EUROPEAN CHEMICALS AGENCY

Helsinki, 21 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114379315-44-01/F
Substance name: 2-ethyl-4-methylimidazole
EC number: 213-234-5
CAS number: 931-36-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28/02/2017
Registered tonnage band: [redacted]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment;**

2. **Identification of DNEL(s) and risk characterisation (Annex I, Section 1.4. and 6.): revise DNELs for long-term systemic effects via inhalation and dermal routes for workers using the assessment factors according to ECHA Guidance R.8 for DNEL derivation and revise the risk characterisation accordingly *or* provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation;**

3. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: revise exposure estimates for exposure scenarios ES3, CS2-4; ES5, CS2-6; ES7, CS2; ES9, CS7-8 and ES10, CS2-12 using a model within its domain of applicability and in accordance with the guidance for the model used and revise the risk characterisation accordingly or provide adequate measured representative exposure data;**

4. **Exposure assessment (Annex I, Section 5.1.1.) for human health: provide documentation for the recommended personal protective equipment;**
   - specify the filter type/class for the respiratory protective equipment.

You have to submit the requested information and update the chemical safety report in an updated registration dossier by **28 May 2018**

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1.

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

1. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

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 (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

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, then the CSA shall also include the additional steps: 5) Exposure assessment, including generation of exposure scenario(s) and exposure estimation, and 6) 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.

According to Annex I, Section 5.0. of the REACH Regulation, 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 of the REACH Regulation.

ECHA notes that you have classified the pure substance as:

- Acute Tox. 4 (H302: Harmful if swallowed).
- Skin Irrit. 2 (H315: Causes skin irritation).
- Skin Sens. 1B (H317: May cause an allergic skin reaction).
- Eye Damage 1 (H318: Causes serious eye damage).

and the crude substance as:

- Acute Tox. 4 (H302: Harmful if swallowed.
- Skin Corr. 1B (H314: Causes severe skin burns and eye damage.
- Skin Sens. 1B (H317: May cause an allergic skin reaction.
- Eye Damage 1 (H318: Causes serious eye damage).
- Carc. 2 (H351: Suspected of causing cancer.

Therefore, the registered substance fulfils the criteria set out in Article 14(4) of the REACH Regulation and an exposure assessment and a risk characterisation are required in the CSA.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, Section 5.0. of the REACH Regulation, it has to cover all hazards that have been identified according to Sections 1 to 4 of Annex I of the REACH Regulation. As further outlined in ECHA Guidance on information requirements and chemical safety assessment, Part B, chapter B.8 Scope of Exposure Assessment (version 2.1, December 2011), such identified hazards necessitating exposure assessment are also including 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"*. 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 PECs, is mandatory for the water, sediment and soil environmental compartments"*.

In your CSR, you did not provide an exposure assessment and a risk characterisation for the environment based on the following justification:

> *"In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment".*

ECHA disagrees with your claim that no hazard was identified for the environment and notes that adverse effects were actually observed in some environmental toxicity studies. In particular, a 96h-EC50 of 68.1 mg/L was obtained in the short-term toxicity study to fish. These effects have been observed below the highest test concentration recommended in the test guidelines (i.e. typically 100 mg/L for short-term aquatic toxicity tests). Therefore, ECHA considers that the required exposure assessment and risk characterisation needs to address the environment as well.

In your comments, you have agreed to provide an exposure assessment and corresponding risk characterisation for the environment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to provide in your CSR an environmental exposure assessment covering all life-cycle stages of the registered substance originating from manufacture and identified uses, and subsequently provide a risk characterisation for each exposure scenario to demonstrate the safe use of the substance.

2. Identification of DNEL(s) and risk characterisation (Annex I, Sections 1.4. and 6.)

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 (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I, Section 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 Chapter R.8 provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information to fulfill the REACH obligations.

ECHA notes that the assessment factors (AF) applied were neither derived in accordance to the default assessment factors recommended in the ECHA Guidance R.8 for DNEL derivation nor did you provide a full justification for the derivation of DNELs, which would be in line with Annex I, 1.4.1

In particular, you have considered allometric scaling to address the uncertainty arising from interspecies variation due to differences in metabolic rate in the derivation of DNELs for long-term systemic effects via inhalation and dermal routes for workers, but you have not applied the additional default assessment factor of 2.5 to address the remaining interspecies differences. If no substance specific data are available, the additional factor of 2.5 for other interspecies differences is to cover the uncertainty of toxicokinetic differences not related to metabolic rate and toxicodynamic differences. Furthermore, you have not given any justification for that.

As explained above, the information provided on DNEL 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.

Consequently, you are given two options: you shall revise the DNELs for workers by applying the assessment factors recommended by ECHA that are appropriate in this case as specified above. Subsequently, you shall re-assess related risks.

In the alternative, you shall, in accordance with Annex I, Section 1.4.1, provide a full justification for the DNELs derived for workers provided in the chemical safety report by specifying how the following has been taken into account:

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.

