EUROPEAN CHEMICALS AGENCY

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

For Octabenzone, CAS No 1843-05-6 (EC No 217-421-2)

Addressees: Registrant(s)[1] of Octabenzone (Registrant(s))

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

Registrants meeting the following criteria are *not* addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the National Institute of Health on behalf of the Ministry of health as the Competent Authority of Italy (evaluating MSCA, 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 4 June 2014.

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 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 Octabenzone, CAS No 1843-05-6 (EC No 217-421-2) 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.

On the basis of an opinion of the ECHA Member State Committee and due to the initial grounds for concern relating to: Human health/Sensitiser; Suspected endocrine disruptor; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage, Octabenzone was included in the Community Rolling Action Plan (CoRAP) for substance evaluation to be

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

evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of Italy was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA noted additional concerns regarding potential risk for environmental compartments (sediment, soil), potential human exposure via the environment and reproductive toxicity.

The evaluating MSCA considered that no further information was required to clarify the concern for sensitisation. The evaluating MSCA considered that further information was required to clarify other abovementioned concerns (see section II).
Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. On 20 March 2014 the evaluating MSCA sent the draft decision to ECHA.

On 29 April 2014, 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

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s). The information contained therein is reflected in the Statement of Reasons (Section III) and amendments to the Information Required (Section II) were made.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 15 January 2015 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, three Competent Authorities of the Member States and ECHA submitted comments and proposals for amendment to the draft decision.

On 20 February 2015 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 those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and where considered appropriate, the draft decision was amended accordingly.

Referral to Member State Committee

On 2 March 2015 ECHA referred the draft decision to the Member State Committee.

By 23 March 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the

proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 20 to 23 April 2015, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 22 April 2015. ECHA took the decision pursuant to Article 52(2) and 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 the registered substance subject to the present decision:

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

2. A range finding study for an Extended One Generation Reproductive Toxicity Study (EOGRTS – EU B.56/OECD 443) performed according to draft updated OECD 421(http://www.oecd.org/env/ehs/testing/section4healtheffects.htm – v. 05 March 2015) which shall additionally include immunological parameters as further specified in Section III.2;

3. Long-term toxicity testing to sediment organism (test method: Sediment-Water Chironomid Toxicity Using Spiked Sediment, OECD 218);

4. Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, OECD 216);

5. Effects on terrestrial organisms - Long-term toxicity to 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);

6. 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));

7. Descriptive text (justification) for each adopted refinement on environmental exposure for all scenarios;

8. Clarification of the adopted risk management measures (RMMs) as specified in Section III.8. below;

9. Environmental regional assessment: regional PECs with the related assumptions and regional risk characterisation for all compartments;

10. Proper characterisation of the risk for soil compartment as specified in Section III.10. below.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **24 March 2017** 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. Pre-natal developmental toxicity study

There is no information on developmental toxicity available for octabenzone. A prenatal developmental toxicity study is a standard information requirement according to Annex IX, 8.7.2. of the REACH Regulation. To clarify the concern on developmental toxicity the Registrant(s) shall perform a pre-natal developmental toxicity study. On the basis of this information the evaluating MSCA will evaluate the need to request further information in order to clarify the concern.

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

Therefore, pursuant to Article 46 (1) of the REACH Regulation, the Registrant(s) is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

ECHA notes that the Registrant(s) has requested in the written comments an extension of the deadline to submit the requested information and has provided supporting documentation to substantiate this request. Therefore, taking into account the additional statement of the [redacted], ECHA agrees to extend the deadline from the date of the decision and has set the date accordingly.

2. Range finding study for an Extended One Generation Reproductive Toxicity Study

During the evaluation process an additional concern for reproductive toxicity has been identified indicating a possible need to conduct an EOGRTS to clarify this concern.

During the consultation phase of the draft decision several proposals for amendments (PfAs) were made by other MSCAs and were later commented by the Registrant(s). Two MSCAs considered that further information was required to clarify the concern for endocrine disrupting (ED) properties and reproductive toxicity of the substance subject to the present decision and submitted PfAs to this end.

