EUROPEAN CHEMICALS AGENCY

Helsinki, 13 January 2015

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

For Tetrahydrofuran (THF), CAS No 109-99-9 (EC No 203-726-8)

Addressees: Registrants of Tetrahydrofuran (Registrant(s))

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent for comment, 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.

Registrants 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 Federal Institute for Occupational Safety and Health (BAUA) as the Competent Authority of Germany (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 the REACH Regulation.

This decision is based on the registration dossiers on 29 April 2014, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant(s) in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers 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 Germany has initiated substance evaluation for Tetrahydrofuran, CAS No 109-99-9 (EC No 203-726-8) based on registrations 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 for concern relating to human health/CMR, exposure/wide dispersive use, consumer use, workers exposure and aggregated tonnage, Tetrahydrofuran 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

Germany was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the consumer use and the workers exposure. 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 19 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.

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). On basis of this information, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

In accordance with Article 52(1) of the REACH Regulation, on 4 September 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, ECHA submitted a proposal for amendment to the draft decision.

On 10 October 2014 ECHA notified the Registrant(s) of the proposal 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 the proposal for amendment within 30 days of the receipt of the notification.

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

On 20 October 2014 ECHA referred the draft decision to the Member State Committee.

By 10 November 2014, in accordance to Article 51(5), the Registrant did not provide comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 24 November 2014 in a written procedure launched on 13 November 2014.

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 for clarification whether risks for workers and/or consumers can be expected or not. The Registrant(s) are required to provide

1. Information that allows addressing the risk for workers of flammability of Tetrahydrofuran.

2. Information that allows addressing risks because of peroxide formation.

3. Information on product integrated risk management measures which are applied to control the risks concerning the high flammability and peroxide formation of Tetrahydrofuran during the use and storage of consumer products.

4. Justification of the derivation of the consumer DNELs.

5. Information on the maximum THF concentrations and additional product information including the intended purpose for all product subcategories of PC 35 ("[redacted]" (ES 12.1) and "[redacted]" (ES 12.2)) and exposure scenarios which addressed the issues of reasonable foreseeable use in cases of undiluted or improper diluted washing and cleaning products by adults and other affected population groups e.g. children.

6. Information on post-application exposure particularly the exposure time after use for PC 35, "[redacted]" in the exposure scenario (ES 12.3).

7. Additional product information including the intended purpose for PC 1, "[redacted]" (ES 13.2) and reliable operational conditions at least the used product amount and the maximum package size as well as an exposure scenario which address these issues.

8. Consumer exposure scenarios and exposure calculations for PC 9a, "[redacted]" (ES 13.3) and PC 9a, "[redacted]" (ES 13.4) which reflect the condition of use by consumers.

9. Consumer exposure scenarios concerning their identified consumer uses PC 3, 4, 9b, 9c, 13, 18, 23, 24, 31 & PC 0 (others: PC 5 & 10).

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by 20 July 2016 an update of the registrations containing the information required by this decision and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

1. Information that allows addressing the risk for workers of flammability of Tetrahydrofuran

Tetrahydrofuran (THF) is labeled as highly flammable (H225). The flash point of -21 °C and the boiling point of 65 °C are low. Because of these physico-chemical properties, under ambient conditions the formation of an explosive atmosphere is possible. By itself, the mere possibility of formation of an explosive atmosphere does not give sufficient information to determine the likelihood and severity of an event occurring due to the physicochemical properties of the substance. Annex I of the REACH Regulation considers the risk to be adequately controlled if the likelihood and severity of an event occurring due to physicochemical properties of the substance is negligible. On this basis it is necessary to obtain further information to clarify whether there is indeed a risk of flammability of Tetrahydrofuran for workers or whether this is negligible.

A comprehensive risk characterisation has to include the risk arising from the physico-chemical properties, such as, in this case, flammability. In order to arrive at this risk characterisation an assessment is required which has to consider the type of use (as identified by PROCs) and the conditions of use (e.g. the level of containment etc.) which shall be provided by the Registrant(s). This information will allow an assessment to

determine the necessary risk management measures required for safe use of the substance.

Notes for consideration of the Registrant(s)

The assessment can be quantitative or qualitative. Acknowledging the difficulties faced by Registrant(s) to carry out assessments based on likelihood of events on behalf of a number of users of their substances a qualitative or semi-quantitative assessment (such as a control banding approach) is deemed to be the most appropriate. One tool which the Registrant(s) may find useful is the German "EMKG concept":
www.baua.de/emkg
www.baua.de/emkg-en
EMKG Module Fire and Explosion Risk:
http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/pdf/Fire-explosion-risk.pdf?__blob=publicationFile&v=3

Further information that may be helpful in such an analysis can be found under:
http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/EMKG/Control-guidance-sheets.html
Synopsis of English control guidance sheets from the International Chemical Control Toolkit and COSHH Essentials:
http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/pdf/CGS.pdf?__blob=publicationFile&v=2

The method of assessment and its outcome shall be reported in the chemical safety report. The resulting measures required for safe use must be communicated to the users of the substance.

