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 44(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 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, 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 3 May ECHA received comments from the concerned registrant of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the registrant's comments stating that the registrant agrees to provide information required under endpoints 1, 2, 3 and 4. The MSCA did not amend Section II or Section III of the draft decision.

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 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 using the indicated instructions and the registered substance subject to the present decision:

1. Further information on the justification behind the derivation of the critical DNEL(s), including the underlying derivation of missing endpoint-specific DNELs,
2. Further information on exposure of workers via inhalatory route,
3. Further information on exposure of consumers due to the use of products containing the substance in concentrations up to [redacted],
4. Further information on consumers' long term exposure.

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(s) 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 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 derives acute and long-term systemic effect DNELs for the dermal route based on a short 5 days dermal test with a NOAEL for testicular toxicity. In the oral treatment prenatal developmental toxicity study on rats, effects on liver and AChE were reported at lower doses than those eliciting testicular toxicity. Oral to dermal route extrapolation for those effects should be considered. Furthermore it is not clear why the registrant did not derive all endpoint-specific DNELs in order to select the lowest as the critical DNEL(s)[1] according to ECHA´s guidance on IR-CSR (ECHA, 2010)[2].

Based on the available information, the evaluating MSCA cannot confirm that the DNEL for long-term systemic effects for dermal route as derived by the registrant is adequate to prevent adverse effects observed as maternal toxicity (liver toxicity and inhibition of AChE activity) and corresponding developmental 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 is requested.

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

2. Further information on exposure of workers via the inhalatory route

Exposure of workers via inhalation was considered by the registrant to be negligible and no inhalatory exposure was estimated for the workers exposure scenarios. Whether the inhalatory exposure can be considered negligible should be concluded with reference to the inhalatory DNEL. The registrant does not provide any supporting evidence that the inhalatory exposure is in a range much below the DNELs and thus be negligible in the risk calculation.

Based on the available information the evaluating MSCA cannot confirm that the inhalatory exposure to the substance is negligible and thus that the following risks are controlled.

In order to clarify this concern further information on exposure for workers via the inhalatory route during specific activities as defined by the listed PROCs is requested.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to provide further information based on the assessment of exposure of workers via inhalatory route.

3. Further information on exposure of consumers due to the use of products containg the substance in concentrations up to [redacted]

According to the registered information a maximum concentration of [redacted] of the substance is present in some products like air care product. However for the estimation of exposure in the exposure model, the concentration of [redacted] is used by the registrant.

Based on the available information the evaluating MSCA cannot confirm that the exposure of consumers due to the use of products containing the substance at concentration in a range up to [redacted] has been assessed and the risks are controlled.

In order to clarify this concern further information on the exposure of consumers due to the use of products containg the substance in concerntrations up to [redacted] is been requested.

[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.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to provide further information on exposure of consumers due to the use of products containg the substance in concentrations up to [redacted].

4. Further information on consumers' long term exposure

According to the registered information the registrant did not assess consumers' long term exposure. The provided justification that consumers' exposure "are considered to be acute / short term, only acute values are presented" is not considered well founded in light of information that consumers may be repeatedly or continuously over a certain period of time exposed to the substance from different product categories.

Based on the available information the evaluating MSCA cannot confirm that the exposures of consumers are of acute or short duration only. Neither can the evaluating MSCA confirm that the risks for long term systemic effects are adequately controlled.

In order to clarify this concern further information on consumers' long term exposure is requested.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to provide further information on consumers' long term exposure.

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]

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Deputy Executive Director