EUROPEAN CHEMICALS AGENCY

Helsinki, 19 December 2014

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

For 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate, CAS No 2386-87-0 (EC No 219-207-4)

Addressees: Registrant(s)[1] of 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (Registrant(s))

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft of 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 Health and Safety Authority as the Competent Authority of Ireland (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 dossier(s) 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 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 subsequent decision under the current substance evaluation or 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 Ireland has initiated substance evaluation for 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate, CAS No 2386-87-0 (EC No 219-207-4) 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.

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

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health/suspected CMR; sensitiser; exposure/worker exposure; high RCR, 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate 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 Ireland was appointed to carry out the evaluation. The evaluating MSCA considered that further information was required to clarify the following concerns: mutagenicity and worker 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 6 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, Section II was amended to refine the information request 2(h) relating to worker contributing scenario 5 of exposure scenario 1 and worker contributing scenario 6 of exposure scenario 2. The Statement of Reasons (Section III) was changed accordingly.

In accordance with Article 52(1) of the REACH Regulation, on 24 July 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 29 August 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 accordingly, in particular to clarify the sampling requirements for germ cells in the transgenic rodent somatic and germ cell mutation assay (OECD 488) and to remove information request 2(h).

On 8 September 2014 ECHA referred the draft decision to the Member State Committee.

By 29 September 2014, 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(s) on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 13 October 2014 in a written procedure launched on 2 October 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 using the indicated test method and instructions (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

1. Transgenic rodent somatic and germ cell gene mutation assays (TGR) (test method OECD 488). The TGR somatic test shall be conducted in mice treated for 28 days via oral route (gavage), and tissues (stomach, liver, nasal tissue) shall be harvested three days after cessation of treatment. Mutation frequency shall be assessed in stomach, liver and nasal tissue. Germ cells shall be sampled three days post exposure and stored. Cells shall be sampled from seminiferous tubules in addition to spermatozoa from the vas deferens/cauda epididymis. The germ cells shall be analysed for mutation frequency only in the case where positive test results are obtained for any of the somatic tissues.

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

2. Worker exposure assessment:

a. Information to clearly identify exposure scenarios where local exhaust ventilation (LEV) is a required risk management measure (RMM). Where tasks or processes are identified where the use of LEV is not technically feasible, the inhalation and dermal exposure estimates shall be refined, in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14[2], to remove the LEV modification factor.

b. Information on the specification of gloves where these are identified as a required RMM, including the material type, thickness and breakthrough times of the gloves.

c. Information on the specification of respiratory protection equipment (RPE) in worker contributing scenario 3 of exposure scenario 6, including a choice of possible mask and filter types, where appropriate and the training required.

d. Information to clearly identify exposure scenarios where protective clothing and personal protective equipment (PPE, e.g. face shield, chemical googles, rubber boots), other than that addressed under points b) and c), is a required RMM. In these cases, the specification of the protective clothing and other PPE, and the training requirements, shall be documented.

e. Quantitative dermal exposure estimation, in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14, for worker contributing scenario 6 (PROC 8a) in exposure scenario 1 and worker contributing scenarios 7 (PROC 7) and 11 (PROC 10) in exposure scenario 2.

f. Information on all activities covered by exposure scenarios 3, 6 and 7. Where activities are identified which are not adequately covered by the worker contributing scenario(s) reported in each exposure scenario, the dermal and inhalation exposure assessment shall be refined in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14 using a suitable exposure model and appropriate additional worker contributing scenarios.

[2] Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupational exposure estimation (http://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf)

g. Justification for the choice and combination of Riskofderm input parameters used for worker contributing scenario 4 in exposure scenario 4 or alternatively, a refinement of the exposure assessment in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14 where the combination of input parameters cannot be justified.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **26 September 2016** an update of the registration(s) containing the information required by this decision[3], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

Based on the evaluation of all relevant information in the registration dossiers for 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate, 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.

1. Transgenic rodent somatic and germ cell gene mutation assays (TGR) (test method OECD 488) in mice by oral route

Further information on mutagenicity, specifically gene mutation, is required in order to enable the evaluating MSCA to conclude on whether the registered substance has the potential to cause gene mutations.