The first PfA stated that the ED potential of octabenzone needs to be further investigated since the 4-generation toxicity study (dated 1969) submitted by the Registrant(s) does not cover several important parameters, such as sperm parameters, estrous cyclicity and that microscopic examination was only investigated on F3a offsprings. Moreover, in the same PfA, the MSCA noted that some effects on endocrine organs have been observed in the 90-day toxicity study performed in rats (thyroid, female gonads and adrenals weight). Furthermore, the same MSCA proposed that there is a need to investigate on the ED potential of octabenzone since a read-across with oxybenzone for the genotoxicity endpoint has been proposed by the Registrant(s) and accepted by the evaluating MSCA and since this analogue substance has been shown to induce MCF-7 cell proliferation *in vitro*. Therefore, in

[2] The deadline set by the decision already takes into account the time that Registrant(s) 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 Registrant(s) (Article 53(1) of the REACH Regulation).

order to clarify this ED concern on octabenzone, this PfA proposed a tiered approach based on: (i) inclusion of additional hormonal parameters in the PNDT study; (ii) in case of hormonal disturbance in the PNDT study, request an EOGRTS.

The second PfA (from another MSCA) stated that there is a concern for fertility and pre-, peri- and post-natal developmental effects as covered by the standard information requirements of REACH Annexes IX and X, section 8.7.3, as amended, governing EOGRTS. In the view of that MSCA, this data gap is not covered by the required pre-natal developmental toxicity study (OECD 414). Indeed, the available 4-generation study (1969) in the registration dossier is inadequately reported and did not include examination of relevant parameters such as effects on oestrus cycle, sperm parameters, organ weights, pathology and histology. Furthermore, relevant and sensitive endpoints for assessment of endocrine disrupting potential – such as nipple retention and anogenital distance (AGD) - were not included in the outdated pre-guideline test protocol from 1959. As neither the available studies nor the requested PNDT study cover the (minimum) standard information requirements for reproductive toxicity and as there are no valid waivers from the standard information requirement (Annex X, 8.7.3.), there is an uncovered concern for reproductive toxicity. Furthermore, this PfA notes that several other benzophenone substances have been identified as potential endocrine disrupters.

The Registrant(s) has provided comments to these PfAs considering that there is no concern for octabenzone. In the comments made by the Registrant(s) on these PfAs it is stated that, the studies submitted in the registration dossier are suitable to clarify the concern on endocrine properties. The Registrant(s) is of the opinion that the ED concern for octabenzone is not justified as shown by a variety of *in vitro* and *in silico* comparative investigations published in peer-reviewed journals where the registered substance did not show any activity towards the ED system like certain other benzophenone substances. The Registrant(s) stated that in these studies octabenzone was shown to display no estrogenic, androgenic or anti androgenic activity, in contrast with some other benzophenone derivatives.

The Registrant(s) also stated that the available 4-generation study clearly demonstrated that there is also no concern for reproduction toxicity in an *in vivo* study. Hence, octabenzone in the view of the Registrant(s) is not raising any concern regarding endocrine disruption, fertility and reproduction. The Registrant(s) consider further fertility testing not necessary, and taking into account the hundreds of animal lives spared, also not appropriate.

As explained above, for octabenzone there are two major data gaps relative to the standard information requirements of REACH: fertility and pre- and post- natal developmental toxicity.

Regarding the fertility data gap, it cannot be considered to be covered by the in vitro assays on estrogen or antiandrogen activities, as such assays only investigated whether some endocrine-related mode of action can be elicited by octabenzone. However, these assays did not provide any information on impaired morphology or function at tissue or organ level. Most importantly, the available 4-generation study (1969) in the registration dossier does not match the current standard information requirements with regard to reproductive toxicity according to REACH Annex X Section 8.7.3. In particular, the study only provided a gross examination of fertility parameters (according to the outdated standards of the time when it was performed) but it did not include the examination of the most sensitive parameters such as effects on oestrus cycle and on sperm quality, serum hormone measurements, histopathology of ovaries, uterus, and testes; also the study did not consider effects on sexual development and pubertal timing (anogenital distance, testis descent, vaginal patency). The study leaves relevant uncertainties and does not allow

concluding on reproductive toxicity.

Moreover, the fact that repeated dose toxicity and chronic studies did not reveal effects on reproductive organs cannot rule out the potential effects on fertility by octabenzone, because these studies were performed in adults and did not examine the likely most sensitive lifestages, the intrauterine, postnatal and peripubertal phases and the investigation of the reproductive tissues and parameters was obviously less detailed than it would have been in an up-to-date reproductive toxicity study.

