Helsinki, 29 May 2015

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXX-XX-XX/F)

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

**For 2-methylpropan-2-ol, CAS No 75-65-0 (EC No 200-889-7)**

**Addressees: Registrant(s)[1] of 2-methylpropan-2-ol (Registrant(s))**

This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrant(s) holding active registrations on the day the draft decision was sent are *not* addressees of this decision if they are: i) Registrant(s) who had on that day registered the above substance exclusively as an on-site isolated intermediate under strictly controlled conditions and ii) Registrant(s) who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the Health and Safety Executive as the Competent Authority of United Kingdom (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 is based on the registration dossier(s) on 4 July 2014 i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) 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 the United Kingdom has initiated substance evaluation for 2-methylpropan-2-ol (tert-butyl alcohol, TBA), CAS No 75-65-0 (EC No 200-889-7) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

for concern relating to carcinogenicity, mutagenicity and human exposure (risk characterisation ratios (RCRs) close to 1 for several worker and consumer scenarios), TBA was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of the United Kingdom was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA noted additional concerns regarding human health and the environment. The additional concerns for human exposure related to the scope of the exposure assessment, the practicality of recommendations for respiratory protective equipment (RPE) to be used by professionals working in sectors that traditionally have little or no experience with this risk management measure (RMM) and concerns regarding the application of strictly controlled conditions for the use of TBA as a transported isolated intermediate. In light of the lower derived no-effect levels (DNELs) that have been calculated by the evaluating MSCA, concerns have also arisen about the level of risk that exists for each scenario. For the Environment, evaluation raised concerns that the substance poses an environmental risk, as either the predicted environmental exposure concentrations are underestimated, and/or the value of the PNEC is overestimated.

The evaluating MSCA considered that further information was required to clarify the following concerns; Human exposure and potential environmental risks. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 18 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

**Registrant(s) commenting phase**

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s).

During this commenting period, the Registrant(s) requested an additional 30 days to provide further information and this was agreed. As part of this submission (update 4 July 2014) the Registrant(s) updated the human exposure assessment and revised the analysis of downstream uses of TBA. The new information in the revised CSR satisfied many of the information requirements placed on the Registrant(s) in the initial draft decision but also changed the exposure picture. As a result of these changes, some of the initial information requirements in section II have been modified to address uncertainties that have emerged from the updated CSR. The Statement of Reasons (Section III) was changed accordingly.

**Commenting by other MSCAs and ECHA**

In accordance with Article 52(1) of the REACH Regulation, on 30 October 2014 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.

Subsequently, a Competent Authority of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 5 December 2014 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and amended the draft decision.

On 15 December 2014 ECHA referred the draft decision to the Member State Committee.

By 5 January 2015, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 19 January 2015 in a written procedure launched on 9 January 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision.

**1. Information on worker exposure, specifically:**

a) each Registrant(s) that manufactures TBA shall provide a description of the strictly controlled conditions that are in place at their manufacturing sites within the EU and evidence that each Registrant(s) supplying TBA to downstream users for use as an intermediate has secured confirmation from those downstream users that strictly controlled conditions are in place in accordance with the criteria set out in Article 18 of the REACH Regulation, unless this has already been provided in their registration dossier;

b) a qualitative risk characterisation is required to clarify whether additional risk management measures (RMMs) are required to protect against local eye irritation arising from incidental splashes; and,

c) contextual information is required for the analogous measured data used to assess professional cleaning and degreasing also professional use of coatings, paints, inks and surface agents. The contextual information should as a minimum confirm that the measurements relate to personal samples, state the reference periods that the measurements relate to and provide information on the location (indoors or outdoors) where the samples were collected. If all of this information is available in the source reference for the data (Bock, 2000), provision of this reference will be sufficient to fulfill this requirement.

**2. The Registrant(s) with the individual transported isolated intermediate registration shall provide evidence that they have secured confirmation from downstream users that strictly controlled conditions are in place to support their claim that their registration of TBA meets the criteria set out in Article 18 of the REACH Regulation.**

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the

following information in the technical dossier and chemical safety report:

**3. Site specific monitoring of TBA in effluent before and after wastewater treatment.** Unless the Registrant(s) can provide justification for the removal efficiencies used in the CSR, site-specific monitoring of TBA in effluent is required. If site specific monitoring is required, the Registrant(s) shall follow the advice detailed in REACH guidance R16 , section 16.3 (version 2.1, 2012). The number of sites shall be justified by the Registrant(s). Samples shall be taken concurrently from both the influent and effluent for each wastewater treatment plant at each site. The number of samples and period of sampling shall be statistically justified by the Registrant(s). The Registrant(s) shall also ensure a suitably accurate substance-specific analytical method is used. The limit of detection shall be justified by the Registrant(s).