In your comments, you have agreed to provide a detailed justification for not using default assessment factors.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise DNEL(s) for long-term systemic effects via inhalation and dermal route for workers using the default assessment factors and other recommendations of ECHA Guidance R.8 for DNEL derivation and revise the risk characterization accordingly or provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation.

3. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health

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

As described in section 1 above, the registered substance fulfils the criteria set out in Article 14(4) of the REACH Regulation and an exposure assessment and a risk characterisation are required in the CSA.

Annex I, Section 5.2.4 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.

Further, Annex I, Section 5.2.5. states that appropriate models can be used for the estimation of exposure levels. However, special consideration shall be given to representative exposure data where available, when conducting the exposure assessment.

Following a proposal for amendments from one Member State Competent Authority (MSCA), ECHA notes that according to the information provided in the technical registration dossier and in the CSR, the worker exposure estimates in the CSR have been calculated using EasyTRA 4.1.0. Furthermore, it is stated that EasyTRA works in compliance with ECETOC TRA version 3 (as of July 2012) for the calculation of worker exposure levels. It is further stated by you that "*following modifications are possible for the worker exposure assessment, that are already suggested in the ECETOC TRA guidance document TR114: factor for peak exposure, use of the exact concentration instead of ECETOCs category approach, and use of the exact process duration instead of ECETOCs category approach.*"

ECHA points out that the ECETOC version 3 applies the same TRA modifiers for concentration of the substance in a mixture as currently used in TRA v2 for inhalation exposures as explained in the ECETOC TRA Technical Report No 144, page 20 and in Table 6. The inherent conservatism of such a banded modifier is consistent with a screening approach. ECETOC TRA v. 3 does not support the use of linear correction factors to the initial TRA estimates. The TRA is a tier 1 model based on a banding approach and supposed to be inherently conservative. The banded modifiers are supposed to be consistent with the screening approach of a tier 1 model. According to ECETOC TR 114, if the concentration of the substance in a mixture is > 25 %, the mixture should be treated like the pure substance, for concentrations 5-25 % an exposure reduction of 40 % should be applied, for concentrations 1-5 % an exposure reduction of 80 % and for concentrations <1 % an exposure reduction of 90 % (see TR114, p.20).

In your CSR a linear relationship between concentration and estimated exposure for inhalation and dermal route has been assumed in several contributing scenarios (CS) for several exposure scenarios (ES) when the exposure estimates were calculated (namely ES3, CS2-4; ES5, CS2-6; ES7, CS2; ES9, CS7-8 and ES10, CS2-12). As a consequence, the estimated exposure values would be higher and the RCRs above 1 for some contributing scenarios (e.g. the contributing scenarios 2 (PROC 8a), 3 (PROC 8b) and 4 (PROC 9) in exposure scenario 3 (charging and discharging of substances and mixtures, professional)).

Therefore, the risks arising from the use of the substance in a mixture might not be adequately controlled.

The ECHA Guidance (R14 Version 3.0 August 2016) advises that estimation of exposure can be made from either (a) actual exposure measurements or (b) exposure estimation by analogous situations or exposure models which are applicable. It also advises that it is generally not admissible to further refine the outputs of the exposure models through, for example, applying linear reductions for elements such as concentration in mixtures or duration of exposure unless robust scientific justification is provided.

ECHA notes that you are using exposure estimates in your exposure scenarios which have been calculated by using a model in an inappropriate manner. By applying linear approach, you have submitted risk characterisation ratios (RCRs) for the substance subject to the present decision that are unreliable and cannot be compared against the derived no-effect level (DNEL) as foreseen in the risk characterisation (Annex I, 6.2.).

In your comments on the MSCA's proposal for amendment to the draft decision, you are claiming that the use of exact concentration is possible in ECETOC TRA and to justify it you are referring to the ECETOC TR No 114, section 2.2.7, page 14, referencing to the Raoult's and Dalton's law. You also claim that you are using substance specific and more refined Tier 2 approach requiring a specific justification which is found in the respective tables in the CSR you provided.

As mentioned before, ECHA highlights that if a model is used to estimate exposure, it has to be used within its boundaries, i.e. without modifying the underlying basis of the model or robust scientific justification should be provided.

Thus, ECHA notes that ECETOC TR No 114 page 14 (Substances in mixture) is referring to the earlier version of Technical Report 107 (2009) where it is explained that although "*as a first approximation the concentration of a chemical in the room air is assumed to be directly proportional to the concentration in the mixture*" and that "*this approach is scientifically covered by Raoult's and Dalton's law*", in reality this approach is "*only valid within the restrictions of an "ideal solution"*". Thus, it is concluded that to take into account the uncertainties resulting from both false positives (measured vapour pressure is lower than anticipated) and false negatives (the measured vapour pressure is higher than anticipated) the ECETOC TRA tool uses the conservative exposure modifying factors available in ECETOC TR No 107, page 12, Table 2. An alternative is also mentioned that would consist of "*adjust the vapour pressure to reflect the partial vapour pressure for the component of interest. The resulting vapour pressure may result in moving the exposure estimate from one volatility band to a lower volatility band*".