In line with the PfAs received, ECHA notes that the above described 4-generation study is inadequate as performed with an outdated pre-guideline test protocol. Furthermore, as also explained above, it is highlighted that relevant and sensitive endpoints were not included in the outdated protocol for a 4-generation study. It is important to note that the PfA requesting the EOGRTS has been considered to address the concern for reproductive toxicity. ECHA agrees that the concern should eventually be clarified with the request of an EOGRTS (B.56, OECD 443) to fulfil the existing data gap with regards to fertility, peri- and post-natal developmental toxicity as well as to further clarify the concern on the endocrine disrupting potential.

However, the limited available information that is also of insufficient quality, as explained above, does not allow to decide on the design of the EOGRTS, including the selection of appropriate dose level. For this reason a range finding study according to the draft updated OECD TG 421 (http://www.oecd.org/env/ehs/testing/section4healtheffects.htm – v. 05 March 2015) is necessary and additional parameters regarding immunotoxicity shall be included. Such additional immunological parameters in maternal animals shall, as a minimum, include white blood cell counting and spleen/thymus histopathology.

Depending on the outcome of the above range finding study, ECHA, on the basis of the evaluation of the evaluating MSCA, will decide on the need to perform and the design of a EOGRTS EU B.56/OECD 443. However, due to the limitation of this range finding study performed according to the updated draft OECD 421, a negative outcome will not exclude that further requests to clarify the concern will be needed.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision:

A dose range finding according to the draft updated OECD 421 (http://www.oecd.org/env/ehs/testing/section4healtheffects.htm – v. 05 March 2015) in order to decide on the EOGRTS design. In addition, immunological parameters in maternal animals (white blood cell counting and spleen/thymus histopathology as a minimum) shall be included.

3. Long-term toxicity testing to sediment organisms

The information request is relevant to clarify the identified additional concern: potential risk for environmental compartment (sediment)

The Registrant(s) provide a justification for waiving the information requirements on the sediment compartment according to the results of the exposure assessment.

The Registrant(s) consider all the relevant uses of the registered substance safe with a Risk Characterization Ratio below 1. $PNEC_{sed}$ and the Risk Characterization arguments for sediment are on the ground of a screening approach based on the Equilibrium Partitioning Method (EPM) utilising $PNEC_{water}$. The $PNEC_{water}$ otherwise is based on acute aquatic toxicity data, considered not suitable for the risk assessment by ECHA.

Moreover the applicability of the EPM for the sediment compartment toxicity assessment is questionable, because of the high absorption properties of octabenzone and due to initial concerns related to exposure consideration (wide dispersive use, high tonnage).

Given the low water solubility (value used for CSA: <0.73 µg/L) and the high log Kow (calculated logKow 7.6 at 25°C) of the registered substance, octabenzone is known to partition strongly to sediment and suspended solids. In such cases, it may be both impractical and uninformative to test pelagic species via the water phase. Furthermore, by the results obtained for the distribution modeling, the Registrant(s) indicated that the substance will be preferentially distributed into the compartments soil and sediment. Tests with sediment dwelling species may provide more useful information on the toxicity of the substance in the compartment in which it will be mainly found.

According to the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7b, Section R.8.10.1, several factors have to be considered when using the equilibrium partitioning method (EPM) for the estimation of the toxicity of chemicals to sediment organisms. This method considers only uptake via the water phase. However, because octabenzone is a highly adsorbing chemicals, uptake may also occur via other exposure pathways like ingestion of and direct contact with sediment. Since EPM approach is considered only as a screen for assessing the level of risk to sediment dwelling organisms, ECHA considers the need of performing tests with benthic organisms using spiked sediment to support a refined risk assessment for the sediment compartment. Moreover, as already stated, the screening approach of the EPM is based on acute aquatic toxicity data, considered by ECHA not suitable for the risk assessment; as consequence, the screening results from Risk Characterization Ratio are not adequate.

