ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002577-67-04/F Helsinki, 20 December 2012

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

For Cyclohexanone, CAS No. 108-94-1, EC No. 203-631-1, 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 the ECHA has performed a compliance check of the registration dossier for Cyclohexanone, CAS No. 108-94-1, (EC No. 203-631-1) submitted [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year.

The compliance check was initiated on 21 December 2010.

On 21 December 2011 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. Due to ECHA being closed between 23 December 2011 and 1 January 2012, the Registrant commenting period was prolonged until 27 January 2012.

On 27 January 2012 ECHA received comments from the Registrant to ECHA's draft decision.

On 4 April 2012 the Registrant updated his registration dossier. ECHA considered the Registrant's comments received and the information submitted in an updated dossier. On basis of that, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 19 July 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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 22 August 2012 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.

ECHA reviewed the proposal for amendment received and decided to amend the draft decision.

On 3 September 2012 ECHA referred the draft decision to the Member State Committee.

On 18 September 2012, the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 October 2012 in a written procedure launched on 26 September 2012 and ECHA took the decision pursuant to Article 51(6) 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

1) Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annexes I and VI of the REACH Regulation, the Registrant shall provide the following information and update the Chemical Safety Report accordingly:

a. Risk characterisation for worker inhalation route (Annex I), as specified under III. 1) a. below;
b. Risk characterisation for worker dermal route (Annex I), as specified under III. 1)b.;
c. Environmental exposure assessment and risk characterisation and subsequent demonstration that the risk to the environment can be considered to be adequately controlled (Annex I, Sections 5.2.4. and 6.3.), as specified under III.1)c. below;
d. Risk characterisation for physicochemical properties of the substance (Annex I, Sections 2, 6.3., 6.4.), as specified under III.1)d. below and;
e. Information on specifications of protective gloves (Annex VI, Section 5 and Annex II, Section 8.2.2.2), as specified under III.1)e. below.

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 **20 December 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 Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and with Annexes I and VI 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 Chemical Safety Report (CSR)

Annex I sets out the general provisions for assessing substances and preparing CSR.

a. Risk characterisation for worker inhalation route (Annex I);

Pursuant to Article 14(4)(b) and Annex I, Sections 6.3. and 6.4. of the REACH Regulation, a risk characterisation is to be performed on the substance that meets the criteria for certain hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) or is assessed to be PBT or vPvB. For human health, the risk characterisation consists of a comparison of the exposure of each human population known to be likely exposed with the appropriate DNEL.

The registered substance is classified as Acute Tox. 4 (inhalatory route) (hazard classes 2.6 and 3.1, respectively) according to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). In addition, following the CSA, the Registrant has self-classified the substance as R38 – irritating to skin, R41 – risk of serious damage to eyes and R21/22 – harmful in contact with skin and if swallowed according to Directive 67/548/EEC, and as Acute Tox. 4 (oral and dermal route) (hazard class 3.1), Skin Irrit. 2 (hazard class 3.2) and Eye Damage 1 (hazard class 3.3) according to CLP Regulation.

The Registrant is requested to provide missing information on risk characterisation for workers inhalation route to ensure that the risk to workers can be considered to be adequately controlled in all exposure scenarios, and to update the CSR.

The original draft decision sent to the Registrant contained requests to reassess the DNEL and risk characterisation for worker inhalation route. In response, in the updated dossier, the Registrant has recalculated the DNEL for worker inhalation route, but the Registrant did not provide sufficient information for risk characterisation for worker inhalation route. The current version of the CSR, as updated by the Registrant, still does not provide adequate information on the details of operational conditions, risk management measures and exposure estimates to demonstrate how the risk characterisation has been derived. In particular, it is not described how the inhalation exposure estimates have been derived and whether any specific risk management measures need to be considered where exposure may become elevated. From the CSR data it is not clear e.g. what suitable and adequate respiratory protection may be required to protect workers against emissions or processes where aerosols are generated through, for instance, spray painting (PROC 7 or PROC 11), respiratory protective equipment may be required to protect workers against emissions.

