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For final decision: Decision number Helsinki, 21 May 2014

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

For n-Hexane, CAS No 110-54-3 (EC No 203-777-6)

Addressees: Registrant(s)[1] of n-Hexane (Registrant(s))

This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as Annex 1 to this decision.

Registrant(s) meeting the following criteria are *not* addressees of this decision:
i) Registrant(s) who 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 Federal Institute for Occupational Safety and Health (BAuA) as the Competent Authority of Germany, the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registrations of the Registrant(s) submitted after 7 July 2012.

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 concerned registrants 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 n-Hexane, CAS No 110-54-3 (EC No 203-777-6) based on registration dossiers submitted by the Registrant(s) 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 and neurotoxicity, Exposure/Wide dispersive use, high aggregated tonnage, n-Hexane was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA

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

website on 29 February 2012. The Competent Authority of Germany (evaluating MSCA) was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify theconcerns related to worker and consumer 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 28 February 2013.

On 4 April 2013 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 6 May 2013 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. Some Registrant(s) updated their dossiers before 7 July 2012. The evaluating MSCA considered these comments and updates. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

In accordance with Article 52(1) of the REACH Regulation, on 31 October 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently one Competent Authority of the Member States submitted proposals for amendment to the draft decision.

On 5 December 2013 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 the proposals for amendment within 30 days of the receipt of the notification.

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

On 16 December 2013 ECHA referred the draft decision to the Member State Committee.

By 7 January 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 21 January 2014 in a written procedure launched on 10 January 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 in a revised version of the chemical safety report:

Exposure assessment for workers (as further specified in Section III):

1. Information that allows addressing the risk of flammability of n-hexane in the exposure scenarios referring to the exposure assessment for workers.

2. Sufficient and consistent information regarding the operational conditions and effectiveness of RMMs described in the exposure scenarios including:

   a) Information regarding effectiveness of protective measures for those cases where default values (i. e. default assumptions in a widely used exposure estimate tool) have not been used
   b) Information regarding operational conditions allowing refined assessments for exposure scenarios that are incomplete or for which a safe use could not be demonstrated

3. Sufficient and consistent information regarding the use of PPE/ Specify details of PPE including:
   a) Specification of gloves and duration of use
   b) Specification of respiratory protection and duration of use

4. Exposure assessments taking into account peak exposure and to show that the risk can be controlled adequately.

Exposure assessment for consumers (as further specified in Section III):

5. Information that allows addressing the risk of flammability of n-hexane in the exposure scenarios referring to the exposure assessment for consumers.

6. Exposure assessments for consumer use concerning uses identified by the Registrant(s) (PC 28 & 39) to show that the risk can be controlled adequately.

7. Exposure assessments for consumer use of PC 1, 4, 8, 9a, 9b, 9c, 15, 18, 23, 24, 31, 34 for all affected population groups e.g. children to show that the risk can be controlled adequately.

8. Exposure assessments for consumer use of PC 1, 4, 8, 9a, 9b, 9c, 15, 18, 23, 24, 31, 34 concerning all relevant exposure routes (inhalation for PC 9b, 9c & 24, dermal route for sprays) to show that the aggregated risk can be controlled adequately.

9. Exposure assessments for consumer use of PC 4, 8, 9b, 9c, and 34 regarding effectiveness of recommended risk management measures (concentration limits in consumer products) to show that the risk can be controlled adequately.

10. Valid exposure assessments with respect to consumer exposure scenarios with implausible exposure estimates: PC 1, 4, 8, 9a, 9b, 9c, 15, 18, 23, 24, 31, 34 including clear identification of the used operational conditions to show that the risk can be controlled adequately.

11. Exposure assessments of single exposure events for PC 1, 8, 9a, 9b, 9c, 15, 23, 24, 31 to show that the risks from these events are adequately controlled.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **28 November 2014** an update of the registrations containing the information required by this decision.

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III. Statement of reasons

Based on the evaluation of all relevant information submitted on n-hexane and other relevant and available information, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk regarding its physical chemical properties (high volatility and flammability) as well as exposure via dermal and inhalation routes.

