ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003909-61-03/F Helsinki, 13 December 2013

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

For fatty acids, C5-10, esters with pentaerythritol, CAS No 68424-31-7 (EC No 270-291-9), 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 dossier for fatty acids, C5-10, esters with pentaerythritol, CAS No 68424-31-7 (EC No 270-291-9) submitted by [redacted] (Registrant).

This decision is based on the registration dossier 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 after 5 September 2013, 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. The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 29 March 2012.

On 21 August 2012 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 19 September 2012 ECHA received comments from the Registrant to ECHA's draft decision.

On 4 January 2013 the Registrant updated his registration dossier (submission number [redacted]).

On 22 March 2013 the Registrant updated his registration dossier (submission number [redacted]).

ECHA considered the Registrant's comments and the updated dossiers. Based on the comments and the updated dossiers, Section II of the draft decision was amended and the Statement of Reasons (Section III) was modified accordingly.

On 5 September 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) below;
b. Composition (Annex VI, 2.3.), as specified under section III.(b) below;
c. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as described under section III.(c) below.

Taking into consideration the data currently available in the dossier, ECHA considers the following. Section III below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, in that case it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **13 March 2014**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

(a) Name or other identifier of the substance (Annex VI, 2.1.)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) - referred to as "the Guidance" thereinafter. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported. ECHA observes that the Registrant did not provide sufficient information on the naming of the registered substance (as explained under points (i) and (ii) thereinafter), including also the assigned EC and CAS identifier (as indicated in point (iii) thereinafter).

(i) A chemical name representative of the registered substance

The chemical name originally specified in the registration dossier ("Fatty acids, C5-10, esters with pentaerythritol") did not take into account the level of esterification of pentaerythritol in the substance. ECHA requested in the draft decision the Registrant to revise the name so as to take this element into account. ECHA also requested the Registrant to ensure that the fatty acids starting material designated in the chemical name of the registered is constructed around specific principles specified in the draft decision.

ECHA notes that the Registrant revised, in a registration update following the notification of the draft decision (thereinafter the "update dossier"), the chemical name assigned to the registered substance to "Tetra-esterification products of C5, C7, C8, C10 fatty acids with pentaerythritol". With this updated name, the Registrant not only qualified the level of esterification but also defined more narrowly the fatty acids starting material from which the substance is manufactured. The updated chemical name indicates in particular that the registered substance corresponds to the esters of "C5, C7, C8, C10 fatty acids". ECHA understands that such fatty acids refer to a starting material comprising, in line with the Guidance, all four linear carboxylic acids with chain lengths C5, C7, C8 and C10. However ECHA also notes that the Registrant indicated, in the Description field in IUCLID section 1.1 of the update dossier, that the fatty acids used present "*a variable type of alkyl group: i.e.*

n-alkyl or iso-branched-alkyl chain" and is therefore not limited to linear structures. ECHA points out that this declaration on the presence of branched fatty acids structure constitutes information which was not specified in the original dossier.

ECHA therefore concludes that, already due to the presence of both linear and branched carboxylic acids in the fatty acids used for the manufacturing of the registered substance, the chemical name assigned in the update dossier to the registered substance is still inappropriate for its identification.

The Registrant is accordingly required to revise the chemical name assigned to the registered substance as specified in the first bullet point of sub-section (iv) below.

(ii) The manufacturing process

- Identity of the fatty acids starting material

The fatty acids starting material used to manufacture the registered substance had not been identified to a sufficient level of detail in the dossier initially submitted. ECHA pointed out in its draft decision that UVCB substances such as this starting material cannot be sufficiently identified by a chemical name only. As the composition of such starting material is to a significant extent known and is one of the factors determining the composition of the registered substance, compositional information of that starting material (in terms of identity and upper and lower concentration levels of the different carboxylic acids) is a necessary element for its identification and therefore for the identification of the registered substance itself. ECHA thus requested in the draft decision the Registrant to provide this information which was missing in the original dossier.

ECHA notes that the Registrant indicated, in the manufacturing process description in IUCLID section 3.1 of the update dossier, that the fatty acids starting material used for manufacturing the registered substance is the result of the formulation of [redacted] different fatty acids with different carbon number. For each fatty acid, the Registrant specified the backbone type ([redacted]) and the relative concentration for a typical formulation.

