EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288490-44-01/F Helsinki, 26 November 2014

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

For 4-methylpentan-2-one, CAS No 108-10-1 (EC No 203-550-1), 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 for 4-methylpentan-2-one, CAS No 108-10-1 (EC No 203-550-1), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 12 June 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 17 October 2013.

On 16 December 2013 ECHA sent the draft decision to the Registrant and invited him in accordance with Article 50(1) of the REACH Regulation to provide comments on the draft decision. That draft decision was based on submission number [redacted].

On 30 January 2014 ECHA received comments from the Registrant on the draft decision and on 28 February 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 12 June 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposal for amendment to the draft decision was submitted.

On 18 July 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 16-18 September 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 17 September 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised exposure and risk assessments for professional use of glues for flooring and coatings (Annex I, Sections 5. and 6.) as specified in Section III. A.1. below;

2. Revised consumer exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) as specified in Section III. A.2. below;

3. Documentation for the recommended personal protective equipment, i.e. gloves to be worn when handling the substance or mixture (Annex I, 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2.(b)(i)) as specified in Section III. A.3. below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **2 June 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

According to Article 14(1) and (4) and Annex I, Section 0.6., the Registrant is required to perform a chemical safety assessment (CSA) for the registered substance. The CSA shall cover 1) Human health hazard assessment, 2) Human health hazard assessment of physicochemical properties, 3) Environmental hazard assessment and 4) PBT and vPvB assessment. If as a result from these steps, the substance meets the criteria for any hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), or is assessed to be a PBT or vPvB, the CSA shall also include the additional steps: Exposure assessment, including generation of exposure scenario(s) and exposure estimation, and Risk characterisation. The additional steps of the CSA shall be carried out in accordance with Sections 5 (for Exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

As pointed out under Section III.A above the registered substance has a harmonised classification (i.e. according to the CLP Regulation) meeting the conditions of Article 14(4) and Annex I, Section 0.6, meaning that Exposure assessment and Risk characterisation are required.

1. Revised exposure and risk assessments for professional use of glues for flooring and coatings

Pursuant to Annex I, Section 5.2.4. an estimation of exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) for which exposure to the substance is known or reasonably foreseeable. In particular, for workers, the exposure estimation shall take account of the activities related to the actual use of the substance and the duration and frequency of their exposure to the substance. Annex I, Section 5.2.5., further specifies that adequately measured and representative exposure data shall be considered, if available.

Within the dossier the Registrant proposes professional uses of products for application through use of brush and roller. ECHA notes that uses such as applying coatings and [redacted] in large quantities may not be adequately covered by the assessment.

In particular, there are indications from the consumer exposure assessment suggesting that the exposure levels for professionals could be anticipated to be, on a daily basis, of the same order as for those produced through consumer uses when professionals carry out equivalent tasks in domestic premises. However, in the CSR professional uses and consumer uses currently appear to have widely different exposure estimates associated with these tasks. Applying [redacted] in large quantities, which has been identified as a high exposure event for the consumers, will be a routine job, for example for flooring professionals. Consequently, ECHA is concerned that the Registrant may have underestimated the exposure estimation for this use for professionals.

Furthermore, ECHA notes that the operational conditions assumed for professionals seem to be unrealistic (e.g. use of ventilation arrangements are assumed that may be impracticable for application in the domestic environment where ventilation possibilities are usually limited).

In his comments submitted on 30 January 2014, the Registrant indicated his intention to refine his exposure assessment for professional use of glues for flooring and coatings in a later update of his dossier. However, in the dossier update received on 28 February 2014 (submission number [redacted]) the exposure assessment has not been revised. Therefore the draft decision has not been modified with regard to this issue.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide in the CSR revised exposure assessment and risk characterisations for exposures resulting from the use of the registered substance within professional flooring and coating products. In particular, the Registrant is requested to elucidate the inconsistencies between the professional and consumer assessments. The Registrant's assessment shall rely on realistic assumptions that could be supported, for example, by appropriate measurement data.

2. Revised consumer exposure assessment and risk characterisation to take account of the activities of consumers and the duration and frequency of their exposure to the registered substance

Pursuant to Annex I, Section 5.2.4. an estimation of exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) for which exposure to the substance is known or reasonably foreseeable. Such estimations shall take account of spatial and temporal variations in the exposure pattern. Pursuant to Annex I, Section 5.2.5., adequately measured and representative exposure data shall be considered, if available. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered.

ECHA notes that in his consumer exposure calculations, the Registrant has averaged out exposure firstly over one day, and then over a year, in order to compare the resulting average "long-term systemic exposure" to a corresponding DNEL and achieve risk characterisation ratios below 1. However, as noted in the REACH *Guidance on information requirements and chemical safety assessment*, (ECHA (2010); Chapter R.8: Characterisation of dose [concentration]-response for human health, p.8): "*The actual daily dose is independent of the exposure frequency. This means that if for a certain scenario, worker or consumer exposure is for instance only for a number of days per year, the exposure value is the actual dose on the exposure days, and not the daily dose averaged out (and thus divided!) over the whole year.*" Therefore, the long term exposure to be compared to the DNEL long term shall not be the exposure level calculated by averaging exposure events over the year, but the actual daily exposure.

