EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002307-78-02/F Helsinki, 4 May 2012

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

For Methyl methacrylate, CAS No 80-62-6 (EC No 201-297-1), 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 (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for Methyl methacrylate, CAS No 80-62-6 (EC No 201-297-1) submitted by [redacted] (Registrant), latest submission number [redacted], for above 1000 tonnes per year.

The compliance check was initiated on 25 February 2011.

On 9 June 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 8 July 2011 the Registrant provided to ECHA comments on the draft decision and indicated sending an update of the dossier with the requested information. ECHA received a dossier update on 27 October 2011 and amended the draft decision accordingly.

On 20 January 2012 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 of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

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)(c), 10(b), 14 and Annex I of the REACH Regulation, the Registrant shall submit the following information in the form of an updated Chemical Safety Report (CSR):

a. Refinement of exposure scenario development, exposure assessment and risk characterisation (Annex I, 5.1.1, 5.2.2, 5.2.4) by providing consistent information on identified uses, operational conditions and risk management measures for:
    1) Environment
    2) Workers
b. Refinement of worker exposure estimation for processes with elevated process temperatures
c. Refinement of worker exposure assessment using the report of the risk assessment completed under Regulation (EEC) No 793/93 or scientifically supported justification for deviating from it
d. Documentation on risks to workers adequately controlled for all exposure scenarios
e. Exposure assessment and risk characterisation for worker short-term inhalation exposure

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 **4 May 2013**.

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 Articles 6 ad 7 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and/or 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.

Missing information related to Chemical Safety Report

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR).

Pursuant to Annex I, 0.5 of the REACH Regulation, where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessment shall be justified. The registered substance has been evaluated under risk assessments completed under Regulation (EEC) No 793/93 (report published 2002[1], referred further as EU RAR (2002)), so this assessment should be taken into account in relevant parts of the CSR. The Registrant has already referred to the data presented in the EU RAR (2002) in some parts of his dossier and CSR.

(a) Refinement of exposure scenario development, exposure assessment and risk characterisation (Annex I, 5.1.1, 5.2.2, 5.2.4) by providing consistent information on identified uses, operational conditions and risk management measures

Pursuant to Articles 41(1)(c), 41(3), 14(1, 3 and 4) and Annex I of the REACH Regulation, a Chemical Safety Report shall be provided, including exposure assessment and risk

[1] http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/SUMMARY/methylmethacrylatesum024.pdf

characterisation addressing all identified uses of the substance. Annex I sets out the general provisions for assessing substances and preparing CSRs.

Pursuant to Annex I, 5.1.1 the refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation. The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report. The Registrant has included all the iteration steps of exposure estimation in his CSR which increases the size of tables and the inconsistencies of the information. The Registrant should refine his assessment by removing unnecessary iterations from his CSR.

ECHA Guidance on Information requirements and chemical safety assessment, Part A: Introduction to the Guidance document, Version 1.1, December 2011, Section A.2.4.3.3 describes generic exposure scenarios as follows: *"A generic ES (GES) may be defined as a single ES that describes the relevant OC and RMMs for the typical use conditions relevant to operations of a DU sector, in particular SMEs. This means that the GESs supporting the substance are oriented towards the areas of application of the substance. Thus DUs only have to select the GES(s) relevant to the sector for which the GES is intended and for which the use is supported. To account for potentially different substances with differing hazard and physico-chemical characteristics being used for the same application, it is necessary to support each GES with a statement specifying the 'boundaries of application'. This may provide additional help to DUs on the extent to which the advice can be reliably applied."*

ECHA Guidance on Information requirements and chemical safety assessment, Part D, Exposure Scenario Building, Version 1.1, May 2008, Section D.3.3.1 explains on p. 22 the generation of generic exposure scenarios as follows
"M/I or their associations may wish to develop generic ES, i.e. single ES that describes the relevant OC and RMMs for the typical use conditions relevant to operations of a DU sector. GESs supporting the substance would be oriented towards the areas of application of the substance. The preparation of such GES requires the following:

- *a thorough understanding by the M/I of the activities (Uses) through the life cycle of the substance that give rise to exposure/emissions. This requires appropriate communication within the supply chain,*
- *the evaluation of each of the activities to identify the appropriate RMMs and OCs, in line with the generic workflow as described in Section D.3.2 and the other sections of part D.*
- *the consolidation of the various RMMs into one composite ES, termed the Generic Exposure Scenario, GES".*

This implies that operational conditions (OC) and risk management measures (RMM) shall be realistic, sufficiently concrete and practically relevant to the operational conditions to be expected for the identified use.

