EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114290517-42-01/F Helsinki, 5 February 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For citral, CAS No 5392-40-5 (EC No 226-394-6), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for citral, CAS No 5392-40-5 (EC No 226-394-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 24 July 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 8 May 2013.

On 29 October 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 27 November 2013 ECHA received comments from the Registrant on the draft decision.

On 24 January 2014 the Registrant updated his registration dossier (submision number: [redacted]). The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 24 July 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 29 August 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and did not amend the draft decision.

The present decision relates solely to a compliance check requesting information in form of pre-natal developmental toxicity study (Annex X, Section 8.7.2.), reassessment of the skin senstisation hazard information (Annex I, 3.1.5. of the REACH Regulation), Revised DNELs for workers and for the general population (Annex I, 1.4.1 of the REACH Regulation), exposure assessment and risk characterisation to demonstrate that the risk to the environment can be considered to be adequately controlled (Annex I, Sections 5 and 6 of the REACH Regulation), and a qualitative assessment of likelyhood that skin irritation is avoided when implementing exposure scenarios (Annex I, 6.5 the REACH Regulation.). The other information requirement for two-generation reproductive toxicity study (Annex X, Sections 8.7.3) is addressed in a separate decision although all requests were initially addressed together in the same draft decision.

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 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 relating to pre-natal developmental toxicity study, reassessment of the skin senstisation hazard information, revised DNELs for workers and for the general population, exposure assessment and risk characterisation to demonstrate that the risk to the environment can be considered to be adequately controlled, and a qualitative assessment of likelihood that skin irritation is avoided when implementing exposure scenarios 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

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annex X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route.

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

2. A reassessment of the skin sensitisation hazard information on a basis of the study giving rise to highest concern

or

A full justification for why the study giving rise to the highest concern was not chosen to draw conclusions for skin sensitisation and a robust study summary for the study chosen (Annex I, 3.1.5. of the REACH Regulation);

3. Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA

or

A full justification for not using the recommended assessment factors in the DNEL derivation (Annex I, 1.4.1 of the REACH Regulation);

4. Exposure assessment and risk characterisation to demonstrate that the risk to the environment can be considered to be adequately controlled (Annex I, Sections 5 and 6 of the REACH Regulation);

5. A qualitative assessment of likelihood that skin irritation is avoided when implementing exposure scenarios (Annex I, 6.5 the REACH Regulation.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

C. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **12 August 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.)

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

There is information available on this endpoint only for a pre-natal developmental toxicity study in a first species for the registered substance in the technical dossier. However, there is no information available for a pre-natal developmental toxicity study in a second species. Consequently there is an information gap for Annex X, Section 8.7.2. and it is necessary to provide information for this endpoint.

ECHA further observes that the Registrant has neither provided any study record of a pre-natal developmental toxicity study in a second species in the dossier that would meet the information requirement of Annex X, Section 8.7.2. nor adapted this information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route in rabbits.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, notes that the dossier contains several studies on rats. He also notes that the exposure from all routes is limited both for workers and consumers and that US Food and Drug Administration has given Generally Recognised as Safe (GRAS) status to the registered substance. The Registrant asks ECHA to postpone the substance evaluation until the requirements of the compliance check have been implemented, as the substance has been placed on the 2015 CoRAP list.

ECHA notes that the Registrant has updated the dossier with an adaptation concerning the testing requirement for the pre-natal developmental toxicity in the second species. The content of the adaptation is similar to the comment from the Registrant. ECHA acknowledges the comment from the Registrant and notes that pre-natal developmental toxicity test in a second species is a standard requirement at this tonnage level when the test conducted on the first species is negative. The argument that there is no human exposure is not adequate, since the highest exposure level for long-term inhalation exposure for workers is 1.90 mg/m3 and 0.69 mg/kg bw/day for long-term dermal exposure. This means that, even though consumer exposure is low, the worker exposure may reach a level where there are risks for adverse developmental effects. A study by the oral route is requested, based on the fact that the oral route is relevant for human exposure, and because systemic availability is ensured by the oral administration. In addition, ECHA notes that carrying out the required reproductive toxicity tests does not prevent or delay substance evaluation, since the concern triggering the substance evaluation is sensitisation and human exposure.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