Exposure Assessment for workers

In many aspects the relevant exposure scenarios are unclear. This means that the information presented in the registration dossiers cannot be considered sufficient to judge residual risk in the various uses.
In order to judge the possibility to handle n-hexane in a safe way, the Registrant(s) are requested to supply additional information as described below.
In view of multitude of exposure scenario descriptions in the Chemical Safety Report, it was not possible to evaluate each individual scenario in the same detail. Therefore in some requests for information reference is made to specified lists of scenarios in the Annex 2. However, this does not exclude that other, not listed scenarios, are also concerned.

1. **Provide information that allows addressing the risk of flammability of n-hexane in the exposure scenarios referring to the exposure assessment for workers.**

REACH Art 14(4)(a) requires exposure assessments of substances that fulfil the criteria for certain hazard classes. For n-hexane due to its classification as Flammable Liquid, Cat 2 according to Annex VI of EC 1272/2008 this hazard should be assessed. In addition REACH Annex I requires in Chapters 2, 5 and 6 an assessment of the hazards of physicochemical properties of the reported substance and therefore the resulting risk.

The description of some scenarios (listed in table 1 in Annex 2 of this document) shows the use of n-hexane in amounts that vary over a wide range, which would make various levels of risk management measures necessary.

In none of the exposure scenarios, the risks originating from the flammability and physicochemical hazard are specifically addressed. This means that based on the available information, the risks of these scenarios in the handling of n-hexane cannot be properly evaluated.

The Registrant(s) are requested to address the risk of flammability for the exposure scenarios listed in Table 1 of Annex 2 by describing specific Risk Management Measures that address the use of various amounts of the substance and to provide a revised version of the chemical safety report in an update of the registration dossiers. In particular all scenarios that use PROCs 7, 11, 14, or 20 should be considered because in view of the description they are likely to be associated to a high risk.

The requested information will allow a full evaluation whether the occupational risks associated with flammability are controlled.

Note for consideration by the Registrant(s):

Examples of relevant RMMs can be found in Control Guidance Sheets Series 100 (basic risk measures). Series 200 (medium risk) and Series 300 (high risk)

(http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf).

2. Provide sufficient and consistent information regarding the operational conditions and effectiveness of RMMs described in the exposure scenarios.

The Registrant(s) provide text modules within the exposure scenarios which describe the operational conditions in terms of engineering control and personal protective measures. Depending on the scenario, specific efficiencies are assigned to certain protective measures in the respective exposure assessment. The efficiencies/ modifying factors and additional information/specifications can be found in the registration dossiers.

It is stated in the ECHA Guidance on information requirements and chemical safety assessment, Part D: Exposure Scenario Building (Version 1.2) that 'If M/I assumes a certain effectiveness of a measure, the source of this assumption needs to be documented in the CSR. It's the responsibility of M/I to make sure that the assumption is taken from a reliable source and applies to the conditions of the specified use (e.g. practices and operation of equipment). This may be based on scientific publications or on the default assumptions used in widely accepted exposure estimation tools.'

The exposure scenarios as provided by the Registrant(s) were reviewed with regard to this aspect. Thereby the latest version of ECETOC TRA was taken into account since some ventilation options and settings were revised.

As indicated in some of the examples provided in the confidential part of this document, the revised settings of the tool do affect some exposure scenarios.

a) Information regarding effectiveness of protective measures for those cases where default values (i. e. default assumptions in a widely used exposure estimate tool) have not been used.

In most exposure scenarios the Registrant(s) use default values for protective efficiencies as provided by ECETOC TRA, version 2. However, in several scenarios different modifying factors are used without any explanation or justification (examples are provided in Annex 2: Table 2-4).

In these cases the reduction of the exposure is not comprehensible. Some of the scenarios have been recalculated without taking the questionable / non-standard modifying factors into account which results in an RCR > 1. Consequently, the knowledge about the efficiency of the concerned measures is crucial to clarify whether the risk in the respective exposure scenario is adequately controlled under conditions as described by the Registrant(s).

"Use of drum pumps equates to LEV at transfer points",
"Use of drum pumps considered to offer LEV effic."

The phrase "use of drum pumps equates to LEV at transfer points" can be found in some exposure calculations in the registration dossiers. In these calculations the Registrant(s) apply an exposure reduction of 80% or 90%. These non-standard modifying factors/assumptions require further justification. This is not provided by the Registrant(s).