ECHA notes that the two main points in your justification to support that the exact concentration can be used, are a low vapour pressure (0.0084 hPa in 50°C) and low estimated dermal absorption. However, the vapour pressure you provided in your comments, is a vapour pressure of the pure registered substance in the temperature of 50°C and it does not reflect the partial vapour pressure in a mixture. In addition, you also state that due to the low vapour pressure, an enrichment of the registered substance in the air above a formulation is most unlikely. However, you have not demostrated that with any data. Also, the linear dependency has not been demonstrated in your justification. ECHA also notes that in the exposure assessment, the potential dermal exposure is estimated and the dermal absorption should be taken into account in the DNEL derivation. Thus, the low

dermal absorption should be reflected in the dermal DNELs and not in the potential dermal exposure assessment.

ECHA notes further that as mentioned in ECHA's Guidance R.14. (version 3.0, August 2016), Appendix A.14-1.4, "*if an initial assessment of exposure is not adequate, i.e. safe use is not reliably demonstrated, a refined assessment is necessary*". Further, several examples of models to be used in a refined assessment include Stoffenmanager, Advanced REACH Tool (ART) and RISKOFDERM (the latter for exposure estimation via dermal route). ECHA notes that you also refer to other exposure models in your argumentation and you have even used ART for estimating the exposure in the contributing scenarios related to spraying applications. However, you have not used it for the other scenarios. As an alternative, exposure measurements in real exposure situations can be carried out.

Therefore, ECHA does not accept your use of linear approach, nor the justification for applying it in the exposure assessment.

You also note in your comments that you have submitted together with the newest CSR in February 2017 an old version of exposure assessment (2013), which you have committed to remove from IUCLID in the next update.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to revise exposure estimates for exposure scenarios (ES3, CS2-4; ES5, CS2-6; ES7, CS2; ES9, CS7-8 and ES10, CS2-12) using a model within its domain of applicability and in accordance with the guidance for the model used and revise the risk characterisation accordingly or provide adequate measured representative exposure data.

4. Exposure assessment (Annex I, Section 5.1.1.) for human health

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

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 (SDS) in order to minimize the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hand or respiratory protection 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 exposure in accordance with Annex II, section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively). The information provided in the SDS shall be consistent with information in the CSR (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment for preventing exposure via inhalation and/or dermal exposure is missing both from the CSR and from the information on safe use within the IUCLID dossier. In IUCLID Section 11 you have reported the following:

"Hand protection: Chemical resistant protective gloves (EN 374), Suitable materials also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): butyl rubber (butyl) - 0.7 mm coating thickness. Use additional heat protection gloves when handling hot molten masses (EN 407), e.g. of textile or leather. Manufacturer's directions for use should be observed because of great diversity of types.
Supplementary note: The specifications are based on tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined through testing.
Eye protection: Tightly fitting safety goggles (cage goggles) (e.g. EN 166) and face shield. General safety and hygiene measures.
Wearing of closed work clothing is required additionally to the stated personal protection equipment."

In the CSR, you indicated the following for skin protection: *The concentration of EMIM is assumed to be above the concentration limit for skin irritation ([redacted]%) in all processes. Hence, the risk of skin irritation is evaluated qualitatively. Likelihood/frequency of dermal exposure is considered to be at most low for the PROCs 1, 2, 3, 8b, 9, 14, 15, 21 due to generally closed processes and the careful handling of the (hot) substance in sampling situations and laboratories. The intensity of exposure may in some cases potentially be medium to high, however, actual exposure will be largely prevented by use of chemically resistant gloves. Likelihood and frequency of exposure may be high due to the open nature of the PROCs 4, 5, 8a, 10, 13. The intensity of exposure may in some cases potentially be high as well, however, actual exposure will be largely prevented by use of chemically resistant gloves. The process of industrial and professional spraying described by PROC 7 and 11 respectively is considered an open process with aerosol formation. Both the likelihood/frequency and the intensity of dermal exposure are considered high. However, actual exposure will be largely prevented by use of chemically resistant gloves. With the protective measures described in the exposure scenario taken into account, the actual dermal exposure is very low and the risk of skin irritation is considered to be controlled."*

ECHA notes that the description of hand protection is sufficiently described in the IUCLID and in the CSR. However, the specific description of respiratory protection is missing. ECHA notes that you have reported in the CSR that the process of industrial and professional spraying (PROCs 7 and 11) is an open process with aerosol formation. In the contributing scenarios 7 and 9 (PROC 10 and PROC 11) of the exposure scenario 10, you have included respiratory protection into the operational conditions and into your exposure assessment.

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. You have reported respiratory protection in the exposure scenario 10 in the CSR as required personal protective equipment to prevent inhalation exposure to the substance. Typically, this information, as a minimum, has to specify the type/class of filters that are capable of preventing inhalation exposure for a pre-determined duration and delivering the assessment

protection factor specified by you. This information should be included into the IUCLID Section 11 and in the CSR.

In your comments, you have agreed to provide more information about the respiratory protective equipment.

Therefore, pursuant to Article 41(1) you are requested to provide documentation for the recommended personal protective equipment:
- specify the filter type/class for the respiratory protective equipment.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 24 January 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-56 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.