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

For Benzene, mono-C10-13-alkyl derivs., distn. residues, CAS No 84961-70-6 (EC No 284-660-7)

Addressees: Registrant(s)[1] of Benzene, mono-C10-13-alkyl derivs., distn. residues (Registrant(s))

This decision is addressed to the Registrant(s) of the above substance with active registrations pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by the National Institute of Health on behalf of Ministry of Health as the Competent Authority of Italy (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 7 October 2015, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Italy has initiated substance evaluation for Benzene, mono-C10-13-alkyl derivs., distn. residues, CAS No 84961-70-6 (EC No 284-660-7) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

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

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to environment/suspected PBT; exposure/wide dispersive use; consumer use and aggregated tonnage, Benzene, mono-C10-13-alkyl derivs., distn. residues was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of Italy was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA identified additional concerns regarding potential risk for soil compartment.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. 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 26 March 2015.

On 7 May 2015 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.

Registrant commenting phase

The Registrant(s) provided comments on the draft decision by the given timeline and on 7 October 2015 submitted an updated registration dossier. The evaluating MSCA reviewed the comments received from the Registrant(s) and the updated registration dossier, including additional data provided on P and B assessment. Having taken the comments and updated dossier into account, the Draft Decision was amended in Section II and Section III.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH regulation, on 21 January 2016 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, some Competent Authorities of the Member States and ECHA submitted comments and proposals for amendment to the draft decision. The evaluating MSCA reviewed the proposals for amendment received and, where considered appropriate, the draft decision was amended accordingly.

On 26 February 2016 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.

Referral to Member State Committee

On 7 March 2016 ECHA referred the draft decision to the Member State Committee.

By 29 March 2016 in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 12 April 2016 in a written procedure launched on 1 April 2016.

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

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods and instructions (in accordance with Article 13(3) and (4) of the REACH Regulation) and two test materials representative of the registered substance (as further specified in Section III):

1. Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) at a temperature of 20°C, as specified in Section III below;
   Simulation tests on these two test materials shall also provide the identification of degradation products, as specified in Section III below. If the first material tested is found to be persistent, there is no need to test the second material;

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods and instructions (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

2. Effects on terrestrial organisms - Long-term toxicity to terrestrial invertebrates (test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232), as specified in Section III below;

3. Effects on terrestrial organisms - Long-term toxicity testing on plants (test method: Terrestrial plants, growth test, OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030), as specified in Section III below;

4. Effects on terrestrial organisms – Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, EU C.21./OECD 216), as specified in Section III below;

5. Update of the Chemical Safety Report (CSR) by inserting Part A, as specified in Section III below;

6. Information related to the environmental exposure assessment and risk characterisation, as specified in Section III below:

   a) A detailed description of adopted Operational conditions (OCs) and Risk management measures (RMMs);
   b) Averaged release factors;
   c) Consumer uses related to PC28 and PC39;
   d) Proper characterisation of the risk for soil compartment.

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **20 December 2019** an update of the registration(s) containing the information required by this decision[2], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

1 Soil Simulation testing and identification of degradation products

Based on initial grounds for concern (suspected PBT/vPvB) and additional concern (potential risk for soil compartment) further information is required to clarify in a conclusive way whether the substance is persistent or not, as explained further below. This is in accordance with the PBT/vPvB assessment strategy (ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment, version 2.0, November 2014).

According to the evidence presented within the registration dossier (physico-chemical properties, environmental fate characteristics and exposure estimations), exposure to soil and sediment is likely. In particular, based on the intrinsic properties of the substance as well as the identified uses reported by the Registrant(s) (use as an agrochemical, some exposure scenario with wide dispersive use e.g. ERC8d) and exposure assumptions (application of sludge from sewage treatment plant (STP) to soil) direct and indirect exposure to soil compartment is likely to occur.

According to Annex IX, 9.2.1.3. and 9.2.1.4., of REACH Regulation a condition for sediment and soil testing is that the substance has a high potential for adsorption to sediment/soil (high values of Koc). ECHA noted that for the registered substace (HAB, Heavy Alkylate Bottoms) this condition is verified.

According to ECHA Guidance on information requirements and chemical safety assessment , Chapter R.11-PBT Assessment -Section R.11.4.1.1. (page 42, Version 2.0 November 2014): "*Soil/sediment simulation degradation testing is warranted if direct or indirect exposure to the substance is likely. Soil and sediment degradation simulation tests should only be considered if these compartments are directly exposed (cf. the emission characteristics of the chemical) or if they are indirectly exposed due to the environmental fate characteristics of the substance. The latter case includes, when the substance is released to surface water but due to high sorption partitions to the sediment or to STP sludge, which is spread on soil*".