However, this information is still not sufficiently detailed for the identification of fatty acids starting material as explained thereinafter:

- The nature of the branching in the C5 acid is unclear. The terminology "[redacted]" for C5 acid in the name "[redacted]" would indicate that this acid specifically refers to "[redacted]". However, the reference to [redacted] in quotation marks does not enable ECHA to associate with certainty the branched C5 carboxylic acid used to the specific branched structure "[redacted]". In addition, the result from the chromatographic analytical report attached in IUCLID section 1.4 of the update dossier makes reference to the presence of "iC5" and "nC5" fatty acid block in the registered substance. ECHA understands that the prefix "i" stands for "iso" while the prefix "n" stands for "normal". This information would indicate the presence of linear C5 fatty acids, which contradicts with the indication from the Registrant that the structure of the C5 acid(s) is branched.

- The Registrant did not specify the branching type and the relative contribution of the branched structures and linear structure in the [redacted] acids.

As the composition of the starting materials (in terms of identity, composition and ratio of the different fatty acids) are factors determining the composition of the registered substance, details of the overall composition of the fatty acids used (in terms of identity and upper and lower concentration levels of each individual linear carboxylic acids and of the branched carboxylic acids presenting the same carbon number) are a necessary element for the identification of the registered substance.

ECHA therefore concludes that compositional information on the fatty acids starting material has still not been provided to a sufficient level of detail for the identification of the registered substance.

The Registrant is accordingly required to revise the chemical name assigned to the registered substance, as specified under the second bullet point of sub-section (iv) below.

- Relevant process parameters

Specifications of the manufacturing process parameters determining the degree of completion of the esterification reaction of the registered substance (such as the acid and saponification values) were not provided in the original dossier. ECHA pointed out in the draft decision that such parameters are essential elements of the manufacturing process as they determine the composition of the registered substance and requested the Registrant to provide this information.

ECHA notes that the Registrant stated, in the documentation attached in IUCLID section 1.4 of the update dossier, that the "*processing conditions (duration, temperature, reflux) allows for complete esterification*" and that "*batch process is controlled by quality parameters, including Saponification number*". However, the Registrant did not define these process parameters (referred to as "quality parameters" by the Registrant), including their values. The provided information does not enable to conclude as to whether residual starting materials such as the carboxylic acids used in the process can for instance be present in the composition of the registered substance.

ECHA therefore concludes that the manufacturing process parameters have still not been described to a sufficient level of detail for the identification of the registered substance.

The Registrant is accordingly required to provide the missing relevant process parameters, as specified under the second bullet point of sub-section (iv) below.

(iii) The EC and CAS information

The EC and CAS name corresponding to the EC and CAS numbers assigned to the substance in the dossier is "Fatty acids, C5-10, esters with pentaerythritol". In line with the abovementioned observations on the chemical name assigned to the registered substance in section III.(a)(i) of this decision, such name does not represent the composition of the fatty acids as it does not reflect the absence of C6

and C9 carbon numbers as well as the presence of both linear and branched structures.

ECHA notes that the Registrant specified, in the information attached in IUCLID section 1.4 of the update dossier, that they "*will maintain a link to the reference substance described with CAS# 68424-31-7 (EC no 270-291-9) Fatty acids, C5-10, esters with pentaerythritol*". ECHA underlines that it is a prerequisite that the CAS number reported in the dossier matches the substance registered under REACH. This information shall not contradict the substance identity provided for by the naming of the registered substance.

The Registrant is accordingly required to revise the EC and CAS information, as specified under the third bullet point of sub-section (iv) below.

(iv) The information required from the Registrant

- A chemical name representative of the registered substance must be provided

Based on the observation set out in sub-section (i) above, the Registrant is accordingly required to revise the chemical name assigned to the registered substance.

In particular, regarding the designation of the fatty acids starting material in the chemical name of the registered substance, ECHA points out that constructing the chemical name on the basis of:

- the main fatty acids (i.e. those linear fatty acids (e.g. C5 fatty acid) and those fatty acids with a specific branched structure (e.g. 3-methylbutanoic acid), which individually present an upper concentration level ≥10% (w/w) in the starting material); and
- the groups of fatty acids of the same carbon number with an undefined branched structure (e.g. C5 branched fatty acids), which present an upper concentration level ≥10% (w/w) in the starting material,

is considered appropriate provided that they altogether compose at least 80 % (w/w) of the substance. If this condition is not met, all fatty acid constituents in the starting material, as identified by their carbon number and alkyl chain type (e.g. linear, branched), shall be taken into account for the naming of that starting material. Where the starting material is composed of one specific fatty acid at a concentration level of ≥80% (w/w), this starting material shall be designated, in the chemical name of the registered substance, by the chemical name of that fatty acid.

