Decision number: CCH-D-2114303418-56-01/F Helsinki, 30 June 2015

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

For 2-phenoxyethanol, CAS No 122-99-6 (EC No 204-589-7), 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 2-phenoxyethanol, CAS No 122-99-6 (EC No 204-589-7), 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 5 March 2015, 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 25 June 2013.

On 3 December 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 15 January 2014, ECHA received comments from the Registrant on the draft decision.

On 2 April 2014, the Registrant updated the registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 5 March 2015, 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, a proposal for amendment to the draft decision was submitted.

On 10 April 2015, ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 20 April 2015, ECHA referred the draft decision to the Member State Committee.

By 11 May 2015, the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2015 in a written procedure launched on 13 May 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

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

1. Revised DNELs for workers and for the general population for long term dermal exposure – systemic effects (Article 14(3) and Annex I) using the recommended assessment factors by ECHA[1] or a full justification for not using the recommended assessment factors in the DNEL derivation, as specified in Section III.A.1 below;

2. Documentation that risks to workers are adequately controlled (Article 14(6), Annex I), as specified in Section III.A.2 below;

3. Environmental exposure assessment and risk characterisation (Article 14(4); Annex I, sections 5 and 6), as specified in Section III.A.3 below;

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 **7 January 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.

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

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.

According to Article 14(3), the chemical safety assessment shall include human health, physicochemical and environmental hazard assessments. If the substance fulfils the criteria for any of the hazard classes or categories referred to in Article 14(4) of the REACH Regulation, the chemical safety assessment shall also include exposure assessment including the generation of exposure scenarios (or the identification of relevant use and exposure categories if appropriate) and exposure estimation, as well as risk characterisation. The additional steps of the CSA shall be carried out in accordance with Section 5 (for the exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

1. DNELs for long term dermal exposure – systemic effects for workers and for the general population

According to Article 14(3) and Annex I, 1.0.3 and 1.4.1 of the REACH Regulation, DNEL(s) (Derived No-Effect Levels) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. Depending on the available information and the exposure scenarios it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers). 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 DNELs reflect the likely route(s), duration and frequency of exposure.

Annex I, 1.4.1 also requires that a full justification for the establishment of DNELs is given specifying, among others, the choice of information used, the route of exposure and the duration and frequency of exposure of the substance for which the DNEL is valid.

The ECHA "Guidance on information requirements and chemical safety assessment" (Volume 8, R.8[2]) provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

In the present case, ECHA points out that since the dermal absorption of the registered substance is, according to the technical dossier, high, >[redacted]% and rapid and the substance is used in coatings, cleaning agents and functional fluids, there may be a concern for workers and general population. Accordingly, it is necessary to identify a respective DNEL for these relevant human populations.

In identifying respective DNELs for these two human populations, ECHA observes that the Registrant has not followed 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 the Registrant has not used the default AF of 5 (workers) and 10 (general

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

population) for intraspecies differences (ECHA guidance R 8; chapter R.8.4.3.3) to derive a DNEL for long term exposure for systemic effects. Instead, the Registrant has used the AF of 3 (workers) and 5 (general population). This means that higher DNELs than those based on the ECHA Guidance are derived.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, proposed to further justify the use of the ECETOC assessment factors in the derivation of the DNELs and referred to distributions of human data for various toxicokinetic and toxicodynamic parameters. Moreover, the Registrant has stated that "the 95th percentile is considered sufficiently conservative to account for intraspecies variability in the general population".

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.*" 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.

In the present case, ECHA Secretariat notes that on one hand some of the Registrant's justification is only based on general considerations and does not provide substance-specific information. Furthermore, the above reference to the 95th percentile is an arbitrary opinion of the Registrant on the level of protection regarded sufficient for the human population; it is not a scientific justification. In addition, ECHA's default factors are based on the available relevant publications and reports. The Registrant's reasoning does not provide ECHA with reasons to alter its default assessment factors.

On the other hand, the information provided by the Registrant which is substance specific does not provide information about inter-human variation in toxic response to the registered substance for the following reasons:
1) The registrant provides pharmacokinetic information on the metabolism of the parent compound, assuming that 2-phenoxyethanol is the toxicophore. However, the Registrant has not provided information to prove that the metabolites of 2-phenoxyethanol are harmless. ECHA cannot therefore verify the Registrant's conclusion that 2-phenoxyethanol is the (only) toxicophore. If the metabolites of 2-phenoxyethanol have appreciable toxicity, then information on the disappearance of the parent compound does not directly inform on the toxicity of the metabolites of 2-phenoxyethanol. Thus the pharmacokinetic information on 2-phenoxyethanol does not provide information on inter-human differences in toxicity of 2-phenoxyethanol.
2) The Registrant provides information comparing the metabolism of 2-phenoxyethanol, particularly noting that metabolism in human is faster in human (including premature newborn infants) than in experimental animals. However, this argument addresses inter-species variation in metabolism, and not inter-human variation in metabolism (i.e. intraspecies variation). The Registrant has not provided in his comment quantification of the variation in metabolism of 2-phenoxyethanol in humans, including premature newborn infants, and so there is not an argument to justify that the lower assessment factor for intra-species variation is valid even in terms of the metabolism of the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant shall submit in the CSR either revised DNELs for workers and for the general population for long term dermal exposure - systemic effects using the recommended assessment factors or a

full justification why the recommended assessment factors are not used in the DNEL derivation 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;
- the DNELs reflect the likely route(s), duration and frequency of exposure.