Furthermore, pursuant to Annex I Section 6.2., the risk characterisation shall consider the human populations exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof. REACH *Guidance on information requirements and chemical safety assessment*, (ECHA (2010); Chapter R.15 Consumer exposure, further specifies that "*if the same substance (for a single registration) occurs in different consumer products or articles that could reasonably be expected to be used jointly and frequently by an average consumer, it is advised to also calculate the combined risk, in order to prevent underestimation of risk*". In the CSR, the overall assessment of consumer exposure takes no account of the combined use of the substance in particular in 31 Product categories (PC) identified for coatings and the 23 categories identified for cleaning agents. The risk characterisation provided by the Registrant was performed per product category only and may not be protective enough.

In his comments submitted on 30 January 2014, the Registrant indicated his intention to refine his consumer exposure and risk assessments in a later update of his dossier. However, in the dossier update received on 28 February 2014 (submission number [redacted]) the exposure assessment has not been revised. Therefore the draft decision has not been modified with regard to this issue.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide in the CSR revised exposure assessments and risk characterisations to take account of the duration, frequency and combination of exposure resulting from the registered substance within consumer products.

3. Documentation for the recommended personal protective equipment, i.e. gloves to be worn when handling the substance or mixture

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a 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.

Pursuant to Annex VI, Section 5 and Annex II, Section 0.1.2. of the REACH Regulation, the information provided in the registration dossier shall be consistent with that in the Safety Data Sheet (SDS). The requirements of Safety Data Sheets are specified in Annex II of the REACH Regulation (amended by Commission Regulation (EU) No 453/2010).

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be indicated in the CSR. Furthermore, Annex II, Section 8.2.2.2. (b)(i) requires the Registrant to describe the relevant RMM in detail (e.g. 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) in order to minimise the exposure for workers handling the registered substance. In particular, the following requirements for hand protection in order to avoid dermal exposure need to be provided consistently in the SDS and CSR:

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

In the CSR, the Registrant indicated the following for hand protection: "*Wear chemically resistant gloves (tested to EN374)*" in combination with additional risk management measures depending on the operational conditions (i.e.: "*no training [PPE15]*", "*basic employee training [PPE16]*", "*specific activity training [PPE17]*", or "*intensive management supervision controls [PPE18]*")

In Section 11 of the technical registration dossier in the part for Exposure controls/personal protection only information on the material is provided:
"Hand protection:
Intermittent contact: Gloves (PVC, neoprene, nitrile rubber) According to permeation index EN 374: 1 (time elapsed > 10 mins)
Prolonged contact: Impervious butyl rubber gloves"

To ensure the safe use of a substance it is essential to have detailed guidance on risk management measures, e.g. personal protective equipment. Gloves are reported in the CSR and in IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. The material type of gloves to be worn is specified as well. However, thickness and typical or minimum breakthrough time when handling the substance are not.

Therefore, pursuant to Article 41(1)(c) and 41(3) of the REACH Regulation the Registrant is requested to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended, with regard to the amount and duration of dermal exposure.
It is recognised that many exposure scenarios for the registered substance will result in exposure to a mixture of chemicals and the appropriate advice on the specific glove requirements for these undefined situations will be within the safety data sheets relating to product formulations. The selection of gloves will be determined by the most relevant components of those mixtures and this information is not required within the CSR or Section 11 of IUCLID.

Notes for consideration by the Registrant:

Regarding how to report the gloves specifications, the information should be included both in Section 11 of the technical IUCLID dossier (Guidance on Safe Use) which is the disseminated part of the dossier and in the CSR where the appropriate measures to adequately control the risk are to be reported. It is the responsibility of the Registrant to ensure consistency of the information among the CSR, IUCLID Section 11 and the safety data sheet.

ECHA notes that the Registrant has used version 2 of the ECETOC TRA model to estimate the worker dermal exposure and that he has applied a maximum glove efficiency of 95 % for spraying applications (e.g. in professional uses of the registered substance as lubricant or metal working fluid). ECHA further notes that in version 3 of the ECETOC TRA model (released in 2012), it is not considered appropriate to assume glove protection efficiency above 90% for professional uses[1]. Pursuant to Article 22(1)(e) of the REACH Regulation, the Registrant shall, on his own initiative, update his registration dossier when new knowledge of the risks of the substance which may lead to changes in the safety data sheet or the chemical safety report is available. ECHA notes that the Registrant indicated he was willing to perform a new exposure assessment for occupational exposure using version 3 of the ECETOC TRA model. When applying version 3 of ECETOC TRA model, the glove protection efficiency for professional uses should be reconsidered accordingly.

[1] ECETOC TRA version 3: Background and Rationale for the Improvements. Technical Report No. 114 (ECETOC, 2012)

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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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