Therefore, the Registrant shall provide missing information for the risk characterisation for workers inhalation route. More specifically, the Registrant is requested to provide the appropriate justification for the values used of exposure estimation within risk characterisation and documentation for exposure evaluations in line with sections 5.2.4 and 5.2.5 of Annex I on the necessary risk management measures, including respiratory protective equipment, which have been used as defaults for exposure assessment and risk characterisation. In addition, the Registrant is requested to provide information on the algorithms used to derive the quoted values for exposure assessment and risk characterisation. Risk characterisation shall take into account combined routes of exposure.

b. Risk characterisation for worker dermal route (Annex I);

As explained under Section III 1 a) above, the registered substance is classified as Acute Tox. 4 (inhalatory route) (hazard classes 2.6 and 3.1, respectively) according to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). and therefore a risk characterisation is to

be performed.

The Registrant is requested to provide missing information on risk characterisation for worker dermal route to ensure that the risk to workers can be considered to be adequately controlled in all exposure scenarios, and to update the CSR.

The original draft decision sent to the Registrant contained requests to fully justify the derivation of DNELs and risk characterisation for worker dermal route. In the updated dossier, the Registrant has recalculated the DNEL for worker dermal route, but did not provide sufficient information for risk characterisation for worker dermal route. The current version of the CSR, as updated by the Registrant, still does not provide adequate information on the details of operational conditions, risk management measures and exposure estimates to demonstrate how the risk characterisation for workers has been derived.

Therefore, the Registrant shall provide missing information for the risk characterisation for workers dermal route. More specifically, the Registrant is requested to provide the appropriate justification for the values used of exposure estimation within risk characterisation and documentation for exposure evaluations in line with sections 5.2.4 and 5.2.5 of Annex I on the necessary risk management measures, including dermal protection, which have been used as defaults for exposure assessment and risk characterisation. In addition, the Registrant is requested to provide information on the algorithms used to derive the quoted values for exposure assessment and risk characterisation. Risk characterisation shall take into account combined routes of exposure.

c. Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4 and 6.3);

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[1] 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.

Further, according to Annex I, section 5.0., the objective of the Exposure assessment is to make quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4 of chapter 0.6 of Annex I.

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- hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F.
- hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10.
- hazard class 4.1:
- hazard class 5.1;

ECHA notes that the registered substance has been classified as R10 – flammable and R20 – harmful by inhalation according to Annex I of Directive 67/548/EEC, and as Flam. Liquid 3 and Acute Tox. 4 (inhalatory route) (hazard classes 2.6 and 3.1, respectively) according to the CLP Regulation. In addition, following the CSA, the Registrant has self-classified the substance as R38 – irritating to skin, R41 – risk of serious damage to eyes and R21/22 – harmful in contact with skin and if swallowed according to Directive 67/548/EEC, and as Acute Tox. 4 (oral and dermal route) (hazard class 3.1), Skin Irrit. 2 (hazard class 3.2) and Eye Damage 1 (hazard class 3.3) according to CLP Regulation.

In the comments to the draft decision, the Registrant stated that: "*Since for cyclohexanone no hazard is identified for the environment, the Registrant sees no need to perform a risk characterisation for the exposure scenarios*". ECHA notes that this statement is in contrary with the ECHA Guidance on information requirements and chemical safety assessment, chapter B.8 Scope of Exposure Assessment. This issue will be further elaborated upon below.

In the original dossier the Registrant has identified a hazard for the environment (key study Brack & Rottler (1994) with a 72h algae EC50 = 32.9 mg/L, CSR, section 7.1.1.3, p. 56) and he has also stated that the substance is "Acute harmful to algae". Therefore, the original draft decision sent to the Registrant required him to carry out the exposure assessment and subsequent risk characterisation also for the environment based on this study in order to address the hazard identified for the environment.