Furthermore, the use of drum pumps is advised only in some (but not in all) of the concerned exposure scenarios provided by the Registrant(s) (examples are listed in Table

2 of Annex 2 of this document).

The uncertainty of this information does not allow to adequately assess the risk associated with these operational conditions.

Therefore, the Registrant(s) are required to provide exposure measurements as a scientific basis for this modifying factor. All scenarios which involve the "use of drum pumps" shall be reassessed based on the exposure measurements.

The availability of measurement data will eliminate the uncertainties associated with the application and allow to reach a conclusion if the risk are adequately controlled.

"1% dermal adsorption factor applied"

The phrase "1% dermal adsorption factor applied" can be found in some exposure calculations provided by the Registrant(s). In the concerned exposure calculations the dermal exposure is reduced by 99% whereas the "Dermal RMM (efficiency)" is either not indicated or denoted as 0. Firstly, it is not clear whether the Registrant(s) are considering the adsorption or absorption of the substance. Therefore the meaning of this term remains unclear in this context. Secondly, no further scientific justification for this non-standard modifying factor/assumption is provided.

In some of the concerned scenarios the use of gloves is advised by the Registrant(s) (e.g. "Wear suitable gloves tested to EN374. [PPE15]"), examples are listed in **Table 3**. However, this is not reflected in the actual calculation.
In summary, it is not possible to decide, whether the (dermal) exposure comprises a risk to the worker.

Therefore, the Registrant(s) are requested to reassess the exposure scenarios considering only standard risk management measures such as PPE. This applies to all scenarios which were assessed using the "dermal adsorption factor".

Note for consideration by the Registrant(s):
In general, it should be distinguished between the use of gloves in industrial and in professional settings since the level of control strategies is assumed to be lower in the latter one. According to ECETOC-TRA version 3, the use of gloves may reduce the exposure by 90% in professional settings assuming that the workers are trained, while a reduction of 80% is considered appropriate in cases without further training. An efficiency of 95% can only be assumed in combination with specific activity training in industrial settings. Experience shows that a reduction efficiency of 80% is regarded more realistic in professional settings [Kliemt, 1995][1].

"SOP"

The presence of an "SOP" is used to assume an exposure reduction of 80% or 90%. In some of these cases further specifications are provided in the registration dossiers (e.g. "Drain down and flush system prior to equipment break-in or maintenance [E55]", "Drain down system prior to equipment break- in or maintenance [E65]").

[1] [Kliemt, 1995]: Kliemt G., Voullaire E, 1995, " Gefahrstoffe in Klein- und Mittelbetrieben: Neue Wege überbetrieblicher Unterstützung", Schriftenreihe der Bundesanstalt für Arbeitsschutz: Forschung, Fb 703;ISBN 3-89429-473-6

However, no further scientific justification for this non-standard modifying factor/assumption is provided. To our knowledge the use of a "SOP" per se does not allow to assume such a reduction.

Therefore, the Registrant(s) are required to provide exposure measurements as a scientific basis for this modifying factor. Furthermore, the Registrant(s) are required to provide consistent information for all scenarios, i.e. to describe the RMMs related to each "SOP" in detail (examples are provided in Table 4 in Annex 2 of this document).

A transparent presentation of the operational conditions will allow elimination of the uncertainties associated with the application and allow to reach a conclusion if the risk are adequately controlled.

b) Information regarding operational conditions allowing refined assessments for exposure scenarios that are incomplete or for which a safe use could not be demonstrated.

As summarised in Table 7 - Table 16 (see Annex 2 of this document), some exposure scenarios and the corresponding RCRs were recalculated based on the information as submitted by the Registrant(s) and taking into account ECETOC TRA , Version 3, whereas the Registrant(s) used Version 2 of this tool.
In numerous exposure scenarios for industrial and professional applications the risk characterisation ratio exceeds the value of 1. This is related both to changes in ECETOC TRA Version 3 as well as to inconsistencies within the description of the exposure scenarios.

However, the reassessment was done on a Tier 1 level only. In order to conclude regarding the risk for workers, further information and a consistent description of the operational conditions and RMMs are needed.

The Registrant(s) are required to provide information (RMMs, reduction factors, consistent descriptions) which allows the refinement of the concerned exposure scenarios for the examples in Tables 7 – 16 of Annex 2 of this document.