2. Documentation that risks to workers are adequately controlled

Article 14(6) as well as Annex I, 0.1, 5.1.1, 5.2.4 and 6.2 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented. According to Annex I, section 0.7, if the substance is placed on the market, the relevant exposure scenarios, including the risk management measures and operational conditions, shall be included in an annex to the safety data sheet in accordance with Annex II to the REACH Regulation (as amended by Commission Regulation (EU) No 453/2010).

Pursuant to Annex VI section 5 and Annex II, section 0.1.2 of the REACH Regulation, the information provided in the Safety Data Sheet shall be consistent with that in the CSR. The requirements of Safety Data Sheets are specified in Annex II (amended by Commission Regulation (EU) No 453/2010).

The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, Annex II, section 8.2.2.2. (b)(i), relates to the provision of information within the Safety Data Sheet and requires the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure in accordance with Annex II, section 8.2.2.2. (b)(i)) in order to minimise the exposure for workers handling the registered substance. Pursuant to Annex VI, section 5 and Annex II, section 0.1.2. of the REACH Regulation the information provided in the the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

To ensure the safe use of a substance, Annex I Section 5.1.1 requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, it is considered gloves should be specified that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. This specific information is missing in the CSR and IUCLID Section 11 and should be provided by the Registrant where exposure is to the pure substance. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include to the breakthrough time and thickness of the glove material.

According to Annex I, 5.2.5, appropriate models can be used for the estimation of the exposure levels.

In the present case, ECHA notes that the Registrant has used ECETOC TRA model to predict the dermal challenge. ECHA observes that the model has been used throughout and correctly within the limitations of the model, to provide predicted quantitative estimates of systemic dose. The Registrant has subsequently sometimes modified the outputs to take account of concentration of 2-phenoxyethanol in the formulations.

In ECHA's view, this model cannot, however, be considered as appropriate because it has the potential to under-predict dermal challenge, i.e, what gets on the skin especially when compared to other specifically developed models, based on real data (e.g. RISKOFDERM, REACH Guidance R14[3]).This is a particular concern for substances that are highly absorbed, such as the registered substance for which dermal absorption is reported in the CSR to be high, >[redacted]% and rapid. ECHA Guidance R.14 (R 14; chapter R.14.4.6.2) states dermal exposure is a complex issue and requires registrants to consider also the possibility of peak internal dose when substances are suspected of having a high rate of dermal absorption. ECHA further notes that the Registrant has developed exposure scenarios that incorporate a wide range of Process Categories (PROCs) including PROCs 7 (industrial spraying), 10 (roller/brush application), 11 (non-industrial spraying), 13 (dipping/pouring), and 19 (hand mixing with intimate contact).

In the dossier, the Registrant states that industrial workers may be exposed to the pure substance, professionals to mixtures up to [redacted]% and consumers to mixtures up to [redacted]%.

ECHA considers that currently in the dossier the risk management measures are not well aligned with the likely real risk, but rather have been determined through modelling alone, identifying gloves as the primary exposure modifier for tasks such as use of cleaning agents. In particular, risk management measures do not address the potential for dermal exposure other than to the hands. As a consequence the risk management measures are not properly described in the CSR. Specifically, the Registrant should identify those tasks where industrial workers and professional workers should wear protective clothing.

ECHA notes that the Registrant has revised the exposure assessment using the updated version (v3) of ECETOC TRA within the EasyTRA tool. In his update the Registrant has removed almost any reference to protective clothing as a risk management measure in the CSR. He also does not provide any information on gloves material etc. in his update even though he in his comments on the DD indicated he would provide the information. The only references to "protective clothing" are now under classification and labelling (p 17 CSR) and under carcinogenicity (p 65 CSR) "Exposure via dermal route is also considered to be negligible in most use scenarios since the employees are wearing gloves and protective clothing."

There is no evidence in the dossier that higher tier tools have been used to predict exposures that may lead to challenge to body parts other than the hands. The original draft decision was based around the potential for exposure to other body parts and for concentrated solutions it would be necessary to propose suitable and adequate personal protective clothing linked to European standards. This information is missing and is required by Annex I section 5.1.1. where the appropriate risk management measures are required to be described. Reference to the glove material and standard for chemical protective clothing are part of that description.

