EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114290254-50-01/F Helsinki, 18 December 2014

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

For ethylene carbonate, CAS No 96-49-1 (EC No 202-510-0), 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 ethylene carbonate, CAS No 96-49-1 (EC No 202-510-0), submitted by [redacted] (Registrant). ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes VII to X was done on the lead registrant dossier of this joint submission.

This decision is based on the registration as submitted with submission [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 24 July 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 7 October 2013.

On 18 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 17 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision on the request to revise the name in the IUPAC nomenclature, while he provided comments on the request to revise the DNEL, to revise environmental release factors, the exposure assessment for dermal route and the risk characterisation accordingly.

On 15 January 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 by removing requests for which the required information was provided in the update. The Statement of Reasons (Section III) was changed accordingly. Other elements of the comments and update relating to the information requirements of the draft decision are reflected in Section III, whereas no amendments to the respective "Information Required" (Section II) were made.

The Registrant's comment on the deadline set in the draft decision and on his willingness to update the registration dossier after the lead company has updated his dossier (following receipt of the final decision) was taken into consideration by ECHA and the deadline was amended. These considerations are reflected in Section III of the draft decision.

On 24 July 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, a proposal for amendment to the draft decision was submitted.

On 29 August 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 8 September 2014 ECHA referred the draft decision to the Member State Committee.

By 29 September 2014 the Registrant did not provide any comments on the proposal for amendment.

After discussion in the Member State Committee meeting on 28-29 October 2014, a unanimous agreement of the Member State Committee on the draft decision was reached on 29 October 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)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised DNELs for workers and for the general population using the recommended assessment factors by ECHA and deriving a DNEL long-term local inhalation for workers
   or
   A full justification for not using the recommended assessment factors in DNEL derivation and a qualitative assessment of local inhalation effects (Annex I, 1.4.1. of the REACH Regulation), as specified in section III A.1;

2. Revised exposure assessment (Annex I, 5.0.) with respect to
   a) A revised exposure assessment for dermal route and risk characterisation according (Annex I, sections 5.2.4. and 6.), as specified in section III A.2.a

3. Documentation for the recommended personal protective equipment, i.e. gloves to be worn when handling the substance need to be specified clearly (Article 14(6), Annex I, 5.1.1.)

B. Deadline for submitting the required information

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 January 2017**.

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 which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. Revised DNELs for workers and for the general population using the recommended assessment factors by ECHA and deriving a DNEL long-term local inhalation for workers or a full justification for not using the recommended assessment factors in DNEL derivation and a qualitative assessment of local inhalation effects (Annex I, 1.4.1. of the REACH Regulation), as further specified below

Annex I, 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The ECHA Guidance on information requirements and chemical safety assessment, R.8 (version 2.1, November 2012) provides further details and specifically provides default factors which should be applied to derive derived no effect levels (DNELs) in the absence of substance specific information.

The assessment factors (AF) applied by the Registrant and the default assessment factors recommended in the ECHA Guidance R.8 are given in detail in Annex I attached to this decision.

ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1. In particular, ECHA notes that for the systemic long term DNELs for inhalation route and dermal route both for workers and the general population the AF for duration of exposure is 1. The starting point for these DNELs is a prenatal developmental toxicity study which uses an exposure period corresponding to a sub-acute study and therefor the default AF of 6 should have been applied.

Furthermore, ECHA notes that the Registrant has not dervived a DNEL for long-term local inhalation to demonstrate that in industrial or professional spray application the risk for respiratory tract is controlled. The Registrant justifies the omission of this DNEL with the argument that no local irritant effects were observed in the oral prenatal developmental toxicity study. ECHA considers this argument not valid as the gastrointestinal tract with its low pH is not as sensitive to local irritation as the respiratory tract. ECHA further observes that the substance is irritating to the eye indicating irritative potential. Therefore a risk characterisation is needed for long-term local inhalation effects either quantitatively based on a DNEL or qualitatively according to *Practical Guide 15 How to to undertake a qualitative human health assessment and document it in a chemical safety report*[1].

As explained above, the information provided on DNELs for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1. because the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. and the deviations are not fully justified. Furthermore a DNEL has not been derived for long-term local inhalation for workers. Consequently it is necessary to revise the DNELs or to provide a full justification.

As regards assessment factors, the Registrant is given two options: The Registrant shall revise the DNELs for workers and for the general population by applying the assessment factors recommended by ECHA that are appropriate in this case. Subsequently, the Registrant shall re-assess related risks. In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the current DNEL derivation for workers and for the general population provided in the CSR by specifying how the following has been taken into account:

- the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- the nature and severity of the effect;
- the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
- and that the DNELs reflect the likely route(s), duration and frequency of exposure.

As regards DNEL for long-term local inhalation for workers, the Registrant is given two options: The Registrant shall derive a DNEL according ECHA Guidance on information requirements and chemical safety assessment, R.8 (version 2.1, November 2012). In the alternative, the Registrant shall perform a qualitative assessment of local inhalation effects.

[1] Link to ECHA Practical Guide 15 is: http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf

ECHA notes that the Registrant, in his official comments according to Article 50(1), refers to a need to coordinate DNEL derivation with the lead registrant when justifying his request to extend the deadline to submit the requested information. That part of the issue is addressed under section III.B. ECHA notes further that the updated dossier does not contain any revision of the DNELs as well as no derivation of DNEL long-term local inhalation for workers nor a qualitative assessment for the local inhalation effects.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the CSR either of the following information: Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA, and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation. In addition the Registrant is requested to submit in the chemical safety report either of the following information: A DNEL long-term local inhalation for workers and re-assessment of related risks *or* a qualitative assessment of local inhalation effects.