ECHA further notes that the registered substance contains exclusively constituents with very low water solubility (<<0.1 mg/L) having very hydrophobic properties (log Kow-values generally > 8) and that information from environmental mass distribution modelling (Mackay level 3 Model, EPIWIN 4.1) indicate that the different types of constituents of the registred substance (HAB) will be distributed significantly in the environment to the sediment and soil compartments.

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

Furthermore the high log Kow values also indicate that a very significant fraction of the individual constituents of the registered substance will adsorb to organic carbon if HAB is being released via waste water to STP-sludge, which after deposition on soil may constitue a major exposure route of the HAB constituents to the soil compartment.

Therefore, in the initial draft decision the Registrants were requested to provide soil simulation study on the registered substance (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) together with the identification of the degradation products to clarify concern with persistency as a first step to clarify the initial PBT/vPvB concern. Regarding an appropriate and suitable test method, the method will have to be substance specific. When analytically possible, identification, stability, behavior, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

In their comments to the draft decision, the Registrant(s) agree on conducting the Soil simulation testing, but they also provide specific comments on QSAR prediction for P and B, on the test material, on the conditions at which the test shall be provided (including T) and on the deadline. Further description of the Registrants comments and ECHA's responses is provided below.

Firstly, in their comments and dossier update the Registrants reported QSAR calculations (EPISUITE) of representative constituents of the UVCB substance to analyze P and B properties of concern. The Registrants concluded that while there is still a concern with the persistence property of the registered substance, modelled BCF values of all representative constituents indicate no concern for bioaccumulation with the registered substance.

ECHA agrees with the Registrants that no robust conclusions on the persistence (P) of the registered substance can be made on the basis of QSAR predictions. With respect to the Registrants conclusion on bioaccumulation potential of the registered substance ECHA notes that the prediction is solely relevant for the constituents. However, the PBT/vPvB concern with the registered substance is not yet clarified since stable degradation products which are potentially PBT/vPvB may still be formed. Hence, ECHA considered necessary the request for the soil simulation testing with identification of the degradation products as a first step to clarify the initial PBT/vPvB concern.

Secondly, due to of the very high complexity of the registered substance, the Registrants proposed an alternative approach to testing the whole substance in the soil simulation test. Therefore, the Registrant(s) suggest to perform the simulation test on a specific surrogate substance, 1,4-di(2-decanyl)benzene, that is considered representative of the major category of Benzene mono-C10.13-alkyl derivs., distn. residues (dialkyl benzenes category, 20-70%) and of the whole registered substance. The Registrants in their comments indicate that "*Due to very high complexity of Benzene, mono-C10-C13-alkyl derivs., distn, the environmental fate studies are technically impossible to perform without significant modifications and/or adaptations of the draft decision. An alternative approach to testing the whole substance would be to test a single substance which represents the multiple components of Benzene, mono-C10-C13-alkyl derivs., distn.residues...*".

ECHA notes that according to R.11 PBT ECHA guidance "*The process of assessing multi-constituent substances (MCS) and UVCB substances comprises several stages, including identification of the constituents, impurities and additives [].. It also involves gathering available data, relating these to the P, B & T properties of constituents and impurities, and, where necessary, generating new information.[]*

Depending upon the type of UVCB, or the consistency of properties of constituents in an MCS, it may be possible to set up blocks, e.g. as in the hydrocarbon block method, that allow for the assessment to proceed, based on information from representative constituents/structures and read across to the blocks. Thus the composition of a UVCB can be defined in terms of representative structures for groups of closely related molecules.[]..In this way it is possible to "map" UVCB substances into a common set of blocks which can be evaluated with respect to the following properties".