2. A reassessment of the skin sensitisation hazard information on the basis of the study giving rise to highest concern or a full justification why the study giving the highest concern was not chosen to draw conclusions for skin sensitisation and a robust study summary for the study chosen (Annex I, Section 3.1.5. of the REACH Regulation)

Annex I, Section 3.1.5. of the REACH Regulation requires that the study giving rise to the highest concern shall be used and a robust study summary shall be prepared for that study or studies and included in the technical dossier. In addition, Annex I, Section 3.1.5. requires that if a study giving rise to the highest concern is not used, then this shall be fully justified.

In the technical dossier, the Registrant has chosen the Local Lymph Node Assay (LLNA) and two Guinea Pig Maximisation Studies (GPMT) as key studies. Another LLNA, another GPMT study, and a review article on skin sensitisation are included as supportive studies. However, no robust study summary is available for the Human Repeated Insult Patch Test (HRIPT) which was used in the CSR for the derivation of the DNEL for local effects. There is no published standard testing guideline for HRIPT and, in addition, the HRIPT method was not described sufficiently. Therefore, it is not possible to assess with which method and under which conditions the test was carried out.

Human data will normally take preference over animal data in DNEL derivation (see: *Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health)*. However, the reporting of the studies must be sufficient to allow for the assessment of such human data. In this case, the reliability of the HRIPT could not be assessed, since the HRIPT test was not sufficiently described and since there is no validation study that would have assessed the reliability of the test.

According to the CSR, both the LLNA and the HRIPT studies lead to similar dose descriptor (NOAEL of about 1400 µg/cm^2). However, the DNEL based on the LLNA would be significantly lower than the DNEL based on the HRIPT, since according to the LLNA model, interspecies variation is taken into account as an assessment factor. Therefore, the LLNA study gives rise to the highest concern.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, notes that since both HRIPT and LLNA lead to similar dose descriptors, an interspecies assessment factor is not needed. Furthermore, he points out that intraspecies variation is taken into account. He also claims that "A robust study summary of the mentioned HRIPT and the reasoning given above will be included and the respective endpoint summary will be rephrased in the updated dossier." ECHA welcomes the Registrant's intention to add a robust study summary fot the HRIPT test. However, even the updated dossier does not have robust study summary for the HRIPT test, only a "critical reevaluation of existing studies". In fact, the endpoint study record has not been modified at all after the draft decision was sent (latest modification in 2010). Furthermore, the assessment factor for exposure duration is not used even in the updated dossier.

In addition, the Registrant in his comments notes that the substance "is also listed on the draft list for CoRAP evaluation is 2015" and that not all scientific data would be available at the start of the CoRAP process. ECHA notes that the initial cause for concern in the CoRAP is sensitisation and human exposure. Following the concern raised by the Registrant on interference between dossier evaluation and substance evaluation, ECHA conctacted the evaluating member state to ask if he considers that this draft decision may interfere substance evaluation. The evaluating member state responded that there is no interference and that the draft decision does not have to be modified for this reason. ECHA notes also that the Registrant did not specify why all information requested in this decision would need to be available in order to carry out the substance evaluation related to sensitizing properties and human exposure. Therefore, the draft decision was not amended.

Based on the above, and in accordance with Annex I, Section 3.1.5 of the REACH Regulation, the Registrant is requested to re-assess the skin sensitisation using the LLNA study, or in the alternative to justify the fact that the study giving rise to the highest concern was not chosen and to prepare a robust study summary for the study.

3. Revised DNELs for workers and for the general population using the recommended assessment factors by ECHA or a full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1. of the REACH Regulation)

Annex I, 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

- the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- the nature and severity of the effect;
- the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies.