[3] Link to ECHA guidance document R.14 is: http://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf

Therefore, the Registrant shall, in line with Articles 14(6), 41(1) and 41(3) of the REACH Regulation, provide a revised CSR documenting appropriate risk management measures to adequately reflect the uncertainty arising from the exposure modeling, the potential for real dermal challenge other than to the hands, rapid absorption through the skin, and the deficiencies in the current proposals for personal protective equipment. The workers and professionals should wear, as a minimum, protective clothing to the standard EN 13034:2005, Chemical protective clothing offering limited protection against liquid chemicals (type 6 and type PB [6] equipment).The Registrant is also required to provide in the CSR a description of the gloves to be used when handling the substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the safety data sheets. If it is necessary to protect a part of the body other than the hands, the type and quality of protection equipment required shall also be specified.

The Registrant is reminded that other models proposed in the REACH guidance R.14[2] do provide a more scientifically-based estimation of potential dermal challenge – RISKOFDERM is specifically described and will provide estimates of challenge for specified operational conditions.

3. Environmental exposure assessment and risk characterisation

Article 14(4) and Annex I, section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Article 14(4) and Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in the section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, section B.8.4[4]. states that "according to Annex I of REACH, exposure assessment has to cover all hazards that have been identified according to sections 1 to 4 of Annex I of REACH". Among others such identified hazards necessitating exposure assessment are "hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified".

In the CSR provided by the Registrant the exposure scenarios or exposure estimations for the environment are missing and this has been justified with the following statement:

"*As no environmental hazard was identified no environmental-related exposure assessment and risk characterization was performed*".

[4] Link to ECHA guidance document on Information Requirements and Chemical Safety Assessment part B is: http://echa.europa.eu/documents/10162/13643/information_requirements_part_b_en.pdf

ECHA points out that the registered substance has an EU harmonised classification of Acute Tox. 4 (H302: Harmful if swallowed), Eye irritant 2 (H319: Causes serious eye irritation) according Annex VI to Regulation EC) No 1272/2008 i.e. hazard classes 3.1.2 and 3.3. and thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to require an exposure assessment and risk characterisation in the chemical safety assessment. Additionally, ECHA notes that the substance has a wide-dispersive use (e.g consumer use: cleaning agents and coatings) and effects were observed in certain environmental toxicity studies provided by the Registrant. In particular, in the toxicity studies to aquatic invertebrates a NOEC of 9.43 mg/L was obtained. This value has also been used by the Registrant in PNEC derivation for aquatic environment. ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment[3], section B.8.4.2.2 states that "If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment. In these circumstances there are also unclassified hazards to the sediment and soil compartments because toxicity to aquatic organisms is used as an indicator of concern for sediment and soil organisms and a screening risk characterisation is undertaken using the equilibration partitioning method (EPM) to derive PNECs for sediment and soil. Hence quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments."

In his comments, the Registrant 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.

ECHA Guidance on the Scope of exposure assessment (B.8.1 page 45), which was prepared by ECHA Secretariat in collaboration with all relevant stakeholders, specifies that exposure assessment, and consequently risk characterisation, is mandatory if a substance meets the criteria for at least one of the hazard classes or categories (physical, health or environmental). This is the case for the registered substance which has a harmonised classification of Acute Tox. 4 (H302: Harmful if swallowed) and of Eye irritant 2 (H319: Causes serious eye irritation).

Also, the Guidance on the Scope for exposure assessment (B.8.1. page 43) further specifies that exposure assessment is not being limited only to classified hazards, but it has to be performed for all hazards identified including "hazards for which currently no classification criteria exist, but there is information to show that the substance has such hazardous properties". This is the case for the registered substance where effects were observed in certain environmental toxicity studies provided by the Registrant. In particular a NOEC of 9.43 mg/L was obtained for aquatic invertebrates.

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 disctinct 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 aquatic toxicity to invertebrates and toxicity to aquatic algae 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 points out that it respects the principle of equal treatment. In the case at hand it cannot be argued that similar cases would be treated differently: In the context of requiring an exposure assessment and the subsequent risk characterisation, the REACH Regulation differentiates two different types of substances: (1) substances that do not fulfil the criteria for classification in any of the hazard classes or categories set out in Article 14(4) to the REACH Regulation and Annex I to the CLP Regulation and, (2) substances that do. Only for the latter type of substances it is required to provide an exposure assessment and risk characterisation and therefore, equal treatment cannot be demanded between substances that belong to those two different groups. It can however be argued that the potential

higher risk related to a classified substance merits as well to get more knowledge of identified hazards that do not meet (yet) the threshold for classification.

Hence, the Registrant's claim that no hazard was identified for the registered substance is not supported by the data available in technical dossier.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to generate an exposure assessment and risk characterisation for the environment. The CSR shall be amended accordingly.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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