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions and the registered substance with composition as specified, subject to the present decision:

**4. Long-term toxicity testing on aquatic invertebrates (test method: Daphnia magna reproduction test, EU C.20./OECD 211);** The Registrant(s) shall take measures to minimise any losses that occur due to the volatile nature of the substance. In particular they should refer to the OECD *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures*.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by 05 September 2016 an update of the registration(s) containing the information required by this decision[2], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

The Registrant(s) should ensure that any changes made to the exposure assessment as a consequence of the further data requested are carried through and any necessary amendments made to the risk characterisation.

If the Registrant(s) further revise their CSR and conduct further exposure modelling this should be done using the latest version of the ECETOC TRA (version 3 available from: http://www.ecetoc.org/tra).

III. Statement of reasons

**1. Further information on worker exposure**

This request is relevant to the initial concerns about RCRs close to 1 and the additional concerns over the scope of the worker exposure assessment, the adequacy of the RMMs that are being proposed and the level of risk that exists for each scenario.

Initially a requirement was placed on Registrant(s) to provide descriptive text for each process/task within each scenario to demonstrate how the PROC codes that have been selected match the processes, tasks and activities that the scenario is intended to cover. This information was deemed necessary because it was not clear if all potential sources of worker exposure had been covered by the assessment. In particular, there were concerns about possible professional activities where there may be exposure to products containing TBA. The evaluating MSCA did not have enough information to see where these fitted within

[2] The deadline set by the decision already takes into account the time that Registrant(s) may require to agree on who is to perform any required tests and the time that ECHA would require to designate a Registrant (s)to carry out the test(s) in the absence of the aforementioned agreement by the Registrant(s) (Article 53(1) of the REACH Regulation).

the PROC codes that had been selected and was therefore unable to reach conclusions about risk. Additional information was included in the revised CSR submitted on 4 July 2014. This provided clarification about the types of products where TBA may be found and gave the evaluating MSCA sufficient information to make judgments about the risks associated with each use. The evaluating MSCA was therefore able to remove requests 1a, c, d, e, f, g, h, i, k, and m from the draft decision dated 29 April 2014. This additional clarification has been included following a proposal for amendment (PfA) to provide transparency with regard to the changes.

**Request 1a** in this present decision has been made to clarify elements of the initially proposed request 1b in the draft decision dated 29 April 2014 which were not addressed in the revised CSR. This proposal request 1b asked for additional information to demonstrate how the selected PROC codes match the processes, tasks and activities that the scenario is intended to cover. The revised CSR provided sufficient information to understand the activities covered by the PROC codes for each exposure scenario that has been elaborated within the revised CSR. However, the new assessment did not include exposure scenarios for manufacture and use as an intermediate. This was justified on the basis that these processes are carried out under strictly controlled conditions. Substance evaluation is a risk based process an aim of which is to clarify whether or not there are risks to health arising from the conditions under which a substance is manufactured and used. Where TBA is handled under strictly controlled conditions, the risks to health are expected to be low. However, the updated registration does not include a description of the strictly controlled conditions that are in use at manufacturing sites operating within the EU or evidence that confirmation has been obtained from downstream users that use TBA as an intermediate that they are handling TBA under strictly controlled conditions. It is expected that such information will be provided by Registrant(s) who take advantage of the reduced registration requirements outlined in Articles 17 and 18. For consistency, and to provide evidence to ECHA that sufficient measures have been implemented to manage the risks associated with TBA, the same standard of information should be provided in this case. The Registrant(s) are therefore required to update their registrations with a description of the strictly controlled conditions that are in place at their manufacturing sites in the EU and evidence that confirmation has been obtained from downstream users that use TBA as an intermediate that they also handle this substance under strictly controlled conditions. The Registrant(s) should note that the life cycle information in the IUCLID files needs to be updated to reflect the scenarios that are covered in the updated CSR.

