Decision number: CCH-D-2114302945-50-01/F Helsinki, 30 June 2015

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

For 2-phenoxyethanol, CAS No 122-99-6 (EC No 204-589-7), 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 2-phenoxyethanol, CAS No 122-99-6 (EC No 204-589-7), 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 number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 5 March 2015, 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 23 October 2013.

On 3 December 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 16 January 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments.
The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 12 November 2014 the Registrant updated his registration dossier with the submission number [redacted].

use and exposure categories if appropriate) and exposure estimation, as well as risk characterisation. The additional steps of the CSA shall be carried out in accordance with Section 5 (for the exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

1. DNELs for long term dermal exposure – systemic effects for workers and for the general population

According to Article 14(3) and Annex I, 1.0.3 and 1.4.1 of the REACH Regulation, DNEL(s) (Derived No-Effect Levels) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. Depending on the available information and the exposure scenarios it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers). The following factors shall, among others, be taken into account when deriving DNELs:

-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;
-the DNELs reflect the likely route(s), duration and frequency of exposure.

Annex I, 1.4.1 also requires that a full justification for the establishment of DNELs is given specifying, among others, the choice of information used, the route of exposure and the duration and frequency of exposure of the substance for which the DNEL is valid.

The ECHA "Guidance on information requirements and chemical safety assessment" (Volume 8, R8[2]) provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

In the present case, ECHA points out that since the dermal absorption of the registered substance is, according to the technical dossier, high, >60 % and rapid and the substance is used in cleaning agents, textile processing aids, co-formulants in plant protection products, there may be a concern for workers and general population. Accordingly, it is necessary to identify a respective DNEL for these relevant human populations.

In identifying respective DNELs for these two human populations, ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8[1] 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 the Registrant has not used the default AF of 5 (workers) and 10 (general population) for intraspecies differences (ECHA guidance R 8; chapter R.8.4.3.3) to derive a DNEL for long term exposure for systemic effects. Instead, the Registrant has used the AF of 3 (workers) and 5 (general population). This means that higher DNELs than those based on the ECHA Guidance are derived.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, proposed to further justify the use of the ECETOC assessment factors in the derivation of the DNELs and referred to distributions of human data for various toxicokinetic and toxicodynamic parameters. Moreover, the Registrant has stated that "the 95th percentile is considered sufficiently conservative to account for intraspecies variability in the general population".

[2] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

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, section 0.7, if the substance is placed on the market, the relevant exposure scenarios, including the risk management measures and operational conditions, shall be included in an annex to the safety data sheet in accordance with Annex II to the REACH Regulation (as amended by Commission Regulation (EU) No 453/2010).

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

According to Annex I, 5.2.5, appropriate models can be used for the estimation of of exposure levels.

In the present case, ECHA notes that the Registrant has used ECETOC TRA model to predict the dermal challenge. In ECHA's view, this model cannot, however, be considered appropriate for the following reasons:

- Professional spraying during cleaning has been modelled by use of the ECETOC TRA tool and with exposure modification provided through use of gloves. It is likely that dermal exposure will be more than to the hands only so a reduction in exposure through use of gloves alone is unrealistic for a spraying task.

- The Registrant has provided similar spraying exposure scenarios for foliar application of solutions of 2-phenoxyethanol, both indoors and outside with concentrations up to [redacted]%. The Registrant has used the ECETOC TRA model to assess exposures during spray application. This model is not appropriate for assessing spray application for aqueous solutions. The model also fails to address the potential exposure arising from whole body deposition, resulting from aerosol and potential contact with treated plants. These exposures are best addressed through use of models used to assess plant protection products. One such alternative model for assessing spraying exposures during foliar application may be the UK POEM model and outputs from this model are valid to help determine the exposure level for regulatory purposes and would indicate the need for appropriate risk management measures in the form of gloves and protective clothing.

- With the predicted 60% dermal absorption for this substance, it is critical to have the correct risk management measures in place to prevent those exposures that fall outside the ECETOC TRA modelled range. The ECETOC TRA is not validated and is considered a poor model for estimating dermal exposure to aqueous solutions and generally only considers exposure to the hands and forearms, whereas exposure can occur to other body parts. The model is a poor tool upon which to determine the appropriate suite of risk management measures for a substance with the physical properties, use profile and skin penetration characteristics of 2-phenoxyethanol.

In ECHA's view, the ECETOC TRA model thus has the potential to under-predict dermal challenge, i.e, what gets on the skin especially when compared to other specifically developed models, based on real data (e.g. RISKOFDERM, REACH Guidance R14[3]). This is a

[3] Link to ECHA guidance document R.14 is: http://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf

potential for real dermal challenge other than to the hands, rapid absorption through the skin, and the deficiencies in the current proposals for personal protective equipment. The workers and professionals should wear, as a minimum, protective clothing to the standard EN 13034:2005, Chemical protective clothing offering limited protection against liquid chemicals (type 6 and type PB [6] equipment). Where it is necessary to protect a part of the body other than the hands, the type and quality of protection equipment required shall also be specified.

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

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