In the updated dossier, the Registrant, however, provides that he has not identified a hazard for the environment and therefore has waived the environmental Exposure assessment and Risk characterisation. In the Registrant's view, the substance is not acutely harmful to algae. When doing this, the Registrant has disregarded the above mentioned Klimisch 2 study by Brack & Rottler (1994) because it arguably has several weaknesses. Instead, a weight-of-evidence (WoE) approach has been presented using a different Klimisch 2 study on algae (Bringmann (1978) and a Klimisch 1 study on algae conducted with an analogous substance cyclopentanone (L'Haridon (2003)).

The choice of studies, the suggested read-across to cyclopentanone and the derivation of relevant PNECs, as presented in the updated dossier, will each be dealt with in the paragraphs below.

Regarding the choice of studies by the Registrant, ECHA notes that both the Brack & Rottler (1994) study and the Bringmann (1978) study have shortcomings which lead into similar uncertainties. Based on the data presented in the updated dossier, ECHA, however, considers that the Brack & Rottler (1994) study should not be totally disregarded by the Registrant, but both studies on the registered substance should be taken into account in the WoE approach within the meaning of Annex XI, Section 1.2 of the REACH Regulation. This is because WoE, in order to be sufficient and to meet the requirements of Annex XI, Section 1.2, must be based on several independent sources of information.

In order to justify the suggested read-across to cyclopentanone, the Registrant provided a summary of the physico-chemical and environmental properties of both substances and concluded that: " *read-across between substances can be performed if the physicochemical and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. As described previously the two cycloalkanes cyclohexanone and cyclopentanone are quite similar in structure, physico-chemical properties and environmental fate. Consequently it has to be expected that ecotoxicological effects are quite similar as well. Hence, cyclopentanone is a suitable read across substance to cover*

ecotoxicity endpoints in the environmental risk assessment of cyclohexanone".

ECHA considers that, contrary to Annex XI, Section 1.5 of the REACH Regulation, the Registrant has failed to provide any adequate and reliable documentation in the dossier to support this assertion. Furthermore, the Registrant has failed to establish why the results from the read-across study referred to would be adequate for the classification and labelling and the risk assessment of the substance registered. ECHA also considers that the proposed read-across approach as an element of the weight of evidence justification does not demonstrate that environmental effects or environmental fate of the registered substance may be predicted from the data on the reference substance within the meaning of Annex XI, Section 1.2 and 1.5 of the REACH Regulation. Therefore, ECHA concludes that the read-across presented by the Registrant does not fulfil the above provisions governing read-across and WoE approach under the REACH Regulation.

Regarding the derivation of PNECs, ECHA notes that the original draft decision requested the Registrant to take into account the results of the requested short-term toxicity testing on aquatic invertebrates (preferred species Daphnia) when defining PNECs for different compartments (PNECaquatic and, if necessary, PNECsediment and PNEC soil (equilibrium partitioning method used)). The Registrant provided new PNECs in the updated dossier based on the Bringmann (1978) study and on the L'Haridon (2003) study based on poorly justified read-across on cyclopentanone, but disregarded the algae study by Brack & Rottler (1994).

ECHA further observes that both Bringmann (1978) and L'Haridon (2003) studies conducted on algae and used by the Registrant in the WoE approach show effects above 100 mg/l, which is the limit test concentration for acute aquatic toxicity according to standard OECD and EU Guidelines (OECD TG 201/EU Method C.3; OECD TG 203/EU Method C.1). In this respect, ECHA draws the attention to the Registrant to the ECHA Guidance on information requirements and chemical safety assessment, chapter B.8 Scope of Exposure Assessment. The Guidance provides that if there is an adverse effect seen at concentration higher than 100mg/l found in studies performed according other than the above mentioned EU & OECD Guidelines (as is the case for Bringmann (1978) study), this needs still to be taken into account for PNEC derivation (or valid justification provided, why these effects are not taken into account) and, consequently, the exposure assessment needs to be carried out, as for any other identified hazard.

