EUROPEAN CHEMICALS AGENCY

Helsinki, 21 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114379316-42-01/F
Substance name: 1-methylimidazole
EC number: 210-484-7
CAS number: 616-47-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10/06/2016
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. **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 recommended by ECHA and revise the risk characterisation accordingly *or* provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation**

You have to submit the requested information in an updated registration dossier by **28 May 2018**.You also have to update the chemical safety report, where relevant.

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. Identification of DNEL(s) and risk characterisation (Annex I, Sections 1.1., 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 not derived in accordance to the default assessment factors recommended in the ECHA Guidance R.8 for DNEL derivation, and that you have not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1. in the absence of applying the recommended AFs. 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 will cover the uncertainty of toxicokinetic differences not related to metabolic rate and toxicodynamic differences. Furthermore, you have not given any justification for not using the additional factor.

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 agreed to provide a detailed justification for not using the 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.

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 9 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 proposals for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendments.

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.