Summarizing, because octabenzone is highly adsorptive and it has a very low solubility in water and due to initial concerns of Exposure/Wide dispersive use; Consumer use; Aggregated tonnage, the evaluating MSCA identified additional concern regarding potential risk for the sediment compartment. ECHA does not consider the EPM as adequate for the estimation of toxicity to sediment organisms and expresses the need to assess the effects of sediment-bound substances to benthic organisms as foreseen in ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7b, Section R.7.8.10. Moreover, in their comments, the Registrant(s) consented to the requirement of the long-term toxicity testing to sediment organism. ECHA notes that the Registrant(s) has requested in the written comments an extension of the deadline to submit the requested information and has provided supporting documentation to substantiate this request. Therefore, taking into account the additional statement of the [redacted], ECHA agrees to extend the deadline from the date of the decision and has set the date accordingly.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned Registrant(s) are required to carry out the following study using the registered substance subject to this decision: Long-term toxicity testing to sediment organism (test method: Sediment-Water Chironomid Toxicity Using Spiked Sediment, OECD 218), taking into account all possible routes of exposure.

4-6. Effects on terrestrial organisms

The information request is relevant to clarify the identified additional concern: potential risk for environmental compartment (soil).

The Registrant(s) provide a justification for waiving the information requirements on the terrestrial compartment, according to the results of the exposure assessment. The Risk Characterization arguments presented by the Registrant(s) are on the ground of a screening

approach based on the Equilibrium Partitioning Method (EPM) utilising $PNEC_{water}$. Considering that some soil Risk Characterization Ratios (RCR= PECx10/PNEC based on EPM) obtained with the screening approach are close to 1 (see Section III.10), and assuming that octabenzone is considered persistent in soil and it shows an high potential to partition to soil, then ECHA expresses the need to investigate further this compartment and to conduct toxicity tests in all three compartments with soil organisms to derive a robust and conclusive PNECsoil.

The ECHA guidance on information requirements and chemical safety assessment, Chapter R.7.C, Section 11, (version 1.1), states that *"the use of the EPM method provides only an uncertain assessment of risk and, while it can be used to modify the standard data-set requirements of Annex IX and X, it cannot alone be used to obviate the need for further information under this Annex."* Moreover, it is stated that *"it will normally not be possible to derive a robust PNEC for the purposes of a soil screening assessment from acute aquatic toxicity testing showing no effect. This is particularly true for poorly soluble substances."* As the water solubility is less than 1mg/l, the absence of acute aquatic toxicity is not a reliable indicator for potential effects on soil organisms due to the low exposure in the test.

As stated by the Registrant(s), by the results obtained for the distribution modelling, it is clear that in the soil and sediment compartments. According to ECHA guidance on information requirements and chemical safety assessment, Chapter R.7C, Section 11, 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.
According to all those considerations, ECHA expresses the need to investigate further soil toxicity, in order to derive a robust and conclusive PNECsoil, and to characterise properly the risk for soil, because, in view of the evaluation of exposure information provided by the Registrant(s), soil exposure to the substance. it is not excluded. In view of the inadequacy of the information provided for the hazard assessment (short-term aquatic toxicity values), and the uncertainty on the applicability of the EPM method on octabenzone, the screening assessment is not adequate to clarify the identified concern for soil compartment and therefore it cannot be applied following the Integrated Testing Strategy. According to column 2 of the Annex IX, section 9.4, since the substance is highly adsorptive, and is considered persistent, the test should be a long-term test.

In the commenting phase, the Registrant(s) agree(s) on conducting the test "Effects on terrestrial organisms - Long-term toxicity to invertebrates (test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)", considered the appropriate test.

The Registrant(s) suggest to perform only one chronic soil study, referring to ECHA Guidance R.7C pg. 125 (version 1.1): *"In general, where there is no toxicity L(E)C50 in the standard acute toxicity tests at >10 mg/l, or no effects in chronic toxicity at the limit of water solubility, or the screening assessment based on EPM shows no concern, then a single short-term soil test on a suitable species would be adequate to meet the requirements of Annex IX "* and *"Where the substance is highly adsorptive[…], this single test should be a long-term test"*. However, ECHA considers that the cited three cases for which it is recommended to opt for one chronic soil study are not covered by octabenzone: as already explained, the acute tests are uninformative and the EPM is not recommended because this method considers only uptake via the water phase. Moreover the effects of chronic toxicity at the limit of water solubility have not been tested yet. Therefore, the results of the soil macro-organisms test cannot be used to waive the tests to other taxonomic groups.