ECHA understands from the Registrant(s)' comments that the test material choice is based on (i) availability of the test material, (ii) quantitative representation in the group (20-70%) and (iii) not-readily biodegradable results with another substance within this category in a 28-day standard ready biodegradability study. ECHA recognizes the difficulty to perform a soil simulation test with identification of degradation products on this highly complex UVCB substance and agrees with the Registrant(s) that there may be other ways of testing which would provide sufficient information to clarify the identified concerns as long as the material choosen are representative of the whole UVCB substance

However, ECHA considers that the test material chosen by the Registrant(s) is not sufficient to represent the whole registered substance for the clarification of the PBT/vPvB concern and the potential risk for the soil compartment, and the testing of an additional representative structure is necessary. In particular, ECHA notes that while the test material proposed by the Registrant(s) belongs to a class of constituents (dialkylbenzenes) that comprises 20-70% of the components of the registered substance this is one of the simplest of the 21 representative classes identified by the Registrant(s) (no complicated branching, only one phenyl ring). Therefore, in addition to test '1,4-di(2-decanyl)benzene' as proposed by the Registrant(s), ECHA requires to test an additional substance belonging to a different class that fulfil the following conditions: (i) represent a worst case class for testing in terms of suspected PBT/vPvB properties including consideration of its transformation products (e.g. more branching, more alkyl chains, presence of fused ring structures or more phenyl rings) and (ii) it is still present in a significant amount in the registered substance. The choice of the representative class is to be justified by the Registrant(s) to demonstrate the fulfilment of the above criteria. Furthermore, the Registrant(s) shall demonstrate why the chosen test materials are representative of their respective chemical class and of the whole UVCB substance in order to clarify the initial PBT/vPvB concern.

In reference to the test material, the Registrant(s) agree with ECHA <u>to perform the soil simulation study on two tests materials</u>. In particular, in the Registrant(s)' comments to PfAs it is reported that "*Discussions were held with experienced synthetic chemists to determine what other representative structures are possible to synthesize. Of the five categories which were classified as persistent based on the criteria of European Commission's Technical Guidance Document on Risk Assessment and Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB Assessment, the synthetic chemists have identified substances from the category, Diphenylalkanes, as having a high potential for being successfully synthesized. In addition to the Diphenylalkanes being representative of a chemical structure suggestive of a potentially more recalcitrant biodegradation profile, the category comprises an average of 5.5% of LAB Bottoms with a range of 0.8-12.1%*.[..]" Moreover the Registrant(s) propose to perform the soil simulation testing in a tiered approach. "*1,4-di(2-decanyl)benzene is tested first and if not persistent in the soil simulation study according to the Annex XIII criteria, a second constituent is tested. If 1,4-di(2-decanyl)benzene is found to be persistent, there is no need to test further constituents of LAB Bottoms. In this way the testing is minimized and unnecessary testing cost is avoided*".

ECHA agrees with the Registrant(s) that the category chosen, Diphenylalkanes, could be a representative class that fulfils the conditions reported above by ECHA. However, ECHA highlights that Registrant(s) shall justify why the two test materials chosen are representative of the whole UVCB substance. Moreover, it seems suitable the use of the tiered approach indicated by the Registrant(s) in the soil simulation test.

Thirdly, in their first comments the Registrant(s) indicated that "*While the registrant understand that since the 32nd meeting of the Member State Committee new simulation degradation studies are required to be carried out around neutral pH values and at 12°C, contract labs we have spoken to are still working to develop this capability. The majority of their standard units will not able to conduct the studies at the lower temperature. Until this capability is well defined in CRO's, the Registrants believe it would be better to conduct the studies at the standard temperature of 20°C and, if needed, a correction based on the use of the Arhenius equation should be used and half-life values extrapolated. An additional advantage of conducting the simulation study at a higher temperature would be the increased chance of degradation products being created at high enough concentrations to be identificable*".

ECHA notes the Registrant(s)' proposal to perform the test at 20 ºC to improve the capacity to identify degradation products (and making a correction according to the Arrehnius equation). In this specific case since the identification of the degradation products is relevant for the clarification of the PBT/vPvB concern, ECHA agrees with the Registrant(s)' proposal to perform the study at 20 ºC.

Moreover, in their comments the Registrant(s) indicated in respect to the requested soil degradation study that it should be done at a neutral pH (reference is being made to the 32nd meeting of the Member State Committee). ECHA notes that at that meeting the Committee was addressing the pH of surface water (OECD 309) and sediment (OECD 308) simulation degradation tests and not soil simulation degradation test. According to OECD 307 a soil degradation test should include testing in four different soil types with specific pH as specified in the test guideline (paragraphs 23 and 24, OECD 307).

Furthermore, regarding to the application rate that should be estimated based on the most relevant route of entry when the major route of entry in soil is through sewage sludge, this aspect is relevant for the registred substance and for the test requested. Therefore, the Registrant(s) should take into account paragraphs 21 and 41 of OECD 307 related to the expected sludge concentration and the amount of sludge added to the soil should reflect normal sludge loading to agricultural soils.