Notes for consideration by the Registrant

Any relevant new information on toxicological studies shall be taken into account when revising the DNELs.

2. Revised exposure assessment (Annex I, 5.) with respect to
a) A revised exposure assessment for dermal route and risk characterisation (Annex I, sections 5.2.4. and 6.)

Pursuant to sections 0.6.2. and 0.6.3. of Annex I of the REACH Regulation the chemical safety assessment (CSA) performed by a Registrant shall include an exposure assessment according to section 5 and risk characterisation according to section 6 of Annex I. of Annex I. Annex I, section 5.2.4. of the REACH Regulation requires the Registrant to perform an estimation of the exposure levels for all human populations (workers, consumer and humans liable to exposure via the environment) for which exposure to the substance is known or reasonably foreseeable. Each relevant route of exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. In addition, Annex I, section 5.2.5. of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

ECHA notes that the Registrant has used ECETOC TRA version 2 to estimate exposure for a variety of worker and consumer exposure scenarios. More precisely the Registrant has used the local exhaust ventilation (LEV) exposure modifier even when inappropriate such as for estimating dermal exposure.

ECHA underlines that the Guidance on information requirements and chemical safety assessment, R.14 (version 2.1, November 2012) (section R.14.4.8, page 21) advises against the use of the LEV modifier for dermal exposure estimation.

ECHA notes that when using the LEV modifier the calculated exposure estimates are likely to be unrealistically low, as explained further in the above mentioned Guidance, and therefore the worker exposure assessment for the dermal route needs to be revised. Taking into account the need to revise the calculated DNEL(s), the Registrant shall ensure that the calculated risk characterisation ratios will still be below 1, in order to demonstrate the safe use of the registered substance.

As explained above, the information provided on the dermal exposure estimates for the registered substance in the CSR does not meet the general provisions for preparing a CSR as described in Annex I. Consequently it is necessary to revise the dermal exposure estimates.

ECHA notes that the Registrant expressed in his official comments according to Article 50(1), the willingness to revise the exposure assessments for dermal route and risk characterization accordingly. However, ECHA notes that the Chemical Safety Report included in the latest updated dossier does not contain any revision of the exposure assessments and risk characterization for the dermal route.

Based on the above the Registrant shall revise the exposure assessment for dermal route and assess related risks. The revised DNELs requested under section II.A.1 shall be taken into account when assessing the related risks. The CSR shall be amended accordingly.

3. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance (Article 14(6), Annex I, 5.1.1.)

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.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (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 accordance with Annex II, section 8.2.2.2. (b)(i)). The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier.

To ensure the safe use of a substance Annex I Section 5.1.1 requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the hands for a pre-determined duration shall be specified. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material.

Therefore, pursuant to Article 41(1)(c) the registrant is required to provide in the CSR a description of the gloves to be used when handling the pure substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the safety data sheets.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 6 months from the date of adoption of the decision. In his comments on the draft decision of 18 November 2013 the Registrant requested an extension of the timeline to 36 months, i.e, the deadline indicated in the draft decision addressed to the lead Registrant. He sought to justify this request with the need to wait for the lead Registrant to submit a registration dossier update to make sure that all information is harmonised, to avoid confusion among downstream possibly arising from different DNELs by different suppliers and to ensure equal treatment. He further noted that as regards issues related to chemical safety assessment the requests in the draft decisions received by each registrant of this substance were very similar or exactly the same in content and therefore should be processed together. ECHA considers the request reasonable and justified by the need to have coordinated updates of relevant information requirements requested in the draft decision of lead and member registrants. Therefore, ECHA modified the deadline of the decision and set the deadline first to 36 months. Following proposals for amendment made by Member States, the deadline set in the relevant decision to the lead Registrant was changed from 36 months to 24 months from the date of the adoption of the decision. Therefore, to ensure consistency in DNELs and co-ordination of updates, also the deadline of the present decision was modified accordingly.

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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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Director of Evaluation

Annex I.

Assessment factors (AF) applied by the Registrant:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5
- exposure duration: 1
  (overall AF: 12.5)

For workers - systemic long term – dermal route:
- interspecies: 10
- intraspecies: 5
- exposure duration: 1
- absorption difference dermal-oral: 1
  (overall AF: 50)

For the general population - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 10
- exposure duration: 1
  (overall AF: 25)

For the general population - systemic long term – dermal route:
- interspecies: 10
- intraspecies: 10
- exposure duration: 1
- absorption difference dermal-oral: 1
  (overall AF: 100)

For the general population - systemic long term – oral route:
- interspecies: 10
- intraspecies: 10
- exposure duration: 1
  (overall AF: 100)

The default assessment factors recommended in the ECHA Guidance, R.8:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 6 (sub-acute to chronic)
  (overall AF: 75)

For workers - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 6 (sub-acute to chronic)
- absorption difference dermal-oral: 1
  (overall AF: 300)

For the general population - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)

- intraspecies: 10 (general population)
- exposure duration: 6 (sub-acute to chronic)
  (overall AF: 150)

For the general population - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 6 (subchronic to chronic)
- absorption difference dermal-oral: 1
  (overall AF: 600)

For the general population - systemic long term – oral route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 1 (a chronic study)
  (overall AF: 100)