Another comment of the Registrant(s) is related to the plant test and soil microorganism test, considered by Registrant(s), not appropriate for the substance since the main

exposure is via pore water: "*Nevertheless, test on toxicity to soil micro-organism and test on toxicity to plants are scientifically not justified. For both tests the main exposure pathway is the soil pore water. However, the substance has a very low water solubility of below 0.001 mg/L, a logPow of 7.4 and a logKoc of 4.8 and is not readily biodegradable. Therefore, the substance will be bound to the solid soil phase and does not enter the pore water.*"

The registrant(s) reiterated the above mentioned considerations on the irrelevance of tests on plants and microorganisms due to a lack of exposure via soil pore water. ECHA highlights that both tests (on toxicity to soil micro-organisms and on toxicity to plants) are valid for any route of exposure, provided that the specific conditions foreseen in the OECD protocols are followed (e.g. OECD 208 sections 15 and 16, OECD 216 sections 19 and 20, for substances with low water solubility). This approach makes for octabenzone the required tests adequate and relevant, in order to derive a robust and conclusive PNECsoil, and to characterise properly the risk for soil.

Moreover the Registrant(s) expressed the opinion that the OECD 209 test on activated sludge respiration inhibition showed no effects, so effects on soil microorganisms are unlikely: "*Additionally, in an acute aquatic toxicity test on microorganisms (OECD 209) inhibition in the respiration rate was not observed in any of the test concentrations. Therefore, it can be assumed that the substance is not toxic to microorganisms in soil either.*"

ECHA highlights that the microorganisms test provided by the Registrant(s) is a screening test with only one nominal concentration much higher than the solubility limit of the substance. According to Guidance R.7B (R.7.8.17.3, version 1.2) "*Microbial toxicity testing above the solubility limit of a chemical is to be avoided, similar to toxicity test with higher organisms. It is also unrealistic because insoluble chemicals will be removed in the primary settling tank or fat trap of full scale installations, and thus will not reach the activated sludge.*"

Moreover, following the indications of the ECHA IR&CSA Guidance R.7C: "*Where inhibition of sewage sludge microbial activity has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived.*" This means that the information on microbial activity on STP may be used to justify the need to further investigate the effects of the substance in the micro-organisms taxonomy group, but cannot be used to waive the need to provide such information.

Therefore, ECHA considers the provided results on activated sludge not suitable to conclude on the soil microorganism effect.

In conclusion, according to the Integrated Testing Strategy, in view of the inadequacy of the information provided for the hazard assessment (short-term aquatic toxicity values), and the inapplicability of the EPM method on octabenzone, the screening assessment is not adequate to clarify the identified concern for soil compartment and then it cannot be applied.

The Registrants are reminded that the specific conditions foreseen 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.) should be used to avoid uninformative tests.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following studies using the registered substance subject to this decision:

Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, OECD 216);
Effects on terrestrial organisms - Long-term toxicity to 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);
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).

7. Descriptive text (justification) for each adopted refinement on environmental exposure for all scenarios

The information request is relevant to clarify the initial concerns: Exposure/Wide dispersive use; consumer use; aggregated tonnage; moreover the information request is essential to clarify the additional concern: potential risk for environmental compartments.

The Registrant(s) has conducted an environmental exposure assessment in accordance with Article 14 and Annex I of the REACH Regulation but a more detailed description of the exposure scenarios has to be provided to come to a conclusion on the adequacy of the assessment.

The data provided in the CSR are not properly justified in the case of deviation from default parameters.

In the commenting phase, the Registrant(s) sent an update including an environmental report that covers all model input and output data. However the request in the initial draft decision is not considered completely fulfilled. Therefore, in order to clarify the initial and additional concerns, the Registrant(s) are requested to provide a descriptive text with more information about the refinement of the fraction of main local source, the fraction of tonnage released to each compartment and the daily amount. Moreover, the Registrant(s) are requested to clarify the references of each information provided.

8. Clarification of the adopted Risk Management Measures (RMMs)

The information request is relevant to clarify the initial concerns: Exposure/Wide dispersive use; Consumer use; Aggregated tonnage; moreover the information request is essential to clarify the additional concern: potential risk for environmental compartments (sediment, soil).