How the communication of the measures to substance users in the supply chain could be implemented is currently under discussion with stakeholders, but the main vehicles for communication are the safety data sheets and exposure scenarios. The risk management measures should deal with different aspects of the risk such as prevention of an explosive atmosphere (through ventilation etc.) and removal of ignition sources (e.g. grounding/bonding of equipment), and include mitigation measures (e.g. fire detection, use of fire retardant clothing etc.).

The indication of required risk management measures should be in the form of standard phrases, which may need to be developed, but would be based on existing collections of standard phrases such as the phrases from the Control Guidance Sheet by EMKG or from the GESTIS-database (www.dguv.de/ifa/gestis-database) on hazardous substances. It is recommended that the Registrant(s) use these or other standard phrase catalogues such as the EuPhrac catalogue (http://www.esdscom.eu/english/euphrac-phrases/).

2. Information that allows addressing risks because of peroxide formation.

The CLP labelling (EUH019, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures) indicates the possibility that THF may form peroxides. This means that the risk because of this hazard needs to be considered in the various uses of the substance. In order to assess this risk information is needed for which uses and under which conditions peroxide formation may occur.

THF is mainly used as a technical grade solvent that contains suitable stabilizers which minimize the risk of peroxide formation. However, in certain solvent processing steps the amount of stabilizer may be diminished (e.g. in distillation or separation steps). In such cases, peroxide formation and explosion is a risk. The dossier information does not allow to

assess in which cases such a risk may be present. Therefore, the Registrant(s) are requested to supply this missing information.

The following Exposure Scenarios are considered as being especially relevant in this aspect:
ES6 (Use of THF in functional fluids – Corrosion inhibitors - industrial),
ES7 (Use of small quantities of THF within laboratory settings - industrial),
ES10 (Use of THF in functional fluids – Corrosion inhibitors- professional) and
ES11 (Use of small quantities of THF within laboratory settings – professional).

3. Information on product integrated risk management measures which are applied to control the risks concerning the high flammability and peroxide formation of Tetrahydrofuran during the use and storage of consumer products

THF is labeled as highly flammable (H225) and the formation of peroxide in high concentrated consumer products is likely. Some of the consumer products in the registrations dossiers contain THF in high concentrations up to [redacted] %. Therefore risks of burning and explosion cannot be excluded during application and storage of these consumer products if they come in contact with a source of ignition e.g. lit cigarettes, abrasive grinding wheels and other equipment that produces sparks, welding torches, hot surfaces, portable electrical equipment like mobile phones, radios etc.

However, the registrations dossiers do not give any information on already implemented risk management measures in consumer products (e.g. concentration limit, packaging size, closure opening, stabilizer etc.). Therefore risks for consumers due to these physicochemical properties cannot be excluded.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit information on product integrated risk management measures which are applied to control the risks concerning the high flammability and peroxide formation of Tetrahydrofuran during the use and storage of consumer products.

ECHA notes that for consumers, only product intergrated risk management measures are appropriate to control the risks. The ECHA Guidance on information requirements and chemical safety assessment, Chapter R.13.2.3, version 1.2 from October 2012, points out: "Consumer instructions cannot be expected to be highly effective, unless consumer behavioural data suggest that a sufficient degree of implementation can be assumed. Therefore consumer RMMs that depend on instructions should as a general rule only be introduced when the use of such RMMs can be shown to be effective, necessary and well adhered to by consumers."

4. Justification of the derivation of the consumer DNELs.

If the Registrant(s) maintain the derived no effect levels (DNELs) they currently use in their dossiers, justification for deviating from the REACH Guidance is required.

In fulfilling the information requirements listed in section II., where applicable, it might be necessary to compare the exposure estimates with relevant DNELs, in order to identify whether a risk characterization ratio (RCR) > 1 is obtained and thus further refinement of the risk characterisation is necessary. In this regard, it is noted that the assessment factors (AF) currently used for deriving DNELs for THF by the Registrant(s) in their registration dossiers do not fully comply with the respective REACH Guidance document (ECHA Guidance on Information Requirements and Chemical Safety Assessment, chapter R.8, version 2.1 from November 2012), i.e. some of these AF are considerably smaller than recommended. The Registrant(s) are informed that, based on the outcome of the present substance evaluation so far, an external concentration of 600 ppm (1800 mg/m^3) is considered as the

relevant starting point (Point of Departure, PoD) for DNEL derivation, both with respect to acute narcosis/sedation and repeat-dose effects. Finally, with a view to the possible need for route-to-route extrapolation, it is noted that apparently there is currently not enough reliable information to suggest that absorption rates can be assumed to significantly differ across routes (oral/dermal/inhalation).