3. Provide sufficient and consistent information regarding the use of PPE/ Specify details of PPE

a) Specification of gloves and duration of use

In certain contributing exposure scenarios, the Registrant(s) have provided general instructions to use suitable chemical resistant gloves tested according to EN 374. However, specific information regarding the gloves (material, thickness and breakthrough time) is missing. This means that the protective effect of the gloves cannot be assessed. Consequently, the assumed protective efficiency (80% or 90%) as used in the exposure scenarios is questionable and it is not possible to decide whether the described operational conditions comprise a risk to the workers.

In some contributing scenarios (e.g. Using cleaning agents–professional; Use in coatings-professional) a duration of the task of 8 hours is specified by the Registrant(s). This implies an 8 hour use of personal protective equipment such as gloves whenever such PPE is recommended. As indicated in Directive 89/656/EEC, wearing of PPE should not comprise a burden to the worker. It is well recognized that exceeding a certain duration of use comprises such a burden and can express a risk for workers by itself. Therefore,

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the specified maximum duration of use of gloves shall be taken into account in the exposure scenarios. The maximum duration either has to be calculated from the breakthrough time mentioned above or to be specified according to Directive 89/656/EEC.

The Registrant(s) are required to provide the information regarding the material, thickness and breakthrough time of the gloves in all scenarios where the use of gloves is advised. Furthermore, the Registrant(s) are required to define and communicate the maximum use time of gloves which is either determined by the breakthrough time mentioned above or is specified in accordance with Directive 89/656/EEC. The specified maximum duration of use of personal protective equipment shall be taken into account in the exposure scenario.

The availability of this information will allow to assess if the occupational risks associated with the wearing of gloves protection equipment are properly addressed.

b) Specification of respiratory protection and duration of use

In all exposure scenarios where the use of respiratory protection is recommended in order to control the risk arising from the use of n-hexane the type of mask is only partly specified. In most cases the information whether half mask, full-face mask, or air-supplied respirator is needed is missing. Representative examples are provided in **Table 5** of the Annex 2 of this document.

In the exposure estimation, a protection efficiency of 90% is applied. However, this assigned protection factor (APF) needs to be justified by providing a more detailed description. As a consequence, it is not possible to decide whether the described operational conditions comprise a risk to the workers.

In some contributing scenarios (e.g. Use in coatings – Industrial, PROC 7, Industrial Spraying) a duration of the task of 8 hours is specified by the Registrant(s). This implies an 8 hour use of respiratory protective equipment whenever such RPE is recommended. As indicated in Directive 89/656/EEC, wearing of PPE should not comprise a burden to the worker. It is well recognized that exceeding a certain duration of use comprises such a burden and can express a risk for workers by itself. Therefore, the specified maximum duration of use of RPE shall be taken into account in the exposure scenario. The maximum duration either has to be determined from the filter capacity, or defined in accordance with Directive 89/656/EEC.

Therefore the Registrant(s) are required to provide sufficient and consistent information (type of mask, filter type, efficiency) on the recommended respiratory protection equipment (RPE). Furthermore, the Registrant(s) are required to define and communicate the maximum use time of RPE which is either determined by the filter capacity, or specified in accordance with Directive 89/656/EEC. The specified maximum duration of use of personal protective equipment shall be taken into account in the exposure scenario. This applies to all exposure scenarios which include the use of RPE.

The availability of this information will allow to assess if the occupational risks associated with the wearing of respiratory protection equipment are properly addressed.

Note for consideration by the Registrant(s):
The Registrant(s) should consider that the filter in the respiratory equipment should be adjusted for highly volatile liquids. For n-hexane, a mask of type AX may be more

appropriate (EN 529).

4. Provide exposure assessments taking into account peak exposure and to show that the risk can be controlled adequately

The registration dossiers provided include exposure assessment and risk characterization for exposure of workers in certain contributing scenarios with duration of not more than 15 minutes. Depending on the scenario, this short-term exposure has to be expected to be associated with a clearly higher exposure than the full shift average as long as data are missing. Therefore, acute effects on worker (e.g. dizziness) have to be expected. The relevant scenarios shall be assessed adequately in order to clearly describe the risk arising from the use of n-hexane. Within the registration dossiers this aspect has not been addressed.