The registration dossier contains a number of *in vitro* studies which investigate the potential for the registered substance to induce gene mutations in both bacteria and mammalian cells. In a key Ames test conducted in accordance with OECD 471, positive results were obtained in the presence of metabolic activation for *Salmonella typhimurium* strains TA 100, TA 1535 and in the presence and absence of metabolic activation in *E. coli* WP2 uvrA strain, all of which detect base pair substitutions. In the key mammalian gene mutation assay in mouse lymphoma L5178Y cells (TK+/-), positive results were observed in the presence and absence of metabolic activation. It is noted that the positive response in the absence of metabolic activation in this assay indicates a possible concern for a direct action of the substance as a mutagen at initial sites of contact. There were equivocal results from supporting *in vitro* studies investigating induced DNA damage in mammalian cells: positive results from a sister chromatid exchange assay in the absence of metabolic activation and equivocal results from an *in vitro* unscheduled DNA synthesis (UDS) study. A second gene mutation study in mammalian cells was negative. In an *in vivo* UDS study in the rat, conducted in accordance with OECD 486, no evidence of unscheduled DNA synthesis was reported. A second *in vivo* bone marrow micronucleus assay in mice was also negative however this study is not relevant for the investigation of gene mutation.

The Registrant(s) conclude in the registration dossier that while the weight of evidence from the *in vitro* data indicates a potential to induce mutagenic effects, which did not require metabolic activation, the available *in vivo* data does not support the *in vitro* results and therefore the registered substance is not a direct acting mutagen *in vivo* and is not genotoxic.

ECHA considers that the available *in vitro* data indicates a concern for gene mutation, with a

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

possible concern for a direct action of the registered substance as a mutagen at initial site of contact. The only relevant *in vivo* study for this substance available in the dataset to assess genotoxicity is the UDS study in the rat. The UDS study is an indicator assay to detect presumed DNA lesions in cells of the liver but not in tissues other than the liver. ECHA notes the potential concern identified from the *in vitro* data for direct action of the registered substance as a mutagen at initial sites of contact. In addition, it is noted that nasal tissue was identified as the critical target organ in the 90-day oral repeated dose toxicity study. Although a mechanism of toxicity could not be established for the nasal epithelial degeneration noted in this study, the Registrant(s) concluded the effect was indicative of a systemic exposure, which ECHA agrees with. Therefore, as the *in vivo* UDS study in the liver is not capable of detecting genotoxicity at the initial sites of contact with the body or in target organs other than the liver, it is considered that in this case the UDS study is not the appropriate *in vivo* study to clarify the concern for gene mutation.

An *in vivo* TGR assay is required to clarify the concern for gene mutation. The TGR assay is capable of detecting gene mutations in somatic cells following systemic exposure, as well as those at the initial site of contact with the body. The TGR shall be conducted via oral gavage in mouse, as default species according to OECD 488. In accordance with guidelines for tissue selection outlined in OECD 488 paragraphs 37 and 38, the following tissues shall be analysed: the stomach, as the initial site of contact with the body and as a rapidly dividing tissue; the liver as a tissue exposed to systemically available substances and as the main site of metabolism; and nasal tissue as it was identified as a critical target tissue in the repeated dose toxicity study. In addition, germ cells shall be sampled and stored. In agreement with the proposal for amendment from one Member State Competent Authority the germ cells shall be sampled three days post exposure in accordance with paragraph 35 of OECD 488. According to paragraph 32 of OECD 488 *'The sampling time for male germ cells should be selected so that the range of exposed cell types throughout germ cell development is sampled, and so that the stage targeted in the sampling has received sufficient exposure'*. However it may be sufficient to sample germ cells three days post exposure as stated in paragraph 33 of OECD 488 *'sampling cells from seminiferous tubules in addition to spermatozoa from the vas deferens/cauda epididymis following only a 28 + 3 day sampling regimen would provide some coverage of cells exposed across the majority of phases of germ cell development, and may be useful for detecting some germ cell mutagens.'* Therefore, germ cells should be sampled three days post exposure from seminiferous tubules in addition to spermatozoa from the vas deferens/cauda epididymis.

If the analysis of any of the somatic tissues indicates that the substance is a somatic cell mutagen, the germ cell samples (three days post exposure) shall then also be analysed. If the germ cell samples (three days post exposure) indicate a positive result for mutagenicity the substance should be classified as a germ cell mutagen. Following a proposal for amendment from the same Member State Competent Authority it is considered that where the analysis of the germ cell samples (three days post exposure) is triggered and is negative for mutagenicity it cannot definitively be concluded that the substance is not a germ cell mutagen due to the incomplete exposure throughout germ cell development following a 28 + 3 day regimen (as per paragraph 32 of OECD 488). In this case, the need for further testing to clarify the concern for germ cells will be considered by the evaluating MSCA under the current substance evaluation.

