European Chemicals Agency

For final decision: CCH-D-0000000719-67-05/F Helsinki, 5 October 2010

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

For *Methacrylamide*, CAS 79-39-0, (EC No 201-202-3), 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 ***Methacrylamide*, CAS 79-39-0 (EC Nr. 201-202-3)** submitted by [redacted] (the "Registrant"), latest submission [redacted] for above 1000 tonnes per year.

The compliance check was initiated on 8 June 2009.

ECHA drafted a decision in accordance with Article 41 of REACH. The draft decision on the basis of the compliance check was sent to the registrant for comments on 17 March 2010.

On 16 April 2010, ECHA received comments from the registrant, including the intention of submitting a dossier update by 17 September 2010. ECHA has considered the information received and decided not to amend the draft decision. On 6 May 2010 ECHA sent an explanatory letter to the registrant, informing him that he is entitled to submit the dossier later, within 6 months from the draft decision.

On 11 June 2010, 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 the Member State Competent Authorities, ECHA forwarded the proposals for amendment to the registrant on 13 July 2010 and did not amend its draft decision.

On 26 July 2010, the draft decision was referred to the Member State Committee.

The registrant did not provide any comments on the proposals for amendment.

After discussion in the Member State Committee meeting that was held on 14-16 September 2010, a unanimous agreement of the Member State Committee on the draft decision was reached on 15 September 2010.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

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) and Annex VII of the REACH Regulation the registrant shall submit the information using the test method as indicated on

   - Flammability (Annex VII, 7.10.; EU Method A.10.)
   - Granulometry (Annex VII, 7.14.; Method such as OECD Guideline 110)

2) Pursuant to Articles 41(1)(c), 41(3), 14(4) and Annex I of the REACH Regulation the registrant shall submit the information on

   - The estimated exposure (Exposure scenario and exposure estimation) and the risk characterisation for the use of the substance in preparations. The exposure assessment and the risk characterisation shall cover all stages of the life-cycle of the substance, including preparations.

Pursuant to Article 41(4) of the REACH Regulation the registrant shall submit the information in the form of an updated IUCLID dossier including an updated Chemical Safety Report to ECHA **6 months after the adoption 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, and 14 and/or with Annexes I, III, VI to 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.

1) Missing information related to endpoints

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a registration for a substance produced in quantities of above 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII and VIII of the REACH Regulation and testing proposals for the provision of the information specified in Annexes IX and X.

The technical dossier contained data waivers for the endpoints on:

- Flammability (REACH Regulation Annex VII, 7.10.)

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- Granulometry (REACH Regulation Annex VII, 7.14.)

The **flammability** study was waived as scientifically unjustified: *"not required for solid substances if no structure alert".* Pursuant to Annex VII, 7.10., column 2 of the REACH Regulation, waiving based on the solid form of a substance is acceptable only for explosive and pyrophoric substances. This condition is not fulfilled for the case at hand.

Therefore, the waiving cannot be accepted. The registrant is accordingly requested to submit the information for the endpoint flammability.

The **granulometry** study was waived as scientifically unjustified: "*Inhalation was already identified as relevant exposure pathway in the OECD HPV programme and the regarding inhalation studies do exist*". Pursuant to Annex VII, 7.14., column 2 of the REACH Regulation, waiving of granulometry is possible only if the substance is marketed or used in non solid or granular form. This condition is not fulfilled for the case at hand.

Therefore, the waiving cannot be accepted. The registrant is accordingly requested to submit the information for the endpoint granulometry.

2) Missing information related to the Chemical Safety Report (CSR)

Pursuant to Article 14(4) and Annex I sections 0.6 and 5 of the REACH Regulation, a registration for a substance produced in quantities of above 1000 tonnes per year which meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) shall include for all identified uses an exposure assessment and a risk characterisation as part of the CSR. As from 1 December 2010 the same obligation applies if the conditions of Article 58(1) of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) are met.

In the technical dossier and the CSR the registrant has classified methacrylamide as dangerous in accordance with Directive 67/548/EEC and described the manufacture and uses of methacrylamide, including formulation into preparations. However, further use of the preparations is not described and a risk characterisation in that respect is missing. The downstream uses of preparations containing methacrylamide are to be included as identified uses in the CSR. The registrant is therefore requested to add to the CSR an exposure assessment (consisting of the generation of exposure scenario(s) and exposure estimation) and a risk characterisation for the use of methacrylamide as component of preparations.

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."*

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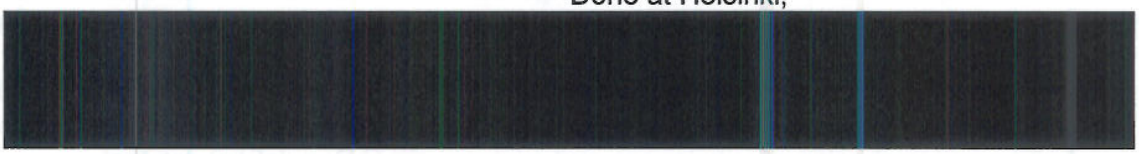
According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the 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 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,



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