The ECHA Guidance on information requirements and chemical safety assessment, Chapter R14 (Version 2.1), recommends the assessment of acute exposure estimates by using the 95th percentile of acute exposure measurements. If no measurements are available, it is possible to generate acute reasonable worst-case value from full shift values by using multiplication factors. However, in the Registration Dossiers the short term or peak exposure is not assessed as described in the abovementioned guidance document: 'Full shift estimates in the ECETOC TRA are assumed to represent the 90th percentile of the exposure distribution. It is also assumed that in general the variability will not be very high. Therefore, it is recommended to multiply a full shift ECETOC TRA estimate by a factor of 2 to estimate the 95th percentile or a factor of 6 to estimate the 99th percentile of the related short term exposure distribution.'

The registration dossiers include DNEL derivations for long-term (systemic) exposure and risk characterisation. It is stated in all registration dossiers that 'DNELs derived for chronic systemic exposures are typically lower than those calculated for acute exposures. Therefore, the chronic systemic DNELs would be protective for both acute and chronic human exposures.' Nevertheless, the short-term exposure values (examples given in table 6 in Annex 2 of this document) exceed significantly the long-term (systemic) DNEL.

Information on the risks of short term peak exposure is missing, although the reported exposure scenarios give rise to the assumption that such peak exposures may occur. Therefore a comprehensive risk assessment of some scenarios cannot be made.

The Registrant(s) are requested to provide exposure assessments taking into account peak exposure and show that the risk can be controlled adequately. This relates in particular to scenarios involving PROCs 7, 8a, 8b, 9, 10, 11, 12, 13, or 19. The Registrant(s) have to demonstrate that these exposure values are regarded safe by setting these values in relation to DNELs (see explanatory note).

In cases where further risk management measures are required, the Registrant(s) shall provide a sufficient description of the RMM and PPE.

Notes for consideration by the Registrant(s):

Based on the current knowledge an exposure assessment based on ECETOC TRA Version 3 would be the most suitable method in this case. Whenever measurements are available these can be used too.

Currently the Registrant(s) refer to the chronic DNEL only. As long as this chronic DNEL

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is not exceeded, peak exposure can be regarded safe. Nevertheless, preliminary calculations show that higher peak exposures have to be taken into account. In this case a relation of exposure values to a short-term DNEL is necessary. The ECHA Guidance on information requirements and chemical safety assessment, Chapter R.8 (Version 2.1), Appendix R.8-8 specifies that 'Depending on the steepness of the dose-response curve for the repeated dose effects, the DNEL for acute toxicity could be set for a reference period of 15 minutes at 1-5 times the value (default 3) of the long-term DNEL.'

Exposure Assessment for Consumer

In many aspects the relevant exposure scenarios are unclear. This means that the information presented in the registration dossiers can not be considered sufficient to judge residual risk in the various uses.
In order to judge the possibility to handle n-hexane in a safe way, the Registrant(s) are requested to supply additional information as described below.

5. Provide information that allows addressing the risk of flammability of n-hexane in the exposure scenarios referring to the exposure assessment for consumers.

REACH Art 14(4)(a) requires exposure assessments of substances that fulfil the criteria for certain hazard classes. For n-hexane due to its classification as Flammable Liquid, Cat 2 according to Annex VI of EC 1272/2008 this hazard should be assessed. In addition REACH Annex I requires in Chapters 2, 5 and 6 an assessment of the hazards of physicochemical properties of the reported substance and therefore the resulting risk.

The description of some scenarios (listed in table 1 in Annex 2 of this document) shows the use of n-hexane in amounts that vary over a wide range, which would make various levels of risk management measures necessary.
In none of the exposure scenarios, the risks originating from the flammability and physicochemical hazard are specifically addressed. This means that based on the available information, the risks of these scenarios in the handling of n-hexane cannot be properly evaluated.

The Registrant(s) are requested to address the risk of flammability for the exposure scenarios listed in Table 1 of Annex 2 by describing specific Risk Management Measures that address the use of various amounts of the substance and to provide a revised version of the chemical safety report in an update of the registration dossiers.

The requested information will allow a full evaluation whether the risks associated with flammability for consumers are controlled.

