EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2018

Addressee: [redacted]

Decision number: CCH-D-2114453297-43-01/F
Substance name: Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate
EC number: 915-687-0
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 23/10/2015
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: provide a qualitative exposure assessment demonstrating the likelihood that skin sensitising effects are avoided for consumer uses in exposure scenario ES 13 and detail the product-integrated risk management measures and revise the risk characterisation accordingly**

2. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for the environment:**

   - **the risk shall be assessed for the total substance,**
   - **a regional assessment shall be conducted,**
   - **release factors shall be revised for exposure scenarios ES 1 to ES 12 in order to ensure that either the default ERC release factors recommended in the latest version of ECHA Guidance R.16 are used or that any non-default ERC release factors are adequately justified,**
   - **the dilution factor used for the exposure assessment in scenario ES 1 shall not exceed 1000,**
   - **a proper justification for the number of emission days applied for exposure scenarios ES 3 to ES 5 shall be provided or the generic number of release days recommended in the latest version of ECHA Guidance R.16 shall be used,**

- **information on the "fraction used at the main source" shall be provided and justified for exposure scenarios ES 6 to ES 8 or by default shall be set in accordance with the recommendations of the latest version of ECHA Guidance R.16.**

You have to submit the requested information in an updated registration dossier and chemical safety report by ***17 June 2019***.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex I of the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation, E1

[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.

Appendix 1: Reasons

Pursuant to Article 41(1)(c) of the REACH Regulation, ECHA may examine any registration in order to verify that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

1. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: consumer exposure assessment

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 5. of the REACH Regulation indicates that the objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance at which humans [...] are or may be exposed. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the relevant uses of the registered substance. In addition, Section 5.1 states that the final exposure scenario includes, where relevant, a description of operational conditions e.g. the activities of consumers and duration and frequency of their exposure to the substance, and risk management measures to reduce or avoid direct and indirect exposure to humans (including workers and consumers).

Further, Annex I, Section 6.5. of the REACH Regulation states that "*for those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.*"

You have provided an exposure scenario, ES 13 (Wide dispersive outdoor use of long-life articles and materials with low release, including coatings, adhesives and plastics) with consumer uses via products that contain the registered substance; consumer exposure for PC 1 (adhesives and sealants), PC9a (Coatings and paints, thinners and paint removers) and PC 32 (polymer preparations and compounds). You have calculated the consumer exposure by Easy TRA using the ECETOC TRA or ConsExpo model.

In ES 13, the concentration of registered substance in the products is [redacted]. The used amount is [redacted] for PC 1 [redacted] and [redacted] for PC9a [redacted] and the used amount is not reported in spray-can applications (PC 9a and PC 32). The exposure time is estimated to be [redacted] in the first two consumer uses and [redacted] in spray applications. The provided exposure levels are below the defined DNELs and combined RCRs are from [redacted] to [redacted] for ES 13.

However, the registered substance is classified as a skin sensitiser (Skin Sens 1A) and a reliable DNEL for skin sensitization could not be derived in the dossier. The current DNEL is derived for the effects identified in the repeated dose toxicity study ([redacted] (2010b). You also state that "*Inhalation Local effects - Long-term (general population): The qualitative assessment revealed the test substance to be a strong skin sensitizer according to the Potency categorization suggested in ECHA guidance document R.8. No data on respiratory sensitization are available. However, the chemical itself is not handled by the general population. It is present at low concentrations in long life articles and materials with low release, including coatings, adhesives and plastics. The anticipated hazard for the general population is therefore low*" in CSR DNEL derivation, section 5.11.2., page 63.

ECHA notes that you describe four consumer uses of certain products that contain the registered substance in the ES 13 and the potential exposure via inhalation or skin by general population is likely in these exposure scenarios. Therefore, the sensitising property should also be addressed by a qualitative exposure and risk assessment for the consumer use (REACH, Annex I, section 6.5.).