In the CSR, the Registrant has built the Generic Exposure Scenario (GES) for workers' exposure and has translated as such this approach to the environmental exposure, carrying out the environmental emission estimation, risk assessment and risk characterisation for each GES). The way the GES approach has been applied, for both workers' exposure and environmental exposure, in the CSR to derive the exposure assessment for the registered substance leads to inconsistencies in the information provided by the Registrant. As a consequence, information provided by the Registrant in the CSR does not comply with the requirements of Annex I, for the reasons listed below in points 1) and 2):

1) Environment

There are inconsistencies between IUs, GESs and Environmental Release Categories (ERCs) identified in the CSR by the Registrant. For example, the combination of Process Categories (PROCs) and ERCs and the description of use appear to be inconsistent for some situations, e.g., in Table 61 on p.94 in Identified Use 2 (Formulator /professional end use/ professional) the PROCs 2, 3 and 4 are not in general applicable for professional use and they do not fit with Environmental Release Categories for wide-dispersive end use (ERC8a, b, c, d, e or f). The Registrant should justify how he can assess environmental exposure when e.g. worker exposure for Exposure Scenario 2 (IU 2) includes process categories for industrial use, e.g. PROC2 and Environmental Release Categories of wide dispersive use. The CSR information for the evaluation of site-specific scenarios is not clear from the documentation received.

As a consequence, the Registrant failed to comply with the provisions of Art 3(37), and Annex I 0.1 of the REACH Regulation.

Therefore, the Registrant is requested to provide more detailed and consistent information on identified uses, operational conditions and risk management measures both in exposure scenario development, exposure assessment and risk characterisation part of the CSR. The Registrant is also requested to indicate the OC/RMMs taken into account in each exposure scenario and sub-scenario, to provide univocal emission estimates for each IU, and to give unambiguous recommendation for downstream users of the substance.

2) Workers

The CSR contains inconsistencies in reporting operational conditions and risk management measures between ES description and exposure estimation part. The descriptions of OCs and RMMs for the same ES/PROC are different in different parts of the CSR. Additionally, the CSR does not show consistent and sufficient documentation that exposure to humans can be considered to be adequately controlled. Indoor/outdoor conditions are given below as an example for these inconsistencies.

In the CSR, e.g. on p. 190 for professional use on GES 6, the location has been given as "inside, outside" and on p.190-191 LEV effectiveness >75 % (with a reference to ECETOC industrial worker, even though this scenario is generated for professionals). The recommendation for LEV for this outdoor/indoor use is not consistent with the table of the mapping of the uses and exposure assessment, as there no ES has LEV (>75 %) for outdoor use. Usually, Ecetoc TRA does not foresee LEV in outdoor uses, but a reduction of 30 % exposure due to outdoor ventilation.

In addition, the information on the DU communication is controversial. Tables 62-64 include a column "*RMMs for communication -Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended*) but all the ext added to the column is in red, so the information to be communicated remains unclear based on these summary tables.

The Registrant is requested to reassess his descriptions of general exposure scenarios and operational conditions as well as risk management measures linked to GES, by providing consistent information on all identified uses, operational conditions and RMMs in all relevant sections of the CSR (exposure scenarios, exposure assessment).

(b) Refinement of worker exposure estimation for processes with elevated process temperatures

Pursuant to Annex I, 5.2.2 of the REACH Regulation the emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented.

In the CSR (p. 88) the Registrant states that "*both for industrial and professional use polymerisation processes and specifically cast sheet production operate at temperatures of around 100 ºC. As for a safety measure this stage of the process is always a closed system and no excess exposure to the registered substance can occur*". Elevated temperature is identified as an operational condition for PROCs 6, 17, 18, 22 and 24 both for the industrial and professional GES.

However, the Registrant's argument on the closed system of the process is challenged in the exposure assessment part of the CSR (attachment [redacted]), where the inhalation estimate for e.g. PROC 6 was 50 ppm for industrial and 100 ppm for professional use (without taking into account the effect of elevated temperature), and personal protection was necessary to ensure the safe use in the CSR. Accordingly, the Registrant's justification for omitting the effect of elevated temperature in exposure assessment based on closed system and unlikely exposure is not appropriate.

The exposure model used by the Registrant enables consideration of elevated process temperature by applying higher (process-temperature related) vapour pressure for the substance. If the Registrant would apply appropriate, higher fugacity in exposure modelling it would lead to RCRs above 1 in many ESs. Given that operational conditions described for exposure scenarios are not taken into account in the exposure estimation, the provisions in Annex I, 5.1.1 and 5.2.4 of the REACH Regulation are not met and a worker exposure assessment for elevated process temperatures is missing.

The Registrant is requested to refine his CSR by including worker exposure assessment (either by data or available monitoring data) for processes with elevated process temperatures.

(c) Refinement of worker exposure assessment using the report of the risk assessment completed under Regulation (EEC) No 793/93 or scientifically supported justification for deviating from it

Pursuant to Annex I, 0.5 of the REACH Regulation, where available and appropriate risk assessments completed under Regulation (EEC) No 793/93 shall be taken into account in the development of, and reflected in, the CSR. Deviations from such assessments shall be justified.

EU RAR (2002) identifies a need for limiting the risks for worker exposures e.g. in the chemical industry, industrial area and skilled trade and during use of casting resins. Especially the activities in cast sheet production, production and use of adhesives and professional floor coating were identified as work raising concern for the safe use of the substance. This report contains relevant information concerning the uses identified in the CSR, e.g. a large set of monitoring data on floor coating. In addition, risk management

measures at Community level are recommended.