The ECHA "Guidance on information requirements and chemical safety assessment" (Volume 8, R8) provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

The assessment factors (AF) applied by the Registrant and the default assessment factors recommended in the ECHA Guidance[1] are given in detail in Annex I attached to this decision.

ECHA observes that the Registrant has not followed the recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1. In particular, ECHA notes that for the systemic DNELs for inhalation route interspecies variation is not addressed at all and for systemic DNELs for dermal route, only allometric scaling is taken into account, whereas the remaining difference has not been addressed.

Furthermore, ECHA notes that for long-term local DNELs derived for dermal route based on skin sensitisation (LLNA), the exposure duration (subacute to chronic) was not taken into account at all as an assessment factor.

[1] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

Thus the Registrant shall revise his DNELs by applying the recommended assessment factors apropriate in this case.

In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the current DNEL derivation for workers and for the general population provided in the chemical safety report by specifying how the following has been taken into account:

- the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- the nature and severity of the effect;
- the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
- and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, notes that in the updated dossier substance specific assessment factors have been used. He also notes that since dose descriptor is based on the impaired body weight gain and local respiratory irritation, allometric scaling sufficiently takes into account interspecies variation. The Registrant also refers to ECETOC guidance and to other publications to support the use of the assessment factors used.

ECHA points out that, according to ECHA Guidance R.8, deviations from default assessment factors should be justified with substance-specific arguments. More specifically the introductory part of paragraph R.8.4.3, page 22 reports: "*However, when the available data do not allow the derivation of substance-specific or analogue-specific assessment factors, default assessment factors should be applied.*" Moreover, ECHA underlines that the guidance document R.8 was developed and approved in cooperation with the Member States, industry and non-governmental organisations in order to define further the derivation of DNELs according to the provisions of Annex I section 1.4.1. ECHA notes that in the updated dossier there are no substance specific assessment factors which would be justified by any substance specific information. As no adequate substance-specific justifications were provided to deviate from default assessment factors. default ECHA assessment factors should be used.

Concerning allometric scaling, ECHA points out that the draft decision and its Annex I do not challenge the Registrant's choices concerning allometric scaling. Instead ECHA underlines the need of substance-specific arguments to justify the Registrant's choice not to apply an AF of 2.5 for remaining interspecies AF when deriving each of the DNELs. ECHA notes that according to Table R.8-6 of ECHA guidance such a default AF would not be needed for local effects on skin, eye and gastrointestinal (GI) tract via simple destruction of membranes, which is not the case for the registered substance. Indeed, the Registrant did not provide any substance specific arguments for deviating from this default assessment factor.

Finally, ECHA notes that the Registrant justifies the use of intraspecies assessment factor of 3 (workers) and 5 (general population) by general references to ECETOC guidance and with two scientific articles referred in that guidance. ECHA notes that the Registrant has not substantiated how the effect levels in the studies available would allow to conclude that a lower intraspecies AF than the default would apply. ECHA concludes that the Registrant did not adequately justify why interspecies and intraspecies AFs deviating from defaults would fulfil the condition of Annex I, 1.4.1. concerning uncertainty arising from intra- and interspecies variation.

Concerning DNEL for skin sensitisation, ECHA notes that the Registrant does not provide any information to support the idea that "the relevant parameters, i.e. induction of skin irritation and skin sensitization, are considered to depend on threshold concentrations rather than exposure duration" and that, therefore, for skin sensitisation assessment factor for exposure duration is not needed. In conclusion, the draft decision was not amended.

Based on the above, the Registrant shall revise his DNELs and reassess related risks. The results of the studies requested under section II.X shall be taken into account when revising the DNELs. If DNELs are not revised, this shall be fully justified. The CSR shall be amended accordingly.