Note for consideration by the Registrant(s):

Examples of relevant RMMs can be found in Control Guidance Sheets Series 100 (basic risk measures). Series 200 (medium risk) and Series 300 (high risk).
(http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf).

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6. Exposure assessments for consumer use concerning uses identified by the Registrant(s) (PC 28 & 39) to show that the risk can be controlled adequately

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(s)."

- The Registrant(s) identified PC 28 and PC 39 as consumer uses. Nevertheless exposure scenarios and risk characterisations for these uses are missing.

  In the updated registration dossiers from 2012, a justification of waiving is added. Therein the Registrant(s) argued that the consumer use is within the scope of the Cosmetic Regulation. Please note, n-hexane is listed in the Annex II (list of substances prohibited in cosmetic products) of the Cosmetic Regulation 1223/2009[2].

The Registrant(s) are required to submit information that allows assessing whether risks for consumers are controlled.

7. Exposure assessments for consumer use of PC 1, 4, 8, 9a, 9b, 9c, 15, 18, 23, 24, 31, 34 for all affected population groups e.g. children to show that the risk can be controlled adequately

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(s)."

Pursuant to Annex I, 5.2.4 of the REACH Regulation "An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed."

- The Registrant(s) identified PCs where a foreseeable exposure for children can be assumed. All exposure scenarios in the registration dossiers (apart from PC 9b & 9c) consider only the 60 kg-adult. The use of special consumer products e.g. hobby glues (PC 1), impregnation and care products (PC 23, 34), paints (PC 9a), ink and toners (PC 18) is also foreseeable for children. Exposure scenarios should demonstrate the safe use of relevant consumer products for children, too.

The Registrant(s) are required to submit information that allows assessing whether risks for all affected population groups e.g. children are controlled.

8. Exposure assessments for consumer use of PC 1, 4, 8, 9a, 9b, 9c, 15, 18, 23, 24, 31, 34 concerning all relevant exposure routes (inhalation for PC 9b, 9c & 24, dermal route for sprays) to show that the aggregated risk can be controlled adequately

[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

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(s)."

Pursuant to Annex I, 5.2.4 of the REACH Regulation "Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed."

- n-hexane has a high vapour pressure (20 kPa). Therefore inhalation is likely for all consumer uses and should be considered in the exposure assessment even in the case where the calculation tool does not provide this exposure route. A dermal exposure for aerosol sprays is also foreseeable and should not be excluded without justification.

  In the updated registration dossiers from 2012, the Registrant(s) recommended to avoid the use of PC 1 and 9b products when the windows are closed. Please note that communicated risk management measures are not appropriate to consumers and therefore can not be considered in the quantitative exposure assessment. For this the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.13 pointed 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."

The Registrant(s) are required to submit information that allows assessing whether risks for consumers are controlled.

9. Exposure assessments for consumer use of PC 4, 8, 9b, 9c, and 34 regarding effectiveness of recommended risk management measures (concentration limits in consumer products) to show that the risk can be controlled adequately

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(s)."

Pursuant to Article 14(6) of the REACH Regulation "Any Registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31."

- A concentration limit of n-hexane is recommended as an appropriate risk management measure for several exposure scenarios. However, exposure estimates to demonstrate their efficiency are not available in the registration dossiers. Calculations by the evaluating MSCA indicate that risks are not controlled due to the concentration limit.

  In the updated registration dossiers from 2012, for PC 1 the proposed concentration limit is above the product concentration in the exposure scenario. Please note, that therefore it is not covered by the exposure scenario.

The Registrant(s) are required to submit information to the recommended risk management measures that allows assessing whether risks for consumers are controlled.

In its proposal for amendment one Competent Authority of the Member States suggested to expand the scope of this request to additional PC's. The ECHA considered the arguments brought forward and decided to not modify the request as the new concern brought forward is already covered by another request of the present decision.

10. Valid exposure assessments with respect to consumer exposure scenarios with implausible exposure estimates: PC 1, 4, 8, 9a, 9b, 9c, 15, 18, 23, 24, 31, 34 including clear identification of the used operational conditions to show that the risk can be controlled adequately

Pursuant to Article 14(6) of the REACH Regulation "Any Registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31."

Pursuant to Annex I of the REACH Regulation, 5.1.1 "If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control."