This testing strategy reflects the information needs that can be established at this stage, which are necessary to clarify the concern related to the potential for mutagenicity of the substance.

In response to ECHA's draft decision, the Registrant(s) indicated their agreement with the evaluating MSCAs evaluation of the mutagenicity data and accepted the request to provide

further information related to somatic and possibly germ cell effects in a TGR. The Registrant(s) also commented on the limited capacity and capability in contract research organisations (CRO) for conducting the TGR but they were unable to provide any evidence from a CRO to support the view that an extension to the current deadline of 21 months was justified. The deadline was not amended. In their comment to the proposal for amendment from the Member State Competent Authority, the Registrant(s) expressed that a 28+3 day sampling regime would be likely to detect cells with damaged DNA and be sufficient to conclude on the respective concern while the Registrant(s) argued that a request for a second TGR would not be justified based on the available information. As stated above currently there is only a need for a first TGR assay and any need for possible further information will be evaluated by the evaluating MSCA after the results of the first TGR have become available in accordance with Article 46(3) of the REACH Regulation.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: Transgenic rodent somatic and germ cell gene mutation assays (TGR) (test method OECD 488). The TGR somatic test shall be conducted in mice treated for 28 days via oral route (gavage), and tissues (stomach, liver, nasal tissue) shall be harvested three days after cessation of treatment. Mutation frequency shall be assessed in stomach, liver and nasal tissue. Germ cells shall be sampled three days post exposure and stored. Cells shall be sampled from seminiferous tubules in addition to spermatozoa from the vas deferens/cauda epididymis. The germ cells shall be analysed for mutation frequency only in the case where positive test results are obtained for any of the somatic tissues.

2. Worker exposure assessment

a. Information regarding the use of local exhaust ventilation (LEV) as a risk management measure (RMM)

With respect to dermal exposure estimation, the default position in ECETOC TRA v3.0 is to not take into account the use of LEV as a RMM. LEV is used as a RMM in the majority of exposure scenarios in the CSR where it is applicable but not for PROC 1 or outdoor tasks where it is not possible to use LEV. The Registrant(s) have modified the relevant dermal exposure estimates calculated using ECETOC TRA v3.0 to take account of the use of LEV.

ECETOC TRA v3.0 has been used to estimate worker exposure during manual cleaning of equipment, which is covered by worker contributing scenarios 5 and 6 in exposure scenarios 1 and 2, respectively. In both cases, LEV is used as an exposure modifier when calculating inhalation and dermal exposure.

Based on the information presented in the CSR regarding the activities and processes covered in the exposure scenarios, the use of LEV as an exposure modifier may be acceptable in some cases. However, there is insufficient information in the CSR to assess the acceptability of this approach.

In particular, it is noted that where the dermal exposure estimate has been modified to take account of the use of LEV, it is not clear from the CSR whether LEV is used at all facilities for all tasks. It is noted that the CSR frequently states that a site "typically has LEV". Where the use of LEV is taken into account in the calculation of dermal exposure, the use of LEV must be explicitly stated as a required RMM.

It is noted that there may be some tasks where LEV may not be available, for example cleaning and maintenance tasks. It is noted also that the use of LEV has been taken into account in estimating inhalation and dermal exposure for manual cleaning tasks in exposure

scenarios 1 and 2. The evaluating MSCA used ECETOC TRA v3.0, removing the LEV modification factor, to estimate the inhalation exposure for worker contributing scenarios 5 and 6 in exposure scenarios 1 and 2, respectively. When these inhalation exposure estimates are compared with the DNEL for long-term inhalation–systemic effects, the resulting risk characterisation ratio (RCR) values are all above 1, indicating that the risk may not be adequately controlled for these contributing scenarios.

Further information is required regarding the requirement for LEV to control exposure. In particular, further information is required to clearly identify exposure scenarios where LEV is a required and mandatory RMM. Where tasks or processes are identified where the use of LEV is not technically feasible, a refinement of exposure estimates is required.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide information to clearly identify exposure scenarios where LEV is a required RMM. Where tasks or processes are identified where the use of LEV is not technically feasible, the inhalation and dermal exposure estimates should be refined, in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14, to remove the LEV modification factor.

b. Information on the specification of gloves

The registered substance is a skin sensitiser and thus a qualitative risk characterisation has been conducted for local dermal effects. As part of this assessment, a number of operating conditions (OCs) and RMM have been recommended, including "substance/task appropriate gloves". There is a high reliance on the use of gloves in all exposure scenarios, and "chemically resistant gloves conforming to EN374 with specific activity training" have been specified in the majority of worker contributing scenarios. In the estimation of dermal exposure, a modification factor for use of gloves has been applied, assuming an effectiveness value of 95%.