Risk management measures (as stated in the ECHA guidance on information requirements and chemical safety assessment, Part D: Exposure Scenario Building) include any action, use of tool, change of parameter state that is introduced during manufacture or use of a substance (either in a pure state or in a preparation) in order to prevent, control, or reduce exposure of humans and / or the environment. The RMM effectiveness is generally defined as the percentage reduction in exposure concentration or emission (release) produced by application of the risk management measure. Moreover the source of the assumption needs to be documented in the CSR.

For Exposure Scenarios 1 and 14 (ES1 and ES14) the Registrant(s) specify the RMM effectiveness but they don't clearly and univocally discriminate the adopted measures that generate the effectiveness and they don't document the sources of the assumptions.
In the ES1 in the section "Risk management measures" it is not clear if the measure is the process without waste water or any sludge distribution on soil. Moreover, in the section

"Other modified EUSES values" the assumption of dust collection is not indicated as RMM even if the related efficiency is reported; in addition the assumption is not supplied by a documented sources (these may be based on scientific publications or on the default assumptions used in widely accepted exposure estimation tools, as stated in the ECHA Guidance, Part D).

In the ES14, in the section "Other modified EUSES values" the Registrant(s) provide the reduction of fraction released to waste water with the justification of application of closed sinks. This assumption is not indicated as RMM and it is not documented.

In their comments, the Registrant(s) gave notice of additional information after conducting the additional tests, and of the update of the exposure assessment including the new information.

Once the additional information mentioned by the Registrant(s) is available, it will be assessed and used to complete the evaluation.

Based on the information as it now stands, the Registrant(s) are requested to update the CSR clearly reporting the risk management measures to reduce or avoid direct and indirect exposure of the different environmental compartments to the substance, also including the sources of the assumptions.

9. Environmental regional assessment and risk characterisation: regional PECs with the related assumptions and regional risk characterisation for all compartments

The information request is relevant to clarify the initial concerns: Exposure/Wide dispersive use; Consumer use; Aggregated tonnage; moreover the information request is essential to clarify the additional concern: potential risk for environmental compartments (sediment, soil).

In the CSR, regional PEC values for all compartments are not specified and no justification is provided for the lack of information. Only in the section 3.7.2 of the IUCLID dossier, the Registrant(s) provide PEC regional values for freshwater pelagic, freshwater sediment, marine water, marine sediment and agricultural soil.
The ECHA guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, indicates that "*The exposure to the environment is in principle assessed on two spatial scales: locally in the vicinity of point sources of release to the environment, and regionally for a larger area which includes all point sources and wide dispersive sources in that area. Releases at the continental scale are considered to provide inflow concentrations for the regional environment. The end results of the exposure estimation are concentrations (PECs) in the environmental compartments air, surface water (fresh and marine), soil, sediment, and biota (e.g. earthworms and fishes for secondary poisoning) and human daily intake of the substance via the environment for both local and regional scale. Continental concentrations are not used as endpoints for exposure*" (R.16.2).
"*The regional concentrations are used as background concentrations in the calculation of the local concentrations. […] Regardless of the default assumptions made at local scale, regional releases to water are based on a scenario where 80% (representing the EU average) of the wastewater is treated in a biological STP and the remaining 20% is released directly into surface waters (*R.16.2.2)".

In the CSR it is not clear if the PEClocal values reported by the Registrant(s) for each scenario include the contribution of regional background (regional PEC values).

Only in the paragraph 10.23 of the CSR, the Registrant(s) specify that the local release of all wide dispersive uses includes the regional exposure.

Taking into account the equation PEClocal=Clocal+PECregional (ECHA Guidance R.16), the PECregional values, obtained by the evaluating MSCA from the difference between the PEClocal and Clocal (which are provided by the Registrant(s) in the section 3.7.1 of the IUCLID dossier for each scenario), do not match with the PECregional values provided in the section 3.7.2 of the IUCLID dossier. Moreover, by the evaluating MSCA calculations, for the ES1, ES3 and ES7 the resulting values of PECregional for the soil compartment are minor than zero and for the ES10 the resulting values of PECregional for each compartment deviate highly from the calculated values for the other scenarios.