Product-integrated measures e.g. concentration, viscosity of the product, maximum volume of the bottle, package size, are the only proper risk management measures that can be applied for consumer products. According to ECHA's Guidance on information requirements and Chemical Safety Assessment, Part E: Risk Characterisation (version 3.0 May 2016): "*Risk management measures for corrosive or sensitising substances in consumer preparations are limited. Compliance in the implementation of technical controls and PPE is usually impossible to determine in a consumer population, therefore product-integrated measures (such as the maximum volume of the bottle, concentrations used, high viscosity of the product, child resistant fastening) are often the only appropriate RMMs that can be applied. Diluted preparations, child-resistant fastenings and product formulation, which prevent splashes (e.g. viscous or paste-like formulation) as well as labelling and correct use instructions are commonly recognized RMMs for consumer products*".

In your comment during the 30 day commenting period of the draft decision, you indicated that you will collect information on the safe handling and labelling of the "do-it-yourself" applications and also ask for new information of the sensitising property of the "do-it-yourself" products from the manufacturers of the products. You also indicated that you conducted a sensitisation study of 2-pack polyurethane formulations with guinea pigs in 1983 and the study showed sensitisation effects only if the formulation contained also isocyanate component. Additionally, you indicated in your comments the standard Hindered Amine Light Stabilizer (HALS) has been on market for more than 40 years and recently conducted study regarding records of known cases of sensitization in humans did not yield any results. ECHA notes that all the information mentioned in your comments have not been provided in the dossier and ECHA has not been able to evaluate the studies or the information. Hence, the compliance of this new information will be examined by ECHA in your updated registration after the deadline set in the adopted decision has passed.

ECHA reminds you that as the registered substance is a skin sensitiser, the substance should be strictly contained and dermal contact should be avoided. The outcome of the risk characterisation should be used to decide whether safe use can be demonstrated by the likelihood of effects being avoided. ECHA notes, that currently the safe use of consumer products has not been demonstrated in your dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to provide a qualitative exposure assessment demonstrating the likelihood that skin sensitising effects are avoided for consumer uses in exposure scenario ES13 and detail the product-integrated risk management measures and revise the risk characterisation accordingly.

2. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for the environment:

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) of the REACH Regulation or is assessed to be a PBT or vPvB, the chemical safety assessment shall include an exposure assessment and risk characterisation. ECHA notes that the registered substance is classified as Skin Sens. 1A (H317: May cause an allergic skin reaction), Aquatic Acute 1 (H400: Very toxic to aquatic life) and Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects). Therefore, an exposure assessment and risk characterisation shall be included in the chemical safety assessment.

The exposure assessment shall be carried out according to Section 5 of Annex I of the REACH Regulation and shall include exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Annex I, Section 6 of the REACH Regulation requires you to characterise the risk for each exposure scenario.

The 13 following exposure scenarios (ES) are presented in your CSR:

- ES1: Industrial Manufacture of Hindered Amine Light Stabilizer (HALS)
- ES2: Industrial formulation of preparations containing HALS
- ES3: Industrial use of HALS: "[redacted]", resulting in inclusion into a matrix, including application in coatings, adhesives and plastics
- ES4: Industrial use of HALS: "[redacted]", resulting in inclusion into a matrix, including application in coatings, adhesives and plastics
- ES5: Formulation of HALS in articles: "[redacted]", resulting in inclusion into a matrix, including application in adhesives and plastics
- ES6: Formulation of HALS in articles: "[redacted]", resulting in inclusion into a matrix, including application in adhesives and plastics
- ES7: Formulation of HALS in articles: "[redacted]", resulting in inclusion into a matrix, including application in adhesives and plastics