The CSR includes a summary table (Table 60, p. 87) where the Registrant links the EU RAR (2002) to his exposure assessment. In addition, the CSR states "*there have been activities at manufacturer/user and national level to implement recommendations from the RAR – specifically towards the improvement of safe handling. Consequently, some of the exposure data included in the RAR may not be applicable to current day working practice.*" The Registrant refers some exposure conditions, e.g. reducing concentration, time or increasing controls to ensure safe handling.

However, the CSR does not present any data how EU RAR is taken into consideration in the development of worker exposure estimates, as the Registrant has generated exposure assessments by standard Ecetoc TRA modelling. In addition, the CSR does not provide any information how the work with high concern on the safe use of the substance, e.g. the high exposures identified in professional floor coating (an example of wide dispersive use) in the EU RAR (2002) have been overcome by the proposed conditions and RMMs in the current CSR.

Therefore, the Registrant is requested to take into account the EU RAR (2002) data in the development of worker exposures and reflect it in his CSR, or justify in the CSR why he has deviated from the EU RAR (2002).

(d) Documentation that risks to workers are adequately controlled for all exposure scenarios

Article 14(6) as well as Annex I, 0.1, 5.2.4 and 6.2-6.4 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in the CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

The risk characterisation for workers for industrial and professional use in the CSR presents controversial information. Within Tables 100 and 106 the Registrant reports the maximum RCR value for inhalation route, maximum RCR value for dermal route and maximum RCR value for combined dermal and inhalation route, but these values are taken from different sub-scenarios. Therefore, the sums of the RCRs from inhalation route and dermal route are higher than 1, e.g. in table 100 (p. 214) the sum of RCRdermal 0.5 + RCRinh 0.7 would lead to a value of 1.2, which would not be an acceptable RCR. How these values derive the reported sum result of 0.92 is not explained in the CSR. The current documentation on risk characterisation does not demonstrate that the risk to humans can be considered to be adequately controlled (Annex I, 6.4). The Registrant shall update his CSR by including either the risk characterisation of all contributing scenarios in the CSR or by including explanation and justification of the current practice in his CSR.

Pursuant to Annex VI, section 5 of the REACH Regulation the information provided in the registration dossier must be consistent with that in the Safety Data Sheet. In addition, Annex I, 0.5 of the REACH regulation states that chemical safety assessment shall be based on the information in the technical dossier. The requirements of Safety Data Sheets are specified in Annex II (amended in Commission Regulation 453/2010). According to section 8.2.2.2 (b) of Annex II, the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material.

The CSR refers to CEN 374 (Protective gloves against chemicals and micro-organisms) and some general information on protective gloves is included in Section 11 of the technical dossier. However, the current CSR or technical dossier do not give in the ES specific information for the type of material, thickness or breakthrough time for protective gloves.

The Registrant is therefore requested to update the risk characterisation of the CSR in order to consistently demonstrate RCRs of less than 1. In addition, the Registrant is requested to provide documentation for the recommended breakthrough times for protective gloves, with regard to the amount and duration of dermal exposure in the CSR.

(e) Exposure assessment and risk characterisation for worker short-term inhalation exposure

Pursuant to Annex I, 5.2.4 of the REACH Regulation requires that exposure estimation shall in particular take account of:
— duration and frequency of exposure according to the operational conditions,
— the activities of workers related to the processes and the duration and frequency of their exposure to the substance.

Pursuant to Annex I, 6.3 and 6.4 of the REACH Regulation 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, and on assessment that 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.

The CSR includes DNEL derivation, exposure assessment and risk characterisation for worker short-term exposures. However, the derivation of the short-term exposures is not correctly calculated, as the short-term values for any PROC in any ES are much lower (usually 10 %) than the 8-h exposures, which is not appropriate. ECHA Guidance on Information requirements and chemical safety assessment Chapter R.14: Occupational exposure estimation (p. 17) states that *"Acute reasonable worst-case values can be derived from full shift values by using a multiplication factor. This factor depends on the conservativeness of the reasonable worst-case short term value required, i.e. on the percentile of the acute exposure distribution that is considered to be the reasonable worst-case value."* The recommended multiplication factor values, depending on the type of exposure pattern may vary between 2 and 6. Accordingly, if modelling data is applied for short-term exposure evaluation, the short-term exposure estimates should be 2-6 times higher than 8-h exposure estimates.

In addition, EU RAR (2002) presents high short-term exposures (above EU STEL 100 ppm = 420 mg/m3) for some uses identified by the Registrant, such as cast sheet production and floor coating. These data from the report have not been included in the CSR.

Therefore, the Registrant is requested to provide appropriate exposure assessment and risk characterisation for worker short-term inhalation exposure to assure that the risks are adequately controlled also during short-term exposures. In the development of these data the Registrant is requested to take into account EU RAR (2002) short-term exposure data and reflect it in the CSR, or justify why he has deviated from the EU RAR (2002).

IV. 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.

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