In the commenting phase, the Registrant(s) referred to a IUCLID update including an environmental report that covers all model input and output data. The provided environmental report consists of a list of many figures that are not elaborated or justified. Moreover, at this time the response of the Registrant(s) could not be evaluated because the foreseen CSR update containing the formerly requested information was missing. In accordance with Article 14 and Annex I of the REACH Regulation, the Registrant(s) are requested to provide a CSR dossier containing all the essential information finalized to carry out the complete exposure evaluation and to demonstrate the control of risks. The Registrant(s) stated that "*the values will be corrected in chapter 3.7 in the IUCLID file when the additional tests have been conducted and the exposure assessment has been updated.*" Once the additional information mentioned by the Registrant(s) is officially available, it will be assessed and used to complete the evaluation.

According to Annex I 5.2.4 of the REACH Regulation and, as specified in the ECHA Guidance R16, the Registrant(s) are requested to provide, in the CSR, reliable regional PECs value for all compartments and to specify if the assumptions for the regional assessment are default or refined.

Moreover, in the CSR the Registrant(s) do not report the risk characterisation for the environment on regional scale. The ECHA Guidance Part E states that "*The risk characterisation for the environment is based on the tonnage relevant for the registration or the evaluation of a substance. The risk is characterised on two spatial scales: the regional scale, accounting for overall emissions into a region, and the local scale, accounting for local emission and the regional background concentration which is added to this. Depending on the tonnage that is relevant for a specific CSA, the contribution of a substance to the regional background can range between insignificant and significant. Because this contribution depends on other factors as well, e.g. identified uses and substance properties, it always needs to be calculated and assessed, both individually and as part of the local risk characterisation*".

Therefore, the Registrant(s) are requested to provide, in the CSR, the regional risk characterisation for each compartment.

At last, the Registrant(s) are requested to provide congruent information in the CSR and in the IUCLID dossier.

10. Proper characterization of the risk for soil compartment

The information request is relevant to clarify the initial concerns: Exposure/Wide dispersive use; Consumer use; Aggregated tonnage; moreover the information request is essential to clarify the additional concerns: potential risk for environmental compartments

and potential human exposure via the environment.

In the CSR the Registrant(s) declare that the equilibrium partitioning method is used. in paragraph 9.0.1 of the CSR it is stated that, in absence of experimentally-derived toxicity data and due to adsorption properties of the substance, the RCRs for freshwater sediment, marine water sediment, soil were increased by a factor of 10 as the equilibrium partitioning method was applied for the PNEC derivation. ECHA agrees with the application of an additional factor of 10 to the PEC/PNEC ratio, as octabenzone is highly adsorbing chemical, in order to allow for uptake of substances via ingestion of sediment. However, for the soil compartment all the reported RCRs are not in compliance with the above assumption. The evaluating MSCA noted that, using the factor of 10, some RCRs soil (ES10, ES14) are close to 1.

Moreover, due to
- the requested clarifications about RMM for the reduction of sludge to soil (ES1),
- the gap about the information on the concentration in air (the ECHA Guidance R.16 states that the calculation of local PEC for the soil compartment is given for the following exposure routes: application of sewage sludge in agriculture and dry and wet deposition from the atmosphere),
- the inconsistency of the regional PEC values and consequently the unreliable local PEC values (the ECHA Guidance R.16 states *that the regional concentrations are used as background concentrations in the calculation of the local concentrations),*
- the lack of justification and references in the case of deviation from default parameters of release fraction to soil (ES10, ES14, ES15, ES16, ES17, ES18, ES19, ES20, ES21, ES22) and fraction used at main local source,

the risk for the soil compartment is not properly characterised and consequently ECHA notes the additional concern of potential risk for soil, due to risk characterisation ratios close to 1.

In their comments, the Registrant(s) gave notice of additional information after conducting the additional tests, and of the update of the exposure assessment including the new information.
Once the additional information mentioned by the Registrant(s) is available, it will be assessed and used to complete the evaluation.

Based onthe information as it now stands, the Registrant(s) are requested to characterise properly the risk for soil, filling all the above mentioned gaps, and considering the results of requested toxicity studies, once available.

Finally, taking into account the requested refinements of the PNEC and local PECs values for each compartment and the relative quantitative exposure assessment, according to the requirements indicated in Annex I Section 6 of the REACH Regulation the Registrant(s) are required to update accordingly the risk characterization.

IV. 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).

V. 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/datasharing_en.asp.

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

VI. 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.

[redacted]
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