Finally, in their comments to the draft decision, the Registrant(s) indicated that the study will be very complex to conduct (synthesis of radiolabeled compound, development of extraction methodology and development of appropriate analytical methods), therefore they requested an additional 6 months to add to the timeline to complete the required dossier update. This request is considered in section IV below.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following studies:

Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) at a temperature of 20°C on two test materials;

Furthermore, identification of degradation products shall also be determined in order to clarify the initial concern on PBT/vPvB. If the first material tested is found to be persistent, there is no need to test the second material.

2.-4. Effects on terrestrial compartment

The information request is relevant to clarify the initial concern on environmental exposure/wide dispersive use and the identified additional concern: potential risk for soil compartment.

No data are provided by the Registrant(s) to evaluate the toxicity to the soil compartment. The waiving is based on ecotoxicity data, environmental fate properties and exposure scenarios, but is not further substantiated: "*Terrestrial toxicity data are not required based on data for long-term toxicity to aquatic invertebrates, adsorption/desorption, and the uses of HAB.*"

ECHA notes that data for long-term toxicity to aquatic invertebrates cannot be used to assess the terrestrial toxicity data because, in view of the high adsorption (log Kow between 6.6 and 9.9) and the insolubility of the substance, the screening assessment based on Equilibrium Partitioning Method (EPM) is not recommended, as specified in ECHA Guidance on IR&CSA, R.7C: "*When the substance is also readily degradable, biotically or abiotically, however, and has a log Kow <5, this screening assessment showing no risk using aquatic toxicity data is sufficient to obviate the need for further information under Annex IX. In other circumstances, the derivation of a PNECscreen derived from aquatic toxicity data alone would be insufficient to derogate from Annex IX or X testing.*"

Moreover, as highlighted above, the adsorption/desorption assessment shows very high values of Koc: this indication cannot be used to waive tests on terrestrial compartment, but may be used as support information to define which test has to be provided.

Regarding to the exposure considerations in the waiving (uses of HAB), ECHA highlights that the terrestrial Risk Characterisation Ratios (RCRs) provided by the Registrant(s) are not valid because are based on a PNECsoil calculated with the EPM, which, as above explained, is not recommended. Moreover, the Registrant(s)' calculation does not seem to be correct: following the indications reported in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterization of dose [concentration]-response for environment, "*in order to take uptake by soil ingestion into account […] the PECsoil/PNECsoil ratio is increased by a factor of 10 for compounds with a log Kow >5*". This is reaffirmed also in ECHA Guidance, Chapter R.7.c (version 2.0 – November 2014), which states that, where no soil toxicity data are available and "*where the adsorption is likely to be high, i.e. where the log Kow or log Koc >5, the PEC:PNEC ratio is multiplied by 10*." In this case, several of the soil Risk Characterisation Ratios, multiplied by 10 (RCR= PECx10/PNEC based on EPM) exceed the trigger value of 1 (scenarios ES2, ES3, ES4, ES9 and ES16).

Data from distribution modelling studies provided by the Registrant(s) predict that the majority of the substance will partition to soil and sediment and, on the basis of the information provided (high Koc values, log Kow between 6.6 and 9.9), this trend seems to be likely. In addition, the substance is not readily biodegradable. In this scenario, a risk for the soil compartment cannot be excluded because it is not possible to exclude direct and indirect exposure to soil for all the exposure scenarios, due to the use pattern and the environmental fate properties of the registered substance.

According to all those considerations, ECHA concludes on the need to investigate further soil toxicity and to characterise properly the risk for soil because, in view of the evaluation of exposure information, it is not excluded soil exposure of the substance.

Under these circumstances, the waiving justifications provided by the Registrant(s) are not adequate and the information requirements have to be fulfilled in order to clarify the initial concern on environmental exposure/wide dispersive use and the identified additional concern on potential risk for soil compartment.

To assess the toxicity in this compartment, in view of the high adsorption (high log Kow values between 6.6 and 9.9) and the insolubility of the substance, the screening assessment based on EPM is not recommended. For substances with such characteristics, long-term toxicity tests are suggested, and the PNECsoil shall be derived from the lowest value obtained.

Then, in view of the characteristics of the substance and in lack of adequate arguments in support of the justification, it is not possible to accept the data waiving and some information requirements, according to Annex IX and X, have to be fulfilled.