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit a justification of the derivation of the consumer DNELs.

5. **Information on the maximum THF concentrations in products and additional product information including the intended purpose for all product subcategories of PC 35 ("[redacted]" (ES 12.2)) and exposure scenarios which address the issues of reasonable foreseeable use in cases of undiluted or improper diluted washing and cleaning products by adults and other affected population groups e.g. children.**

The exposure scenarios in the CSRs of the concerned Registrant(s) cover only the intended use of small amounts [redacted] % THF in PC 35, "[redacted]" and PC 35, "[redacted]" by adults. For both subcategories as risk management measure is noted: "Avoid using at a product concentration greater than 100 %."

This inconsistency is clarified informally by the Registrant(s) providing the missing Appendix 1 of the CSR in course of the current evaluation. In this Appendix 1 further information about the exposure scenarios were provided: for ES 12.1 and ES 12.2 a dilution factor is introduced with reference to AISE REACT 2009 which leads to the low THF concentrations of [redacted] % in the exposure scenarios.

According to a number of registration dossiers washing and cleaning products especially "[redacted]" are commonly and wide-spread used by consumers. It is reasonably foreseeable that such products will be used not only by adults but also older children and used in a pure (undiluted) form to remove stubborn dirt and stains.

Furthermore, also several cleaning activities during a day are foreseeable. Based on the provided data, aggregation by summing up the single exposure estimates of ES 12.1-3 indicates a risk for consumer health.

It is not clear, whether the assumed 100 % concentration is a "worst case" assumption or a realistic THF content for PC 35, "[redacted]" and PC 35, "[redacted]". Probably the high THF concentrations in the undiluted products are not in line with their indicated purpose. Therefore, a detailed assessment of potential risks resulting from reasonable foreseeable use cannot be performed on the basis of available data.

Therefore the Registrant(s) shall provide the realistic maximum THF concentrations in the concerned products and a clear description of the products including their purpose which are covered by ES 12.1 and ES 12.2. In addition, any other information (e.g. OC and RMM) related to safe use of THF in PC35 that is considered relevant to the assessment of risks resulting from reasonable foreseeable use may be provided.

Furthermore the Registrant(s) shall provide exposure scenarios which address these issues adequately. Pursuant to Annex I, 5.2.4. of the REACH Regulation "an estimation of the exposure levels shall be performed for all human populations (...) for which exposure to the

substance is known or reasonably foreseeable". Pursuant to Annex I, 5.2.4. of the REACH Regulation the combined exposure through all relevant routes and sources of exposure shall be addressed. Both requirements are therefore standard obligations of REACH.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit information on the maximum THF concentrations and additional product information including the intended purpose for all product subcategories of PC 35 ("[redacted]" (ES 12.1) and "[redacted]" (ES 12.2)) and exposure scenarios which address the issues of reasonable foreseeable use in cases of undiluted or improper diluted washing and cleaning products by adults and other affected population groups e.g. children.

6. **Information on post-application exposure particularly the exposure time after use for PC 35, "[redacted]" in the exposure scenario (ES 12.3)**

In the CSRs an application time for PC 35, "[redacted]" of 10 minutes coming from AISE REACT is used in the exposure scenario. A post application exposure is reasonably foreseeable, but missing in the CSR. The RIVM cleaning products fact sheet for all-purpose spray cleaners for the "evaporation from constant surface" model (Prud'homme de Lodder et al. 2006) reported an application duration of 10 minutes and an exposure duration of 60 minutes. Exposure calculations based on the reported operational conditions in the CSR and considering the post application exposure indicate a possible risk for ES 12.3 which has to be clarified with the required information.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit information on post-application exposure particularly the exposure time after use for PC 35, "[redacted]" in the exposure scenario (ES 12.3).

7. **Additional product information including the intended purpose for PC 1, "[redacted]"[1] (ES 13.2) and reliable operational conditions at least the used product amount and the maximum package size to allow assessment of risks resulting from the product use as well as an exposure scenario which address these issues.**

The exposure estimate for inhalation in ES 13.2 is not reproducible. Recalculations with several tools e.g. ECETOC TRA, EGRET, and ConsExpo led to higher exposure levels. Furthermore there are uncertainties about the purpose of the [redacted] and its related operational conditions. However, the purpose determines the use frequency and use duration as well as the product amount per application. In particular, the product amount determines the concentration of THF in the air. Therefore a big difference in exposure occurs whether the [redacted]. The maximum packaging size is even an indicator for the intended use. Based on the partly contradictory information in the registration dossiers (e.g. [redacted] as a worst case assumption), exposure estimates by the eMSCA do not allow a final conclusion about possible health risks.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit additional product information including the intended purpose for PC 1, "[redacted]" (ES 13.2) and reliable operational conditions, at least the used product amount and

[1] [redacted]

the maximum package size to allow assessment of risks resulting from the product use as well as an exposure scenario which addresses these issues.

