EUROPEAN CHEMICALS AGENCY

Helsinki, 21.02.2014

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DECISION ON A SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For 2-(4-tertbutylbenzyl)propionaldehyde, CAS No 80-54-6 (EC No 201-289-8), registration number [redacted]

Addressee(s): [redacted]**, Registrant of 2-(4-tertbutylbenzyl)propionaldehyde** (concerned registrant)

Based on an evaluation by the **Swedish Chemicals Agency** as the Competent Authority of **Sweden** (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registration of the concerned registrant after 5 September 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

This decision does not imply that the information provided by the concerned registrant in the registration is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier of the concerned registrant at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Sweden has initiated substance evaluation for 2-(4-tertbutylbenzyl)propionaldehyde, CAS No 80-54-6 (EC No 201-289-8) based on a registration dossier submitted by the concerned registrant and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

The present decision is exclusively addressed to [redacted] and it contains information requests that are additional to the information requests included in the decision addressed to all concerned registrants of 2-(4-tertbutylbenzyl)propionaldehyde.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health effects for reprotoxicity and workers and consumers exposure and a wide dispersive use 2-(4-tertbutylbenzyl)propionaldehyde was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of Sweden was appointed to carry out the evaluation. In the course of the evaluation, the evaluating MSCA noted additional concerns regarding endocrine disrupting properties and developmental toxicity of the substance.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared amongst others the present draft decision

pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted this draft decision to ECHA on 22 February 2013.

On 4 April ECHA sent the draft decision to the concerned registrant and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 6 May ECHA received comments from the concerned registrant of which it informed the evaluating MSCA without delay.

The MSCA considered the registrant's comments received and did amend Section II of the draft decision. The comments were reflected in Section III of the draft decision (Statement of Reasons).

In accordance with Article 52(1) of the REACH Regulation, on 5 September 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Neither Competent Authorities of the Member States nor ECHA proposed amendments to the draft decision and ECHA took the decision pursuant to Articles 52(2) and 51(3) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrant shall submit the following information for the registered substance in compositions [redacted] following the instructions indicated in Section III of the present decision:

1. Further information on the justification behind the derivation of the critical DNEL(s), including the derivation of missing endpoint-specific DNELs.

Pursuant to Article 46(1) of the REACH Regulation the concerned registrant is also reminded of the legal obligation to update the registration dossier with the existing data from the study provided to the evaluating MSCA on developmental effects of the [redacted] test method: One-Generation Reproduction Toxicity Study in Wistar Rats Oral Administration (Gavage), OECD 415, OECD 416).

Pursuant to Article 46(1) of the REACH Regulation the concerned registrant is also reminded of the legal obligation that after generation of new data, estimating exposure or deriving new DNELs, the Chemical Safety Assessment (including the RCRs) should be revised and updated.

Pursuant to Articles 46(2) of the REACH Regulation, the concerned Registrant shall submit to ECHA by 21 August 2014 an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on 2-(4-tertbutylbenzyl)propionaldehyde and other relevant and available information, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the

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environment.

1. Further information on the justification behind the derivation of the critical DNEL(s), including the underlying derivation of missing endpoint-specific DNELs

The registrant has argued that a repeated dose subchronic, rat, oral study with a NOAEL = 25 mg/kg bw/d for testicular effects is appropriate for the derivation of DNELs. However, the NOEL 5 mg/kg bw/d was chosen as a point of departure with the argumentation that this value is supported by NOAEL of 4.1 mg/kg bw/day for maternal and developmental effects in a prenatal developmental study with 14 days of dosing. Furthermore, the registrant used an assessment factor AF of 4 (allometric scalling) as the only interspecies differences assessment factor.

It is not clear why the registrant did not derive all endpoint-specific DNELs in order to select the lowest as critical DNEL(s)[1] according to ECHA´s guidance on IR-CSR (ECHA, 2010)[2]. The Registrant provided a comment including a statement that the default assessment factors have been modified into substance specific assessment factors (AF), considering the intrinsic hazard properties of the registered substance. The justification of this modification is missing or unclear.

In the draft decision sent to the Registrant for comments, the basis for the choice of AF for exposure duration used by the Registrant was stated to be unclear. The Registrant's comment on the AF for time extrapolation of the results of the developmental toxicity study /maternal toxicity study however clarified this specific issue.

Based on the available information the evaluating MSCA cannot confirm that the DNELs as derived by the Registrant are adequate to prevent all reported adverse effects.

In order to clarify this concern further information on the justification behind the derivation of the critical DNEL(s), including the underlying derivation of missing endpoint-specific DNELs and justification of the modification of the default AF into the substance specific is requested.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to provide further information on the justification behind the derivation of the critical DNEL(s), including the underlying derivation of missing endpoint-specific DNELs.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52 and 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 the 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.

[redacted]

Jukka Malm
Deputy Executive Director

[1]These critical DN(M)EL(s), used for the risk characterisation, should be the lowest DN(M)EL obtained for each exposure pattern.
[2] ECHA, 2010. Guidance on information requirements and chemical safety assessment Chapter R.8: characterisation of dose [concentration]-response for human health.