As stated by the Registrant(s), from the results obtained for the distribution modeling (Mackay level III model), it is clear a greater partition of the substance to the soil and sediment compartments. According to ECHA Guidance on information requirements and chemical safety assessment, chapter R.7c Section 11 (version 2.0 - November 2014), substances that show a high potential to partition to soil, and hence may reach high concentrations, or those that are persistent, present a particular concern for soil. In both cases long-term exposure of terrestrial organisms is possible.

Therefore, pursuant to Article 46(1) of the REACH Regulation, in order to clarify the initial concern on environmental exposure/wide dispersive use and the additional concern on potential risk for soil compartment, the Registrant(s) is required to submit the following information derived with the registered substance subject to the present decision:

- Effects on terrestrial organisms - Long-term toxicity to invertebrates (test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222), or Enchytraeid reproduction test (Test method: OECD 220), or Collembolan reproduction test in soil (Test method: OECD 232);

- Effects on terrestrial organisms – Long-term toxicity testing on plants (test method: Terrestrial plants, growth test, OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) and

- Effects on terrestrial organisms – Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, EU C.21./OECD 216).

In their comments, the Registrant(s) agreed on conducting the required tests.

Taking into account the clarifications/justification requested, related to the environmental exposure assessment and risk characterization (see below, paragraph 18), those tests are useful to a proper characterization of the risk for soil compartment. In view of these test results, the Registrant(s) shall recalculate PNECsoil using the lowest value of the newly generated data and apply the correct assessment factor. Moreover, the Registrant(s) shall use the new value of PNECsoil to calculate the ratio PECsoil/PNECsoil (RCR). If the ratio PECsoil/PNECsoil, calculated with the new toxicity value will result >1, an additional refinement of the PNECsoil is possible.

Moreover, to avoid uninformative tests, ECHA strongly recommends to the Registrant(s) to use the specific conditions suggested in the OECD Guidelines to test substances with low water solubility (e.g. OECD 208 sections 15 and 16; OECD 216 sections 19 and 20; OECD 222 sections 20 and 21, etc.).

5. Update of the Chemical Safety Report (CSR) by inserting Part A

According to Annex I, 0.13 of the REACH Regulation, Part A of the chemical safety report (CSR) shall include a declaration that the risk management measures outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those exposure scenarios for the identified uses are communicated to distributors and downstream users in the safety data sheet(s).
The Registrant(s) are requested to update the CSR by inserting Part A.

In their comments, the Registrant(s) agreed that Part A should be included in the CSR.

6. Information related to the environmental exposure assessment and risk characterisation

Regarding environmental exposure assessment and risk characterisation further information needs to be provided by the Registrant(s) to conclude on the initial concerns (wide dispersive use/consumer use/exposure and high aggregated tonnage) and on the identified additional concern (potential risk for soil compartment).

a) A detailed description of adopted Operational conditions (OCs) and Risk management measures (RMMs)

The guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (R.16.1.2.) indicates that "*the exposure estimation consists of the following steps:*
1. Determination of operational conditions (OC) and risk management measures (RMM), including, for example, amount of substance, process temperature, duration and frequency of use or activity etc, and industrial wastewater treatment plants, filters, scrubbers, municipal sewage treatment plants etc.;
2. Release estimation consisting of the determination of the local and regional release rates for each use, starting from the appropriate release factors and the tonnage assigned to any identified use;
3. Environmental distribution and fate and exposure estimation".

Moreover, ECHA's Guidance indicates the default release factors recommended for the corresponding environmental release categories (ERC) which shall be used for the generation of the exposure estimation. According to this Guidance the exposure scenario should contain information (about OCs and RMMs) based on which the assumed release factors and daily use rates can be justified. If other than default ERC release factors are used for emission estimation (for example the ones based on A/B Tables from TGD, 2003), this shall be clearly explained in the chemical safety assessment and these release factors shall be well justified.
A and B tables of the TGD (2003) are acceptable as long as they clearly provide more specific information on RMM/OC. Otherwise, they are considered insufficient to meet the REACH requirements.

In the updated CSR dossier, the Registrant(s) declare the use of spERCs (ESVOC) and of TGD, tables A and B. However, in the most of the provided exposure scenarios, there are not clear justification and detailed references of the adopted RMMs and OCs. Moreover, it occurs that the reported final release fractions are not consistent with the initial values and any justification or support documentation is provided.