8. **Consumer exposure scenarios and exposure calculations for PC 9a, "[redacted]" (ES 13.3) and PC 9a, "[redacted]" (ES 13.4) which reflect the condition of use by consumers.**

The Registrant(s) provide exposure calculations for consumer uses carried out with worker tools. Pursuant to Annex I, 5.2.5. of the REACH Regulation "appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered." ECETOC TRA Worker Tool v.2 and the EASE model were developed for the special consideration of workers' exposure.

The exposure predictions of the ECETOC TRA Worker Tool v.2 (ECETOC 2004; ECETOC 2009) are based on a modified EASE model. The EASE model categorises occupational exposure with reference to historical data collected in the UK's National Exposure Database (NEDB; cf. HSE 2003) and was developed to predict workplace exposure to chemical substances. The underlying data thus are occupational exposure measurements supported by occupational hygiene experts' judgement. All validation of the resulting exposure estimates (ranges in the original model) was performed by comparison to occupational exposure data (HSE 2003; Tickner and Cherrie 2005) and experts' experience using the model in the industry. All modifications to EASE predictions by the ECETOC model and the adaptations of the original use scenarios to the REACH process categories (PROC) were performed to represent workplace situations. Moreover the PROCs are representations of techniques and processes categorised inter alia based on "the principal level of containment and engineering controls to be expected" (ECHA 2010-R.12). Containment levels, engineering controls, and operational conditions (e.g. average room size, industrial hygiene) resulting in specific, empirical data on exposure levels at the workplace are not representative for conditions under which consumers would generally use a substance or mixture.

Based on these considerations the exposure scenarios to predict exposure in ES 13-3 and 13-4 are not suitable to give realistic or sufficiently conservative estimates for consumer uses. Currently the available data only allow to calculate the consumer exposure via a broad consumer exposure scenario with worst-case assumptions. As a preliminary result a health risk for consumers cannot be excluded. Therefore consumer exposure scenarios for the different product types of PC 9a shall be provided e.g. with specific consumer exposure determinants (SCEDs) which would allow to assess the consumer exposure.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the missing consumer exposure scenarios and exposure calculations for PC 9a, "[redacted]" (ES 13.3) and PC 9a, "[redacted]" (ES 13.4) which reflect the condition of use by consumers.

9. **Consumer exposure scenarios and exposure calculations concerning their identified consumer uses PC 3, 4, 9b, 9c, 13, 18, 23, 24, 31 & PC 0 (others: PC 5 & 10).**

Only Registrant(s) who identified one or several of the PC 3, 4, 9b, 9c, 13, 18, 23, 24, 31 & PC 0 (others: PC 5 & 10) as consumer uses are addressees of this request.

Some of the Registrant(s) have identified PC 3, 4, 9b, 9c, 13, 18, 23, 24, 31 & PC 0 (others: PC 5 & 10) as consumer uses. Nevertheless exposure scenarios, exposure calculations, and risk characterisations for these uses are missing in their registration dossiers.

Risks during consumer use of PC 3, 4, 9b, 9c, 13, 18, 23, 24, 31 & PC 0 (others: PC 5 & 10) cannot be excluded. At this stage an assessment or conclusive decision is not possible because no data is available in the registration dossiers or from other sources. To assess the potential risks for consumers during application as well as for aggregated consumer exposure a clear description of the products including their operational conditions and risk management measures, that describe how the substance is used in consumer products and how the consumer exposure is under control – or in short exposure scenarios – for each identified consumer use is needed. Therefore pursuant to Article 14(4) of the REACH Regulation "the exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the Registrant." is a standard obligation under REACH.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) concerned by this information request shall submit consumer exposure scenarios and exposure calculations concerning their identified consumer uses PC 3, 4, 9b, 9c, 13, 18, 23, 24, 31 & PC 0 (others: PC 5 & 10).

Regarding requests 5-9 the Registrant(s) commented that these might require extensive information from the downstream users. They assume that default/worst-case value databases might not be readily available for these endpoints. This would require communication with the downstream users, potentially involving a third party agency to maintain confidentiality of the values. If this would be necessary the 9-month deadline for updating the dossiers would not be sufficient. Therefore they requested to change the deadline to 18 months. ECHA agreed to this and prolonged the deadline to 18 months.

IV. 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]

Jukka Malm
Deputy Executive Director

Annex 1: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

References:

ECHA 2010. Guidance on information requirements and chemical safety assessment; Chapter R.12: Use descriptor system. European Chemicals Agency, Helsinki, Finland. http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

ECHA 2012. Guidance on information requirements and chemical safety assessment; Chapter R.15: Consumer exposure estimation. European Chemicals Agency, Helsinki, Finland.
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