In its draft decision, ECHA required the Registrant to ensure that the reference to the main group(s) of ester constituents presenting the same degree of esterification (i.e. monoesters, diesters, triesters and/or tetraesters with pentaerythritol) is specified in the chemical name of the registered substance. Such main group is the group present at a concentration level of ≥80% (w/w) in the registered substance. If such group does not exist, all the groups present at a concentration of ≥10% (w/w) designate the main group(s) to be referred to in the chemical name. ECHA notes that the Registrant qualified in the update dossier the level of esterification in the chemical name of the registered substance. ECHA would like to stress that the

Registrant shall ensure that the principle set out in the draft decision, as specific in the paragraph above, is complied with.

- Further detail on the manufacturing process must be provided

Based on the observation set out in sub-section (ii) above, the Registrant is required to submit:

- Compositional information of the starting material in terms of identity and upper and lower concentration levels of each individual linear carboxylic acid, each fatty acid presenting a specific branched structure (as it may be the case for the "iso" C5 referred to by the registrant as C5) and each undefined branched fatty presenting the same carbon number; and
- Specifications of the process parameters (including their values) determining the degree of completion of the esterification such as the acid and saponification values.

- The EC and CAS information must be revised

Based on the observation set out in sub-section (iii) above, the Registrant shall delete from the dossier the CAS information currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance. If the Registrant deems it appropriate, he can however specify the current CAS information as "related CAS information" for the registered substance.

The Registrant shall not remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however specify in the dossier that the EC entry currently assigned does not specifically correspond to the registered substance and shall refer to any available and appropriate EC number specifically corresponding to the substance.

ECHA wishes to stress that the information currently contained in the dossier which the present decision does not require to remove or modify is considered as necessary for the determination of the identity of the substance. Such information shall therefore not be removed or modified by the Registrant. In the absence of valid justification, any change made by the Registrant to such information will not be taken into consideration by ECHA and will be considered as a deliberate obstruction to the determination of the identity of the substance.

ECHA recognises that the Registrant may cover different grades of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, the Registrant shall provide the required information on the sources, manufacturing processes and constituents of each grade. ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration.

More generally, the Registrant should note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations. ECHA has established processes, subject to certain conditions, enabling registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

As for the reporting of the information in IUCLID, the chemical name and manufacturing process description should be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively. Any available CAS information should be reported under the CAS information header of the reference substance in IUCLID section 1.1. The CAS entry with CAS number can be reported under the "Related CAS information" header in IUCLID section 1.1. The Registrant should also specify, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 270-291-9 currently assigned does not specifically correspond to the registered substance. This identifier can technically not be modified or deleted at this stage in the present registration update". The Registrant should also specify, in the same IUCLID field, any available and appropriate EC number for the substance.

The Registrant shall ensure that the correct identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this decision is made.

(b) Composition (Annex VI, 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

More specifically, the Registrant reported as compositional information in the original dossier the typical concentration levels of two groups of constituents, i.e. the esters of the "C5-10 fatty acids" with either pentaerythritol or dipentaerythritol. However, the reported composition did not include any qualitative and quantitative information on the constituents which each group consist of. In particular, the degree of esterification of these groups of constituents had not been specified. While ECHA acknowledged that the number of constituents covered by each group can be so large that they cannot be reported individually, information on the relative content of the different fatty acid blocks which each group of ester constituents consists of can nevertheless be provided.

In addition, the Registrant did not provide any information on the minimum and maximum concentration levels of the constituents. Without this information, ECHA cannot conclude on the variability in the composition of the specific substance covered by this registration. ECHA therefore requested in the draft decision the Registrant to provide the missing information on the composition of the registered substance.

In the update dossier, ECHA takes note that the Registrant specified that the relative content of the registered substance does not consist of esters of linear fatty acids only but also of branched fatty acids, which further extend the number of constituents alleged to be present in the composition originally reported.

ECHA also notes that the Registrant declared, in the chromatographic report attached in IUCLID section 1.4 of the update dossier, that *"[t]he concentration of constituents in the UVCB substance is dependent on the concentration of each of the starting materials"*. ECHA recognises that a duly justified statement from the Registrant that the distribution of the different fatty acids in the starting material corresponds to the distribution of the fatty acid blocks in the esters of the manufactured substance would address the requirement on the composition in the draft decision sent to the Registrant. However, the current statement in the chromatographic report is not sufficient as the update dossier does not provide sufficiently detailed information on the composition of the fatty acids starting material used in the process, as explained in section III.(a)(ii) of this decision. In addition, it is unclear how far the chromatographic analysis where the aforementioned statement is specified relates to the substance actually registered, as explained in section III.(c) of this decision. Therefore, ECHA cannot conclude from the abovementioned statement in IUCLID section 1.4 on the contribution of the fatty acid blocks in the composition of the registered substance.