In particular, ECHA notes that:

On-site Treatments

For exposure scenarios ES3 and ES4, the Registrant(s) report generically "Treat onsite wastewater" and "Treat air emission" and indicates the efficiency, but he does not provide any information about the type of treatment. Moreover, for compartment 'air' the reported efficiency does not correspond to ESVOC and no justification is reported.

Fraction tonnage

For exposure scenarios from ES1 to ES7, the Registrant(s) do not clarify the references of the "Fraction of EU tonnage used in region" and "Fraction of regional tonnage used locally" provided in the tables "Conditions of use", section "Amount used, frequency and duration of use (or from service life)".

For the other scenarios, which are related to wide dispersive use, the resulting regional tonnage is not multiplied by a safety factor of 4 and the justification provided by the Registrant(s) is "as for the uses described in this exposure scenario geographical or temporal peak in the use and release of the substance are not to be expected".

The ECHA Guidance Chapter R.16: Environmental Exposure Estimation (R.16.3.2.2.) reports that "*The resulting tonnage is multiplied by a safety factor of 4 to take into account geographical or temporal peaks in the use and the release of a substance, for example the use of anti-freeze compounds in window washing fluids for cars*". As stated by the Registrant(s) in the updated CSR dossier, the substance is however used in fertilizers and plant protection products (ES14), in biocidal products (ES15), in anti-freeze and de-icing products in biocidal products and fertilizers (ES16).

Therefore, for these exposure scenarios the Registrant(s) shall take into account geographical or temporal peaks in the use and the release of the substance and, accordingly, the regional tonnage should be multiplied by the safety factor of 4 in the calculation of daily wide dispersive use.

Emission days

The values of Emission Days, reported by the Registrant(s), are not always consistent with the adopted spERC. The inconsistency needs to be justified in the CSR.

In conclusion, ECHA notes that the Registrant(s) do not provide a clear description of the adopted OCs and RMMs, that appear not well documented, notwithstanding they shall be recommended to downstream users.

Therefore, the Registrant(s), according to the requirements of Annex I 5.1.1. of the REACH Regulation, are requested to provide detailed information on operational conditions and on risk management measures which are clear and well documented. According to the requirements of Annex I 5.2 of the REACH Regulation, the Registrant(s) are also requested to provide a clear and detailed justification for the use of non-default ERC release factors in the exposure estimation.

b) Averaged release factors

For ES16 and ES19, entitled "Miscellaneous uses", the Registrant(s) declare the market sectors without clarify the covered uses and the environmental conditions. The Registrant(s) declare that the release factors belonging to ERCs 8a, 8b, 8d and 9b were averaged.

The ECHA Guidance on information requirements and chemical safety assessment, Part A: Introduction to the Guidance document states that "*The exposure scenario for an identified use (or a group of uses) describes the conditions under which a substance fulfilling any of the criteria of the Article 14(4) hazard classes, categories or properties can be used whilst controlling risks*" (A.2.4.3.1). The ECHA Guidance Chapter R.12: Use descriptor system states that "*the description of the identified uses is consistent with the titles and the content of the exposure scenarios. This consistency is a legal requirement laid down in section 5.1.1 of Annex I of REACH*" (R.12.1) and that "*Different uses (as defined by the registrant) can potentially be addressed in the same exposure scenario, if the same operational conditions and risk management measures apply to all these uses*" (R.12.5.2).

Moreover, as stated in the ECHA Guidance on information requirements and chemical safety assessment, Part D: Exposure Scenario Building, descriptors shall be selected to structure and group the identified uses in a sensible way for exposure scenario building and exposure estimation.

Therefore, for ES16 and ES19, it is not possible to conclude if emissions from the professional and consumer miscellaneous uses are sufficiently addressed in the CSR.

Therefore, the Registrant(s), according to the requirements of Annex I 5.1.1. of the REACH, are requested to develop distinct exposure scenarios for not similar uses, giving the exposure scenario an appropriate short title and a brief general description of the use(s) covered by the ES.

In cases where more than one ERC was assigned, the Registrant(s) are requested to select the relevant and worst-case ERC for the modelling and the risk characterisation.

c) Consumer uses related to PC28 and PC39

In the CSR, in the exposure scenario ES19 the Registrant(s) declare that "*Assessments for PC 28 Perfumes, Fragrances and PC 39 Cosmetics, personal care products are not included in this document as both PCs are cosmetics-related and therefore not part of the REACH Regulation (EC) No 1907/2006 registration. These consumer uses are covered by the EU Cosmetics Directive (76/768/EEC)*."