4. Exposure assessment and risk characterisation to demonstrate that the risk to the environment can be considered to be adequately controlled
(Annex I, 5. and 6. of the REACH Regulation; sections 9.1. and 10.1.2. in CSR)

According to Annex I, Section 0.6, the Registrant is required to perform a Chemical Safety Assessment (CSA) for the registered substance. The CSA shall cover 1) human health hazard assessment, 2) human health hazard assessment of physicochemical properties, 3) environmental hazard assessment and 4) PBT and vPvB assessment. The CSA shall also consider exposure assessment and risk characterisation if as a result from these steps, the substance is assessed to be a PBT or vPvB or meets the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation):

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F;
(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9, and 3.10;
(c) hazard class 4.1; or
(d) hazard class 5.1.

Furthermore, according to Annex I, Section 5.0 of the REACH Regulation, the objective of the exposure assessment is to make quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed, and that the assessment shall cover any exposures that may relate to the hazards identified in points 1) to 4) of chapter 0.6.1 of Annex I of the REACH Regulation.

The Registrant has waived the exposure assessment and risk characterisation for the environment based on the following statement: "*In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.*"

It is apparent from the CSA that the Registrant has self-classified the substance as R38 (irritating to skin) and R43 (may cause sensitisation by skin contact) according to Annex I of Directive 67/548/EEC, and as Skin Irrit. 2 (H315: Causes skin irritation), Eye Irrit. 2 (H319: Causes serious eye irritation) and Skin Sens. 1 (H317: May cause an allergic skin reaction) according to Regulation (EC) 1272/2008. Therefore the substance is hazardous regarding skin corrosion/irritation (hazard class 3.2), serious eye damage/eye irritation (hazard class 3.3) and respiratory or skin sensitisation (hazard class 3.4) according to the definition given in Annex I to Regulation (EC) No 1272/2008.Consequently, the chemical safety assessment of citral shall also include exposure assessment, exposure estimation, and risk characterisation.

Moreover, the CSA explicitly states that substance related effects were detected in short-term toxicity to fish (96h-LC50: 6.78 mg/L, 96h-NOEC: 4.6 mg/L, based on mortality), short-term toxicity to aquatic invertebrates (48h-EC50: 6.8 mg/L, 48h-NOEC: 3.13 mg/L, based on mobility) and toxicity to algae (72h-EC10: 3 mg/L, based on growth rate). Therefore, hazard is identified in aquatic toxicity and, thus an exposure assessment should be carried out for the environment.
In view of ECHA, Annex I, section 0.6 of the REACH Regulation, requires that a substance that meets the criteria for hazard class 3.1 to 3.6 set out in Annex I to Regulation (EC) No 1272/2008 shall be subjected to exposure assessment and risk characterisation. In addition, the Registrant has in the present case identified environmental hazards as short term toxicity to fish, short-term toxicity to aquatic invertebrates and toxicity to algae, which according to Annex I, section 5.0 of the REACH Regulation, shall be taken into account in the exposure assessment.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, argues that the starting point to consider the scope of the exposure assessment is Annex I, Section 5.0 of the REACH Regulation which provides that an exposure assessment for environment has to be performed only if environmental hazards have been identified.

With regard to the comments provided by the Registrant challenging the request for exposure assessment for not being consistent in the understanding of the term 'hazard' in the provisions of the REACH and CLP Regulation, and to neglect general principles of EU law, ECHA points out the following:

Generally, two of the main purposes of both the REACH and CLP Regulation are to ensure a high level of protection of human health and the environment (Article 1(1) of the REACH and CLP Regulation respectively). The additional steps in a chemical safety assessment of exposure assessment and risk characterisation serve this objective as they allow estimating and characterising any risk to mankind or the environment. The formal arguments of the Registrant that this shall be done only for CLP-classified hazards ignore this overall context.