- ES8: Formulation of HALS in articles by low energy manipulation, resulting in inclusion into a matrix, including application in adhesives and plastics
- ES9: Wide dispersive Indoor Use (professional) of HALS: "[redacted]", resulting in inclusion into a matrix, including application in coatings, adhesives and plastics
- ES10: Wide dispersive Indoor Use (professional) of HALS: "[redacted]", resulting in inclusion into a matrix, including application in coatings, adhesives and plastics
- ES11: Wide dispersive Outdoor Use (professional) of HALS: "[redacted]", resulting in inclusion into a matrix, including application in coatings, adhesives and plastics
- ES12: Wide dispersive Outdoor Use (professional) of HALS: "[redacted]", resulting in inclusion into a matrix, including application in coatings, adhesives and plastics
- ES13: Wide dispersive Outdoor Use of long-life articles and materials with low release, including coatings, adhesives and plastics

As explained below, ECHA has identified several issues in your chemical safety assessment.

The risk shall be assessed for the whole substance

The registered substance is a multi-constituent substance consisting of two main constituents:

- Bis (1, 2, 2, 6, 6-pentamethyl-4-piperidyl) sebacate (CAS: 41556-26-7): ca. [redacted] %
- Methyl 1, 2, 2, 6, 6-pentamethyl-4-piperidyl sebacate (CAS: 82919-37-7): ca. [redacted] %

ECHA notes that for your exposure assessment and for every exposure scenario you have adjusted the tonnage for the 2 main constituents in order to account for the portion of the constituents within the substance: [redacted]% of the tonnage for the first constituent, [redacted]% of the tonnage for the second one. On this basis, you have then calculated Predicted Environmental Concentrations (PECs) and Risk Characterisation Ratios (RCRs) for each constituent separately. However, ECHA notes that you have not presented RCRs for the registered substance as such, i.e. for the whole substance.

Each constituent potentially contributes to the risk of the registered substance. RCRs for separate constituents do not fully reflect the risk of the whole substance. Therefore, your approach failed to address the combined risk of each constituent.

ECHA considers that the risks from each constituent can reasonably be assumed to be additive (see SCHER, SCCS, SCENIHR, Opinion on the Toxicity and Assessment of Chemical Mixtures, 2012)[2]. Therefore, for each exposure scenario and each environmental sphere, you should have calculated RCRs for the total substance as the sum of the RCRs from each

[2] Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Scientific Committee on Consumer Safety (SCCS). 2012. Opinion on the Toxicity and Assessment of Chemical Mixtures. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf

constituent. Following this approach, ECHA notes that RCRs for several scenarios and several environmental spheres would exceed 1, indicating that the risks from your substance are potentially not controlled.

In addition, ECHA notes that in section 9.0.2. of your CSR you claim to have used separate input data, in particular physico-chemical data, for each of the two main constituents. However, table 41 of your CSR on the contrary tends to indicate that the same physical/chemical properties (molecular mass, water solubility, log Kow and vapour pressure) have been used for both constituents. ECHA also notes that you have used the same Predicted No Effect Concentrations (PNECs) for both constituents.

ECHA acknowledges that the registered substance is multi-constituent, which may complicate its risk assessment. However, in any case, you need to ensure that the comparison of respective environmental exposure concentrations (PECs) with relevant effect concentrations (PNECs) is meaningful.

If the different constituents of the substance are deemed to be similar with respect to their environmental behaviour and their probable toxicity, then the substance can be assessed as a whole, with a unique PNEC and a unique PEC for each environmental sphere.

On the contrary, when the constituents have different fate and/or hazard profiles, both PEC and PNEC should be derived separately for each constituent or, if applicable, for each block of similar constituents. RCRs can then be calculated for each constituent (or each block of similar constituents), the RCRs of the whole substance being generally calculated as the sums of the RCRs of each constituent (or of each block of similar constituents)[3].

In your comments during the 30-day commenting period to the draft decision, you indicated that you agree with the information requirement in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to revise your CSA in order to characterise for each exposure scenario and each environmental sphere the risks from the registered subtance, taking into account the combined risks from each constituent. You shall revise your CSR accordingly.

A regional assessment shall be conducted

Pursuant to Annex I, Section 5.2.4. of the REACH Regulation, exposure estimation shall take account of the geographical scale of exposure.