According to Article 14(5)(b) of the REACH Regulation the Chemical Safety Assessment (CSA) does not need to include consideration of the risks to human health from the use in cosmetic products within the scope of Directive 76/768/EEC (now Cosmetics Regulation (EU) 1223/2009).

In accordance with Article 14(4) of the REACH Regulation, the CSA shall contain exposure assessment and risk characterisation if the substance is assessed to be a PBT or vPvB or meets the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation). The registered substance is classified as Asp. Tox. 1 H304, i.e. hazard class 3.10 set out in Annex I to the CLP Regulation.Consequently, the CSA of the registered substance shall also include environmental exposure assessment and risk characterisation for uses concerning market sectors PC 28 Perfumes, Fragrances and PC 39 Cosmetics, personal care products.

Therefore, according to the requirements of Annex I 0.6 of the REACH Regulation, the Registrant(s) are requested to perform an environmental exposure assessment and risk characterisation of the uses related to market sectors PC 28 Perfumes, Fragrances and PC 39 Cosmetics, personal care products.

d) Proper characterisation of the risk for soil compartment

The requested information is relevant to clarify the initial concerns: exposure/wide dispersive use; consumer use; aggregated tonnage; moreover the information request is essential to clarify the identified additional concern related to potential risk for soil compartment.

ECHA underlines that, as confirmed by the Registrant(s), according to a model calculation and due to the substance properties, the substance will preferentially be distributed into soil and sediment compartments.

In the updated CSR dossier, section 10.2.1.2, table 233, the Registrant(s) report the Regional exposure concentrations determined with EUSES. In according to Chapter R.16: Environmental Exposure Estimation (R.16.6.6.6.), local PEC_{soil} for each scenario corresponds to the sum of the local concentration (Clocal) and the regional PEC_{soil} (Equation R.16-56). However, the provided regional PEC_{soil} values are greater than local PEC_{soil} values reported in some ESs (ES1, ES8, ES11, ES12, ES13, ES14, ES15, ES17 and ES18) and this incongruence is not justified.

Moreover, as above detailed, for the soil compartment the adopted RMMs, OCs and release factors are not always clarified and justified.

Taking into account the requested clarifications/justification, the risk for the soil compartment is not properly characterised and especially considering that the risk characterisation ratios are close to 1 for the exposure scenarios ES2, ES3, ES4, ES9 and ES16; consequently ECHA notes the additional concern of potential risk for soil.

Moreover, in the CSR the Registrant(s) declare that the EPM is used. ECHA notes that the additional factor of 10 to the PEC/PNEC ratio, as the substance is insoluble (<0,1 mg/L) and the log kow>5, should be applied. However, for the soil compartment, none of the reported RCRs are in compliance with the above assumption. ECHA noted that, using the factor of 10, some RCRs soil (ES2, ES3, ES4, ES5, ES6, ES7, ES9, ES10, ES16, ES19) are higher than 1.

According to requirements indicated in Annex I 0.6 of the REACH Regulation the Registrant(s) are required to characterise properly the risk for soil, filling all the above mentioned gaps and to update accordingly the CSR.

Taking into account the information required the Registrant(s) are requested to refine the quantitative exposure assessment and, according to requirements indicated in Annex I 6 of the REACH Regulation, to update accordingly the risk characterisation.

In their comments, the Registrant(s) agreed on updating of exposure assessment and risk characterisation.

IV. Deadline to provide the requested information

In the draft decision communicated to the Registrants the time indicated to provide the requested information was 42 months from the date of adoption of the decision. Consequently, a proposal for amendment was received, proposing a shorter deadline of 30 months for the provision of the requested information. In the subsequent comments on the proposal for amendment, the Registrant(s) requested that the original timeline of 42 months be maintained and sought to justify this request on the basis of the time required for development of synthesis pathways of the test materials, the specific extraction methodology, and the appropriate analytical methods in OECD 307 experimental test. ECHA agreed with this justification and granted the request. Consequently, the deadline is set to 42 months.

V. Adequate identification of the composition of the tested material

In relation to the required experimental stud(y/ies), the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test(s) must be shared by the Registrant(s).

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

In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the stud(y/ies) on behalf of all of them.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

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

[1]As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process