Both the REACH and CLP Regulation distinguish between the terms 'hazard', 'hazardous' and 'hazard classes'. The legislator would have used the term 'hazard classes' only if that was his intention for Annex I, Section 5 to the REACH Regulation. This becomes clear from the distinct references used in Article 3 of the CLP Regulation, Article 14(4) and Annex I, Sections 0.6.3. and 5. to the REACH Regulation. Under REACH, a hazard is identified by the results generated from the tests used to fulfil the information requirements set out in Annexes VII to XI. Pursuant to Article 13(3) of the REACH Regulation tests define endpoints/effects to be observed and reported for identification of (no)effect levels/concentrations as well as a limit dose and therefore, if a hazard is identified it is when an adverse effect is observed below that limit dose.

The REACH and CLP Regulations can be interpreted in a coherent and consistent way without reducing unnecessarily their respective scopes. The chemical safety assessment/report is regulated by law in order to assess and document that any risks arising from a substance are adequately controlled during manufacture and use. The burden of safe use lies with operators. ECHA therefore considers the additional steps of exposure assessment and risk characterisation for any identified hazard irrespective of classification as a measure in line with the precautionary principle that is underpinning the REACH Regulation (Article 1(3)) and which the Registrant seems to ignore.

Pursuant to Annex I, Section 3.0.2. of the REACH Regulation five environmental spheres shall be assessed for hazards. Annex I, Sections 5 and 6 require an exposure assessment and risk characterisation for the "*environmental spheres for which exposure to the substance is known or reasonably foreseeable*". Following the Registrant's argumentation, the environmental exposure assessment and risk characterisation would only be possible for the aquatic environmental sphere since the results for a number of standard data requirements for the other environmental spheres (e.g. information on soil/sediment toxicity,) do not lead to the classification of substances as hazardous, as no hazard classes or classification criteria exist. It cannot be correct that a large part of standard data requirements set out in the REACH Annexes would become irrelevant. Instead, the legislator has a clear intention to use the standard information required in Annexes VII to X of the REACH Regulation for the hazard assessment without prejudice of classification needs.

For reasons of proportionality, the requirement of a chemical safety assessment is limited to those substances meeting the criteria for classification of any hazard class/category set out in Article 14(4) of the REACH Regulation/Annex I CLP Regulation. In that regard the request by ECHA to understand exposure and risk of the substance subject to the present decision is not exceeding of what is appropriate and necessary to attain the objectives of the legislation The identified hazard in this case has been demonstrated by mortality of fish and immobility of Daphnia as outlined in above. At the same time, as ECHA is not requiring exposure assessment and risk characterisation on all environmental endpoints, it does not exceed what is necessary to address the concern.

ECHA respects the principle of equal treatment as it requires for any substance meeting the criteria for classification in any of the hazard classes/categories an exposure assessment and risk characterisation.

Finally, the Registrant cannot claim that ECHA's action would jeopardise legal certainty as ECHA has issued guidance on when exposure assessment and risk characterisation are expected (Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose[concentration]-response for human health; Version: 2.1; November 2012).

In conclusion, the arguments by the Registrant cannot lead to omitting the required data that is needed in order to comply with the REACH Regulation.

Therefore, ECHA takes the view that the request for an environmental exposure assessment for the substance is warranted. The draft decision was not amended.

Therefore, the Registrant is requested to perform a complete exposure assessment for the environment covering all life-cycle stages of the registered substance originating from manufacture and identified uses, and subsequently perform a risk characterisation for each exposure scenario to demonstrate the safe use of the substance. The Registrant is requested to update the dossier accordingly.

5. A qualitative assessment of likelihood that skin irritation is avoided when implementing exposure scenarios (Annex I, 6.5 of the REACH Regulation.; section 10.2.1. in CSR)

Annex I, 6.5. requires that for those human effects for which it is not possible to determine a DNEL, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out. In this case, DNELs have been derived for threshold effects. However, no qualitative assessment has been carried out for local effects on skin due to irritancy, even though the substance is classified for skin irritation. More specifically, there are no risk management measures for skin protection other than gloves. Therefore, it is possible that skin irritation is not avoided by the risk management measures in other parts of the body than hands. The ECHA practical Guide "How to undertake a qualitative human health assessment and document it in a chemical safety report" (Practical Guide 15) provides further details on how to carry out a qualitative assessment.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, notes that the risk characterisation is based on both a conservative enough DNEL and a conservative exposure assessment. Therefore, gloves as a risk management measure are considered sufficient. He also notes that additional phrase "Avoid skin contact" will be included into relevant exposure scenarios of the updated dossier.

