was initiated on 4 May 2010.

On 4 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.

On 2 February 2011 the Registrant provided to ECHA its comments on the draft decision stating that he agrees with the draft decision.

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

On 23 March 2011 ECHA notified the Registrant of proposals 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 reviewed the proposals for amendment received and decided not to amend the draft decision.

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

On 26 April 2011, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account, but did not amend the draft decision.

A unanimous agreement of the Member State Committee on the draft decision was reached on 10 May 2011 in a written procedure launched on 28 April 2011.

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)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, the Registrant shall submit for the registered substance and update the chemical safety report (CSR) accordingly:

a) Derived No-Effect Levels (DNELs) for dermal and inhalation routes of Repeated dose toxicity and for Reproductive toxicity endpoints (Annex I, Sections 1.0.1 and 1.4.1);
b) Worker exposure assessment and risk characterisation and subsequently demonstrate that the risk to humans can be considered to be adequately controlled (Annex I, Sections 5.2.4 and Section 6.3);
c) Exposure assessment and risk characterisation for waste life-cycle stage (following extrusion stage of the formulation and service life of articles containing the registered substance) (Annex I, Sections 5.0 and 5.2.2); and
d) Operational conditions and risk management measures for all developed scenarios to demonstrate the non-existence of emission to air (Annex I, Section 5.1.1).

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 21 June 2012.

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(b) and 14, and with Annex I** 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.

a) Identification of Derived No-Effect Level (DNEL)

Annex I to the REACH Regulation sets out the general provisions for assessing substances and preparing chemical safety reports (CSR). Articles 10(b) and 14(1) as well as Annex I, sections 1.0.1 and 1.4.1 require the registrant to establish DNEL(s) for the registered substance for each relevant human population and reflecting the likely route(s), duration and frequency of exposure. If more than one route of exposure is likely to occur, a DNEL shall be established for each route of exposure and for the exposure from all routes combined.

ECHA notes that the CSR (paragraph 5.11, Table 20.) provided by the Registrant does not contain worker DNELs for dermal and inhalation routes of Repeated dose toxicity nor for Reproductive toxicity endpoints. In Section 9 of the CSR, the Registrant has, however, assessed long-term exposure of workers via inhalation and dermal routes. Dermal and inhalation routes are relevant routes of exposure for workers according to REACH Guidance 14 for Occupational Exposure estimation p. 2 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf) and REACH Guidance R8 Dose (concentration)-Response characterisation p. 15 and Table R.8-1 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf).

The Registrant is thus requested to derive the appropriate DNELs using data from the studies under Annex VIII, 8.6.1 and 8.7.1 and as recommended by ECHA guidance R.8 Dose (concentration)- Response characterisation and to update the dossier (IUCLID file and CSR) accordingly.

b) Worker exposure assessment and risk characterisation

According to Articles 10(b) and 14(4) of the REACH Regulation, an exposure assessment and risk characterisation shall be included in the chemical safety assessment if the substance meets the criteria for classification as dangerous under Directive 67/548/EEC (from 1 December 2010, replaced by the criteria for the hazard classes and/or categories specified in Article 58(1) of Regulation (EC) No 1272/2008) or is assessed to be a PBT/vPvB.

The registered substance is self-classified by the Registrant as Eye Irritant, Category 2 in accordance to Regulation (EC) No 1272/2008.

The purpose of the chemical safety assessment is to assess and document that risks arising from the substance are adequately controlled. According to Annex I, Section 5.2.4 of the REACH Regulation, an estimation of the exposure levels shall be performed for all human populations likely to be exposed to the substance. According to Annex I, Section 6.3, the risk characterisation for human health consists of a comparison of the exposure of each human population known to be or likely to be exposed with appropriate DNEL. According to Annex I, Section 6.4, for any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, if the exposure levels estimated in Section 6.2 do not exceed the DNELs.

In the CSR, the Registrant has provided exposure estimations for dermal and inhalation routes that show exposure levels for the registered substance that are clearly higher than the no observed effect level (NOEL). This implies that risks to human health arising from the substance may not be adequately controlle [redacted] when the NOEL (given only for oral route) is 150 mg/kg bw/d for the most critical endpoint, reproductive toxicity.

The Registrant is accordingly requested to perform the worker exposure assessment and risk characterisation and subsequently demonstrate that the risk to humans can be considered to be adequately controlled and to update the CSR.

c) Exposure assessment and risk characterisation for waste (following production and service life of the resins with the substance) life-cycle stage

Articles 10(b) and 14(4) as well as Annex I, Section 5 of the REACH Regulation require generation of exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall, in line with Annex I, 5.2.2, consider all stages of the life-cycle of the substance resulting from the manufacture. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage.

ECHA notes that, according to the CSR provided by the Registrant, waste is expected to be generated from the extrusion stage of the formulation and the registered substance is not expected to be released from this waste, as it will be held within a chemical matrix. However, the CSR provided does not specify how waste containing the substance is disposed of/treated and what the possible releases and exposure levels of the substance to the environment are from these operations. According to the Emission Scenario Document on Plastic Additives (OECD, 2004, revised 2009), which is referred to in the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (Version: 2, May 2010, ECHA), no losses of filler are anticipated when disposal is by landfill, however, in case of incineration there may be residues of inorganic materials.

ECHA also notes that in the technical dossier, use in consumer products (e.g. electrical and car parts) is defined as an identified use. However, in the provided CSR there is no information in the exposure scenario and exposure estimation for the waste life-cycle stage of the registered substance in articles.

Therefore, exposure assessment based on treatment technologies for waste (following extrusion stage of the formulation and from the service life of articles containing registered substance) life-cycle stage is needed. The Registrant is accordingly requested to update relevant exposure scenarios and exposure estimations considering waste life- cycle stage of the substance and to update the CSR.

d) Operational conditions and risk management measures driving the air emission factors used for environmental risk assessment

According to Article 3(37) of the REACH Regulation, exposure scenario is defined as "the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment".

Pursuant to Articles 10(b) and 14(4) as well as Annex I, Section 5.1.1 of the REACH Regulation, generated exposure scenarios shall cover a description of the operational conditions and risk management measures applied to reduce or avoid direct and indirect exposure to humans and the different environmental compartments to the substance.

The CSR provided by the Registrant states that the emission to air is 0.0 kg/d, but does not describe the Operational Conditions or the Risk Management Measures employed to achieve zero- emission to air.

Therefore, the Registrant is requested to describe the operational conditions and risk management measures, for all developed scenarios, employed to achieve a non-existent emission to air, and to update the CSR accordingly.

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 technical progress 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]

Jukka Malm
Director of Regulatory Affairs