- The Registrant(s) are required to update or refine the consumer exposure scenarios. Recalculations by the evaluating MSCA led to exposure levels exceeding the appropriate DNEL.

  Due to the inconsistencies and data lacks in the registration dossiers the exposure scenarios and their risk characterisations are not comprehensible. The used operational conditions are not clearly identified; the provided exposure estimates and RCRs are irreproducible, which lead to higher exposure levels with RCR > 1 by recalculation. It is unclear, if risks arise during product application. Based on the recorded information in the registration dossiers risks for consumers cannot be excluded.

Therefore the concern is not clarified and a request for plausible exposure scenarios with clearly defined operational conditions, reproducible exposure estimates, and reproducible RCRs from the Registrant(s) for all identified consumer uses are needed. The Registrant(s) are required to submit information by redrafting the consumer exposure assessment in the registration dossiers that allows assessing whether risks for consumers are controlled.

11. Exposure assessments of single exposure events for PC 1, 8, 9a, 9b, 9c, 15, 23, 24, 31 to show that the risks from these events are adequately controlled.

Pursuant to Annex I, 6.3 and 6.4 of the REACH Regulation the risk characterisation for human health consists of a comparison of the exposure of each human population known to be likely to be exposed with the appropriate DNEL. For any exposure scenario, the risk can be considered adequately controlled, if the exposure levels estimated do not exceed the appropriate DNEL.

The ECHA Guidance on information requirements and chemical safety assessment Chapter R.8 (Version 2.1) sets out: "Note that the repeated exposure resulting from a certain exposure scenario is to be expressed as the actual daily dose, bearing in mind that for workers a day is 8 hours, for human via the environment a day is 24 hours, and for consumers a day is 1–24 hours (depending on the scenario, e.g., type of consumer product). The actual daily dose is independent of the exposure frequency. This means that if for a certain scenario, worker or consumer exposure is for instance only for a number of days per year, the exposure value is the actual dose on the exposure days, and not the daily dose averaged out (and thus divided!) over the whole year."

- The Registrant(s) indicate also single exposure events without further considerations of risks. However, the short-term exposure values as calculated in the registration dossiers exceed significantly the long-term systemic DNEL, e.g. glues for DIY-use (PC1). Even in cases where the use frequency is low the safe consumer use has to be demonstrated.

The Registrant(s) are required to submit information that allows assessing whether risks for consumers are controlled during single exposure events. For risk characterisation, the exposure estimates have to be compared with an appropriate DNEL. In the absence of a short-term systemic DNEL either the long-term systemic DNEL has to be used or a specific short-term DNEL has to be derived. According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.8 (Version 2.1), Appendix R. 8-8, an LC_{50} value or an N(L)OAEC from short-time repeated dose studies (e.g. developmental toxicity studies) can be used as the starting point for DNEL derivation. Alternatively, the DNEL for acute toxicity could be set at 1-5 times the value of the long term DNEL.

In its proposal for amendment one Competent Authority of the Member States suggested editorial changes in the statement of reasons of the request. The text was modified in order to clarify that either a long-term systemic DNEL or a specific short-term DNEL might be used in the absence of a short-term systemic DNEL.

In the comments to the Proposal for amendments the Registrant(s) indicated that the substance is not supplied for use in consumer products. Therefore the Registrant(s) consider that consumer uses are not supported and hence the development of a consumer DNEL is not appropriate. However, the Registrant(s) recognize that exposure to n-hexane may occur as a result of the substance being present as a contaminant in other substances that may be supplied to consumers. The Registrant(s) indicated the intention to update the dossier to include this information and to explain why the current classification limits for n-hexane provide adequate assurance that any health risks to consumers can be considered to be adequately managed.

Note for consideration by the Registrant(s)

Dossier updates were only considered in the decision-making until 7 July 2012. However, any Registrant(s) who indeed does not support any consumer uses and updates his registration dossier accordingly, will not need to fulfil the requests in this decision related to consumer uses.

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

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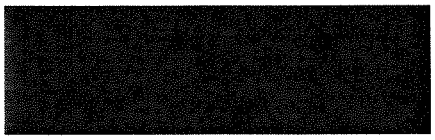
three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/regulations/appeals.
The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



Jukka Malm
Deputy Executive Director

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

Annex 2: Non-public information. This annex is confidential and not included in the public version of this decision.