ECHA agrees with the Registrant that the absence of skin irritation is ensured in hands for which gloves are used as a risk management measure. However, no qualitative risk assessment has been done for other parts of the skin than hands. Furthermore, addition of phrase "Avoid skin contact" is not a sufficient risk management measure to protect other areas of the skin than hands. Therefore, the draft decision was not amended.

Therefore, the Registrant is requested to perform a qualitative assessment of likelihood that skin irritation is avoided when implementing exposure scenarios.

C. Deadline for submitting the required information

In his comments according to Article 50(1) on the initial draft decision the Registrant underlined that the submission of the requested information within the 30 month timeframe is difficult and proposed a timeframe of 36 months. ECHA notes that the deadline was intended to allow sequential testing in reproductive toxicity. The deadline given in that draft decision was also in line with other ECHA decisions addressing the same hazard endpoints. ECHA also notes that the Registrant has not justified the extension with any arguments specific to this particular substance. Therefore, the extension of the deadline was not found appropriate.

However, commenting to the proposals for amendment submitted by the Competent Authorities of the Member States, the Registrant repeated his request to prolong the deadline for submission of requested information from 30 months to 36 months indicating limited availability of the [redacted]. As the two-generation reproductive toxicity study (Annex X, Sections 8.7.3.) request is not addressed in the present decision, ECHA considers that a reasonable time period for providing the information required in the present decision in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. However, in light of the Registrants request for a deadline extension due to limited laboratory capacity, ECHA considers that the time period for providing the required information in the form of an updated registration can be extended to 18 months (12 months plus extra 6 months) from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 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 ECHA's internet page at http://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 I: Assessment factors (AF) applied by the Registrant

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Assessment factors (AF) applied by the Registrant:

For workers - systemic long term – inhalation route:
- intraspecies: 3
- exposure duration: 2
- quality of the database: 2
  (overall AF: 12)

For workers - systemic long term – dermal route:
- interspecies: 7
- intraspecies: 3
- exposure duration: 1
- dose response: 3
  (overall AF: 63)

For workers – local long term –dermal route:
- intraspecies: 10
- exposure duration: 1
  (overall AF: 10)

For the general population - systemic long term – inhalation route:
- intraspecies: 5
- exposure duration: 2
- quality of the database: 2
  (overall AF: 10)

For the general population - systemic long term – dermal route:
- interspecies: 7
- intraspecies: 5
- exposure duration: 1
  (overall AF: 35)

For the general population – local long term –dermal route:
- intraspecies: 10
- exposure duration: 1
  (overall AF: 10)

For the general population - systemic long term – oral route:
- interspecies: 7
- intraspecies: 5
- exposure duration: 1
- dose response: 3
  (overall AF: 105)

The default assessment factors recommended in the ECHA Guidance[2]:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 1 (chronic)
  (overall AF: 12.5)

[2] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

For workers - systemic long term – dermal route:
- interspecies - allometric correction: 7 (mouse to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 1 (chronic)
  (overall AF: 87.5)

For workers – local long term –dermal route:
- intraspecies: 5
- exposure duration: depends on the length of the study

For the general population - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 1 (chronic)
  (overall AF: 25)

For the general population - systemic long term – dermal route:
- interspecies - allometric correction: 7 (mouse to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 1 (chronic)

  (overall AF: 175)

For the general population – local long term –dermal route:
- intraspecies: 10
- exposure duration: depends on the length of the study

For the general population - systemic long term – oral route:
- interspecies - allometric correction: 7 (mouse to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 1 (chronic)
  (overall AF: 175)