ECHA Guidance R.13[4] states that the source of the effectiveness information used in exposure estimates should be documented in the CSR. It is noted that no specific justification is provided in the CSR for the choice of glove effectiveness value of 95% and no information is provided on the specification of gloves, including the material type, thickness and breakthrough time. This information is necessary to assess the adequacy of the gloves identified as a RMM for each exposure scenario and to conclude on whether the estimated dermal exposures are realistic, taking into account the effectiveness value used, and thus on whether the risk to workers is adequately controlled.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required

[4] Guidance on information requirements and chemical safety assessment. Chapter R.13: Risk management measures and operational conditions (http://echa.europa.eu/documents/10162/13632/information_requirements_r13_en.pdf)

to provide information on the specification of gloves where these are identified as a required RMM, including the material type, thickness and breakthrough times of the gloves.

c. Information on the specification of respiratory protective equipment (RPE)

Worker contributing scenario 3, covering industrial spraying, in exposure scenario 6 specifies the use of respiratory protective equipment (RPE) with an assigned protection factor (APF) of 20.

It is noted that no information is provided in the CSR on the type of RPE or the training required. Further information is required in order to conclude on whether the APF is justified and thus to conclude whether the risk to workers is adequately controlled.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide information on the specification of RPE in worker contributing scenario 3 of exposure scenario 6, including a choice of possible mask and filter types, where appropriate and the training required.

d. Information on protective clothing

Protective clothing is identified as a RMM in some exposure scenarios but no information on the specification is provided. For example, chemical resistant and protective suits are mentioned as RMM in worker contributing scenarios 4 and 3 in exposure scenarios 4 and 6, respectively but there is no information on the specification of protective clothing. The use of protective clothing is stated in the inhalation exposure assessments made using ART v1.5 in the joint CSR (i.e. worker contributing scenarios 7 and 11 in exposure scenario 2 and worker contributing scenario 3 in exposure scenario 6), but again no further information on the specification is provided. The joint CSR also indicates that other PPE may be used to minimise clothing contamination (e.g. cotton overalls).

It is noted that contaminated clothing can be a source of exposure, particularly to hands when removing it. While the choice of protective clothing and other PPE does not impact on modelled exposure estimates, they have been identified as a RMM and thus are taken into account in risk characterisation. Further information is required to clearly identify the exposure scenarios where protective clothing and any other PPE (e.g. face shield, chemical googles, rubber boots) is a required RMM. In these cases, the specification of the protective clothing and other PPE, and the training requirements shall be documented.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide information to clearly identify exposure scenarios where protective clothing and PPE (e.g. face shield, chemical googles, rubber boots) other than that addressed under points b) and c) is a required RMM. In these cases, the specification of the protective clothing and other PPE, and the training requirements shall be documented.

e. Quantitative dermal exposure estimates for worker contributing scenario 6 (PROC 8a) in exposure scenario 1 and worker contributing scenarios 7 (PROC 7) and 11 (PROC 10) in exposure scenario 2

A qualitative exposure assessment is reported in the joint CSR for worker contributing scenario 6 in exposure scenario 1 and worker contributing scenarios 7 and 11 in exposure scenario 2 with respect to long term dermal exposure, and therefore no long term dermal exposure estimates are included in the CSR for these contributing scenarios. The Registrant(s) have justified this approach by stating that there is no direct contact with the substance during these contributing scenarios since fully automatic processes are used. It is concluded that no direct dermal contact is likely and thus dermal exposures are expected to be negligible.

ECHA Guidance Part E[5] outlines the steps in conducting a qualitative assessment, which includes conducting an exposure estimation/assessment, which should give "a feel for the degree of exposure and likelihood of contact". It is considered that insufficient justification has been provided to support the conclusion that dermal exposures are expected to be negligible. It is also noted that no information has been provided to indicate that these processes are outside the scope of the available dermal exposure models and thus it was technically not possible to estimate the exposure.