ECHA also notes that the Registrant specified in the update dossier that "[n]*one of the constituents is present at a concentration of > 10%*". As pointed out in chapter 4.3 of the Guidance, ECHA would like to stress that the absence of constituents >10% does not, as such, exempt registrants from reporting individual constituents or groups of constituents in the composition of the registered substance.

ECHA furthermore observes that the Registrant removed, in the update dossier, compositional information originally present in the dossier without being requested by ECHA to do so. More specifically, the Registrant removed, in the update dossier, the concentration level for the esters of pentaerythritol and for the esters of dipentaerythritol specified in the initial submission. The description of the registered substance in IUCLID section 1.1 and the analytical data in IUCLID section 1.4 clearly indicates that the registered substance consists of esters of both pentaerythritol and dipentaerythritol. ECHA underlines that the information on the contribution of the esters from these different polyol blocks is necessary for the identification of the registered substance.

ECHA therefore concludes that the Registrant did not provide the compositional information on the registered substance requested in the draft decision. The current compositional information is still not provided to the required level of detail.

The Registrant is therefore required to submit the following compositional information, in accordance to chapter 4.3 of the Guidance:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered

substance. For the substance which is the subject of this registration, the reporting of the ester functionalised constituents according to groups presenting the same polyol building block (i.e pentaerythritol, dipentaerythritol...) and the same level of esterification (i.e. mono-esters, di-esters, tri-esters...) is necessary for this aforementioned purpose. For each of these groups, information on the relative abundance of the different acid blocks shall also be specified, including any specific linear of branched structure (such as C5 linear saturated and3-methylbutanoic acid block), any undefined branched structure with a specific carbon number (such as C7 branched saturated) as well as any other acid block also present.

For each constituent or group of constituent, the typical, minimum and maximum concentration levels shall be specified.

ECHA wishes to stress that the information currently contained in the dossier which the present decision does not require to remove or modify is considered as necessary for the determination of the identity of the substance. Such information shall therefore not be removed or modified by the Registrant. In the absence of valid justification, any change made by the Registrant to such information will not be taken into consideration by ECHA and will be considered as a deliberate obstruction to the determination of the identity of the substance.

Where the Registrant covers different grades of the substance in a registration based on different constituents, the Registrant shall report separately the source, manufacturing process and the compositional information of each grade. ECHA underlines that the reporting of the composition of different grades under one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration.

ECHA underlines that this registration solely refers to the substance corresponding to esters with pentaerythritol. In the case where the polyol is used in the esterification reaction and ends up as building block of the esters corresponding to the "reaction mass" of pentaerythritol and dipentaerythritol, separate registration(s) shall be submitted.

More generally, the Registrant should note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations. ECHA has established processes, subject to certain conditions, enabling Registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of registration.

Regarding how to report the composition in IUCLID, the following applies: The Registrant shall indicate the composition of the registered substance in IUCLID Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. The relative abundance of the different carboxylic acid blocks within each group of ester constituents should be provided in the Remarks field of the repeatable block for that group.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

(c) Description of the analytical methods (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

More specifically, the Registrant provided in the original dossier a report from the gas chromatographic analysis of a sample of the registered substance. This report included a peak table including relative integral areas. However, the original dossier did not include any information on how the results from the chromatographic analysis could eventually be translated into concentration values of the different constituents and groups of constituents present in the composition. ECHA therefore requested in the draft decision the Registrant to provide the missing description of the analytical methods.

In the update dossier, the Registrant specified that the esters in the registered substance can be individually identified by GC/MS technique. The Registrant also included in the report a table with 93 entries corresponding, according to the Registrant, to the pentaerythritol tetra-ester constituents. However, this report is only partial as it does not take into account the dipentaerythritol constituents also alleged to be present in the composition. It is also unclear how this report relates to the chromatogram attached in the dossier and the registered substance itself. The report does not specify any clear link enabling to correlate the peaks in the chromatogram with the entries in the table. In addition, the reference to the presence of "nC5" (i.e. linear C5 fatty acid blocks) is not consistent with the provided manufacturing process description, as explained in section III.(a)(ii) of this decision.

ECHA therefore concludes that the registration does not include a full description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

IV. 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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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