**Request 1b** in this present decision has been made because the qualitative assessment that was included in the revised CSR in response the proposed to request 1l in the draft decision dated 29 April 2014 did not consider the potential for direct eye contact to occur as a result of incidental splashing that may occur where TBA containing products are sprayed or directly handled in other ways. It is therefore not clear that the risk management measures that have been identified by the Registrant(s) will be sufficient in all cases. For this reason, previous request 1l was deemed to be only partially fulfilled by the information in the revised CSR. Since TBA is classified as an eye irritant, Eye Irrit 2. Mixtures containing TBA at a concentration >= 10 % are also required to be classified as eye irritants. In addition to the hazards of skin irritation and the potential for eye irritation to occur from exposure to TBA vapour, the qualitative assessment should also consider the potential for eye irritation to occur in the case of incidental eye contact with mixtures containing TBA at a concentration of 10% or more and describe the risk management measures that are necessary to address this risk. For uses where RPE has already been identified as a necessary risk management measure, it is preferable to manage the risks from direct eye contact with the use of a full face respirator rather than a half face respirator and goggles.

**Request 1c** in this present decision has been made to clarify elements of the proposed request 1j in the draft decision dated 29 April 2014 which were not addressed in the revised CSR. Previous request 1j asked for additional justification for the use of a concentration modifier to adjust the analogous measured data that was being used to estimate exposures for certain tasks that are included in the scenarios for professional cleaning and degreasing and professional use of coatings (scenarios 3 and 6 respectively in the revised CSR). Concentration modifiers are not used in the revised assessment, but it is noted that in some cases, the Registrant(s) have changed the analogous data that they are using and have extended the range of use situations for which analogous measured data is being applied. Certain information is lacking that is needed in order to confirm that the use situations covered by the analogous data are representative for the use situations the data is being applied to. If ECHA does not have evidence to demonstrate that the analogous data is representative for the use situations it is being applied to, it cannot rely on this information when reaching a conclusion about the level of risk that is associated with these uses. Specifically, the information that is required is confirmation that the measurements being referred to in the CSR are personal samples, the reference periods for these measurements and information on the location (indoors or outdoors) where the data were collected. Any additional details that are available about the tasks covered by the analogous data sets would be useful and should also be provided. If all of the information that is required in section II Part 1c is available in the source reference for the data (Bock, 2000; further details of this reference are missing from the reference list) this requirement can be fulfilled by provision of this reference.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the information specified in Section II Part 1.

During the Member State commenting period two PfAs were made regarding the intention of the evaluating MSCA to re-examine the concern for carcinogenicity following the submission of the requested exposure assessment. As such the following note to Registrant(s) is included:

Note for consideration of the Registrant(s)

In a carcinogenicity study conducted in mice, an increase in thyroid follicular cell adenoma was observed in females at the top dose; a dose equivalent to the maximum tolerated dose (12 % reduction in bodyweight). A similar increase was not observed in males or in rats of either sex; moreover, no signs of thyroid toxicity was observed in the repeated dose studies in either species. A mechanistic study failed to show an increase in transcript levels of UDP-glucuronyltransferase (an enzyme fundamental to a possible mechanism) or any significant increase in the level of thyroid stimulating hormone. Failure to demonstrate the mode of action for these tumours means that human relevance cannot be totally excluded. However, as the tumours were only observed in one sex and one species, at the maximally tolerated dose, a further information request for this endpoint is not yet made in this decision. Once the human exposure information requested by this decision is available in the registration dossiers, the evaluating MSCA will reassess the need to request further information to address the remaining concern for carcinogenic effects.

It should be noted that in response to the submitted PfAs, the Registrant(s) provided a position paper questioning the relevance of the adenomas in mice to humans. This information will be considered fully during the reassessment mentioned above.

**2. Provide details of the strictly controlled conditions that are in place**

This request is relevant to the additional concern over the application of strictly controlled

conditions for the transported isolated intermediate registration that is not part of the joint submission.

In order to benefit from the reduced registration requirements for a transported isolated intermediate set out in Article 18 of the REACH Regulation, an importer should obtain confirmation from downstream users that the substance is handled under strictly controlled conditions during its whole life cycle. There is no evidence in the IUCLID submission that this confirmation has been obtained. It is therefore not possible to determine whether the conditions set out in Article 18(4) of the REACH Regulation are met.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision: provide evidence that they have secured confirmation from downstream users that strictly controlled conditions are in place to support their claim that their registration of TBA meets the criteria set out in Article 18 of the REACH Regulation.

Finally, pursuant to Annex VI, section 5 of the REACH Regulation, the Registrant(s) is reminded that the information provided in the registration dossier must be consistent with that in the Safety Data Sheet.