The evaluating MSCA used ECETOC TRA v3.0 and the information in the CSR relating to these contributing scenarios to generate dermal exposure estimates. When these dermal exposure estimates are compared with the DNEL for long-term dermal–systemic effects, the resulting risk characterisation ratio (RCR) values are all above 1, indicating that the risk may not be adequately controlled for these contributing scenarios. It is considered that quantitative dermal exposure estimation is required in order to evaluate whether the existing RMM and OCs are adequate to control the risk to workers in these contributing scenarios. In accordance with Guidance R.14, an appropriate dermal exposure model shall be used and the input parameters and assumptions used in the exposure model shall be documented.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out a quantitative dermal exposure estimation, in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14, for worker contributing scenario 6 (PROC 8a) in exposure scenario 1 and worker contributing scenarios 7 (PROC 7) and 11 (PROC 10) in exposure scenario 2.

f. Information on all activities covered by exposure scenarios 3, 6 and 7

Only one contributing worker exposure scenario is described for exposure scenarios 3 and 7. Exposure scenario 3 describes the industrial end use as an additive in the production of synthetic polymers and adhesives, and as an antioxidant in insulators. A single worker contributing scenario, PROC 2, is presented for this exposure scenario. Exposure scenario 7 describes the industrial end use in light emitting diode (LED) materials and a single worker contributing scenario, PROC 2, is presented for this exposure scenario.

[5] Guidance on information requirements and chemical safety assessment. Part E: Risk Characterisation

It is considered that the description of the processes covered by these exposure scenarios does not allow an assessment as to whether in each case all tasks are covered by a single worker contributing scenario. Further information on the processes is required in order to determine whether the exposure scenarios sufficiently describe the intended uses and thus whether the recommended RMM and OCs are adequate to control the risk to workers.

With respect to exposure scenario 6, the joint CSR states that for this exposure scenario "the substance is transferred from containers to blending vessels and mixed with other substances". It is noted that there is no worker contributing scenario in the joint CSR which covers the transfer part of the task. Further information is required regarding whether this transfer task is covered by the existing contributing scenarios or whether a refinement of the exposure assessment is required.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide information on all activities covered by exposure scenarios 3, 6 and 7. Where activities are identified which are not adequately covered by the worker contributing scenario(s) reported in each exposure scenario, the dermal and inhalation exposure assessment should be refined in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14 using a suitable exposure model and appropriate additional worker contributing scenarios.

g. Justification for the choice and combination of Riskofderm input parameters used for worker contributing scenarios 4 in exposure scenario 4 or alternatively, a refinement of the dermal exposure estimate

Dermal exposure estimates for worker contributing scenario 4 in exposure scenario 4 was derived using Riskofderm v2.1. The CSR reports the model input parameter assumptions used and justifies the selection of the 75th percentile of the exposure distribution on the basis that the assumptions are conservative. While the selection of the 75th percentile value would normally be acceptable, it is considered that in this case the combination of input parameters used to estimate exposure are not conservative or consistent and have not been adequately justified.

This worker contributing scenario describes the connection and disconnection of hoses and is classified as an automated / semi-automated process. The dermal exposure assessment assumes the task duration to be 1 minute while the corresponding inhalation exposure assessment assumes the duration to be 1 hour. No explanation is provided in the joint CSR for the differing choice of task duration for dermal versus inhalation exposures. It is noted that differences in task duration can affect exposure estimates. In addition, it is considered that the flow rate of 0.2 L/min is slow for a transfer operation. Based on the information provided, it is considered that where transfer is classed as semi-automated, the duration of the task would need to be significantly longer than 1 minute (e.g. 1 hour as per inhalational exposure) and with a higher flow rate. A refinement of the exposure assessment is required to further justify the choice and combination of model input parameters or to refine the exposure estimate.

In response to ECHA's draft decision, the Registrant(s) have indicated their intention to gather more detailed information and refine the exposure assessments accordingly. As no information was provided in an update of the registration dossier, the draft decision was not

amended.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide justification for the choice and combination of Riskofderm input parameters used for worker contributing scenario 4 in exposure scenario 4 or alternatively, a refinement of the exposure assessment in accordance with ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14 where the combination of input parameters cannot be justified.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental stud(y/ies), 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(s) must be shared by the Registrant(s).

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

In relation to the experimental stud(y/ies) 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 stud(y/ies) 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]

Jukka Malm
Deputy Executive Director

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