Moreover, the above mentioned guidance specifies further (in Section 8.4.2.2) that "If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment. /.../ Hence, quantitative exposure assessment, i.e. derivation of PNECs, is mandatory for the water, sediment and soil environmental compartments." As further clarified in the same guidance such identified hazards (among others) necessitating exposure assessment are the "hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified".

For the above reasons, ECHA considers that a PNECaquatic should have been derived taking into account all relevant information, including the Brack & Rottler (1994) study, in the dossier.

In summary, the proposed WoE approach, as presented in the updated dossier, is not sufficient to conclude that the substance is not hazardous to the environment. This is because all the available and relevant data should have been taken into account while concluding on hazard assessment and subsequent PNEC derivation. Additionally, the read-

across study on cyclopentanone fails to show how the data of this substance could be used to the registered substance within the meaning of Annex XI, section 1.5 of the REACH Regulation and therefore should not be used in WoE approach pursuant to Annex XI, section 1.2.

Therefore, ECHA is of the opinion that the Registrant has failed to show that there is no hazard identified to the environment based on studies in the dossier. Moreover, the data presented in the dossier for other aquatic endpoints suggest that hazards for the environment have been identified (e.g. the Brack & Rottler (1994) algae study, the Bringmann (1978) algae study and the Brooke et al. (1984) acute fish study).

In addition, the Registrant's arguments for waiving the exposure assessment are counter to the internationally agreed OECD SIDS assessment of cyclohexanone under the OECD High Production Volume programme (published 2002, assessed 1994) which concluded that "*international information on exposure is needed to assess the significance of solvent and agricultural applications and to develop exposure scenarios specific to other uses identified.*" There appears to be little difference between the uses considered by the OECD programme and those detailed by the Registrant and there is no justification provided from deviating from REACH Annex I, section 0.5.

Accordingly, the Registrant is requested to perform an environmental exposure assessment covering all life-cycle stages of the registered substance originating from manufacture and identified uses, and subsequently perform Risk characterisation for each exposure scenario to demonstrate the safe use of the substance, and update the dossier accordingly. All the available and relevant data and the results of the environmental hazard assessment shall be taken into account in the PNEC derivation.

d. Risk characterisation for physicochemical properties of the substance

Pursuant to Article 14(4)(b) and Annex I, Sections 6.3. and 6.4. of the REACH Regulation, a risk characterisation is to be performed on the substance that fulfils the criteria for certain hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) or is assessed to be PBT or vPvB, and it shall consist of an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

The registered substance is classified as Flammable liquid Cat. 3 according to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).

The CSR attached to the technical registration dossier does not provide information on risk characterisation related to flammability of the registered substance for any of the reported exposure scenarios.

The dossier updated on 4 April 2012 does not contain additional information for risk characterisation for physicochemical properties of the registered substance.

The Registrant is therefore requested to assess the likelihood and severity of any event occurring due to flammability of the registered substance for each exposure scenario, and update the CSR accordingly.

e. Information on specifications of protective gloves

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. The requirements for Safety Data Sheets are specified in Annex II of the REACH Regulation. In particular, Section 8.2.2.2. (b) of Annex II describes the requirements for hand protection in order to avoid dermal exposure:

- the type of material and its thickness, and
- the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure.

The Registrant has provided instructions in all exposure scenarios to use suitable chemical resistant gloves in case of potential skin contact.

Although the Registrant has provided instructions to use suitable chemical resistant gloves in case of a potential skin contact, the specific information regarding the material, its thickness and breakthrough time of the gloves has not been provided, and therefore, the information requirements for exposure control have not been fulfilled.

The dossier update on 4 April 2012 does not contain sufficient information for the specifications of protective gloves, as requested in the original draft decision.

The Registrant is accordingly requested to provide the information on the type of glove material and its thickness, as well as on the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure for all exposure scenarios.

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 or to other international test methods recognised as being appropriate 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.

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