**3. Site specific monitoring of TBA in effluent before and after wastewater treatment**

This request is relevant to the additional concern about the potential underestimation of exposure concentrations. In section 9 of the Chemical Safety Report the Registrant(s) specifies the *Technical conditions and measures at process level (source) to prevent release* to provide onsite wastewater removal efficiency of between >80 to >95% of the registered substance for different exposure scenarios. However, it is unclear whether the claimed level of TBA removal is reasonable. Specific influent concentrations of TBA have been measured, but there does not appear to be any determination of TBA in the effluent (only chemical oxygen demand, which is not substance specific if multiple organic substances are being discharged). Modelling performed during the evaluation suggests the removal levels for TBA could be significantly lower in a waste water treatment plant (WWTP). For example, based on physico-chemical data and a setting of *inherently degradable not meeting criteria* in EUSES 2.0.3, >99% of TBA would be emitted to water in a standard sewage treatment plant (i.e. there would only be <1% removal). Therefore the risk management measures (in particular those described as *activated sludge, anaerobic treatment,* and *dissolved air flotation)* currently specified in the CSR may not be as effective as claimed. Unless the Registrant(s) can provide justification for the removal efficiencies used in the CSR, site-specific monitoring of TBA in effluent is required.

In a recent submission received from the Registrant(s) during the commenting period, monitoring has been performed at two sites where the chemical is used. ECHA agrees that, in principle, for the two sites sampled there is good evidence that a significant proportion of TBA is removed in these industrial wastewater treatment plants. However, the Registrant(s) has not provided information to justify the number of sites sampled, the reason for selecting these sites, or the detection limit for the monitoring (influent and effluent). This information is needed to show why these data are representative for other sites. In particular the Registrant(s) needs to justify why an on-site industrial WWTP can be assumed for all formulation and industrial use sites. The Registrant(s) also uses a $25^{th}$ percentile of the distribution to model removal efficient at wastewater treatment plants at all formulation and industrial sites. However, it is unclear why this percentile is representative, particularly when the REACH guidance suggests a $90^{th}$ percentile to be appropriate.

If the Registrant(s) is unable to provide this information and adequate justification, they will need to conduct further monitoring to fulfil this information requirement.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision: Site specific monitoring of TBA in effluent before and after wastewater treatment.

**4. Long-term toxicity testing on aquatic invertebrates (test method: Daphnia magna reproduction test, EU C.20./OECD 211)**

The request is relevant to the additional concerns regarding the PNEC value. In section 7.1.1.1.2 of the Chemical Safety Report, the Registrant(s) assesses a five-day fish toxicity test using *Clarias gariepinus* (African catfish) to be a long-term study. Since a NOEC is also available from an algal study, the Registrant(s) has derived the aquatic PNEC from the fish test using an assessment factor of 50. The *Clarias gariepinus* test is not considered suitable as a long-term study. This is due to the short duration of the test; the limited end points assessed; that, *Clarias gariepinus* is not a recognised fish species for regulatory ecotoxicity testing purposes (for example it is not listed in any of the standard OECD fish test guidelines) and its relative sensitivity to standard species is unknown. There is also uncertainty about whether the test duration and study conditions were appropriate, as well as the reproducibility of this non-standard test. It is considered that the PNEC can currently only be derived from the acute ecotoxicity data (therefore PNECaq = 0.993 mg/l). When this PNEC is used in combination with the Registrant(s)' current exposure data, risks for a number of Emission Scenarios are identified.

In an updated Chemical Safety Report the Registrant(s) states that the test method is comparable to the OECD 212 (Short-term test on Embryo and Sac-Fry Stages). ECHA agrees that the methodology is similar to the test guideline, but reiterates that the species used is not listed in the test guideline. The time period for the submitted study using *Clarias gariepinus* is one day longer than the OECD 203 acute fish toxicity test, and of a shorter duration than all of the species listed in the OECD 212 test guideline. A time period of five days is not considered by ECHA to provide an assessment of long-term fish toxicity of sufficient sensitivity or certainty.

The Registrant(s) states that the sensitivity of *Clarias gariepinus* is shown by a comparison of the same species and with a standard OECD 212 study for the chemical methyl-tert butyl ether. ECHA does not agree that similar test results for one chemical are adequate to show the validity of *Clarias gariepinus* as being of equal sensitivity more generally.

In line with the current guidance regarding integrated testing strategy and in the interests of animal welfare, a further fish test is not required at this stage. Instead, in the absence of better exposure information a 21-day *Daphnia magna* reproduction study (OECD TG 211) is required to address these risks.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (test method: Daphnia magna reproduction test, EU C.20./OECD 211).

Information requests 3 and 4 will address the additional concerns identified through the Registrant(s) providing further information to support their assumptions, or additional information to refine the PECs or PNEC.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental study, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental study the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrant(s) to perform the study on behalf of all of them.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.