Concentrations of the substance may become significant on a regional scale if there are diffuse sources. A regional assessment is also relevant even if there are only local sources if the substance does not degrade rapidly in the environment (section R.16.1.4.2 of ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (version: 3.0, February 2016)).

[3] By default, risks from different constituents/block of constituents are assumed to be additive, unless it can be demonstrated that their effects are independent or that interactions such as antagonism, potentiation, or synergies exist between the different constituents/block of constituents (see SCHER, SCCS, SCENIHR, Opinion on the Toxicity and Assessment of Chemical Mixtures, 2012).

Based on your CSA, ECHA notes that diffuse sources exist for the registered substance (e.g. professional and consumer uses). Furthermore, ECHA notes that the registered substance is not readily biodegradable. Therefore, ECHA considers that a regional assessment and the derivation of Predicted Environmental Concentrations on a regional scale ($PEC_{regional}$) are required for the registered substance.

The calculation of $PEC_{regional}$ is further explained in Appendix A.16-4 "Model For Regional Assessment" of the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (version: 3.0, February 2016). All regional releases associated with the different identified uses, both industrial and wide disperse sources, are cumulated to estimate the total regional release to surface water, sediment, air and soil. The distribution and fate of the substance within the region are also taken into account using a generic standard environment.

$PEC_{regional}$ are meant to be used not only to assess exposure at the regional scale but also as background concentrations in the calculation of the local PEC.
ECHA notes that no $PEC_{regional}$ and no risk characterisation for regional exposure are provided in your CSR. Moreover, there is no indications either that $PEC_{regional}$ were incorporated as background concentrations for the calculation of local PECs.

In your comments during the 30-day commenting period to the draft decision, you indicated that you agree with the information requirement in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to calculate regional PECs for surface water, sediment, air and soil. You shall characterise the risks at the regional scale for these different environmental spheres. Furthermore, you are requested to calculate local PECs that incorporate the corresponding regional PECs as background concentration. You shall revise your CSR accordingly.

> *Release factors shall be revised for exposure scenarios ES 1 to ES 12 in order to ensure that either the default ERC release factors recommended in the latest version of ECHA Guidance R.16 are used or that any non-default ERC release factors are adequately justified*

Pursuant to Annex I, Section 5.1.1 of the REACH Regulation, exposure scenarios shall include, where relevant, a description of operational conditions (OCs) and of risk management measures (RMMs). As indicated in Annex I, Section 5.2.2. of the REACH Regulation, emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented. These RMMs and OCs should be included in the exposure scenarios provided in the CSR.

Operational conditions consist of a set of actions, tools, parameters such as amount of substance, process temperature and pH, duration and frequency of release, type of use (e.g. indoor or outdoor), containment of process (open or closed), continuous or batch process (leading to an intermittent release), capacity of surroundings, etc. having, as a side effect, an impact on the release and the exposure. Risk management measures consist of technologies and procedures aimed at either reducing the releases and/or preventing a release pathway. Examples of risk management measures intended to reduce release are filters, scrubbers, biological or physico-chemical wastewater treatment plants. Both OCs and

RMMs have an impact on the type and amount of release and the resulting exposure. ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (version: 3.0, February 2016) specifically provides default release factors associated with different Environmental Release Categories (ERCs). These default release factors can be used for a first tier assessment of the emissions. However, better information may be available that could then be used instead. In particular, release factors can be refined by taking into account RMMs and OCs. In this case, it is important to explicitly link such RMMs and OCs to the release factors and communicate them properly to the downstream users in the exposure scenarios.

ECHA notes that for all exposure scenarios but ES 13, you have used release factors that deviate from those recommended in the latest version of ECHA guidance R.16.

Firstly, for exposure scenario ES 1 for the production site in [redacted], you have assumed that no releases occur:

- in air, with the justification that the substance has a very low vapour pressure,
- in wastewater, with the justification that the substance is not released to sewage and filter residues are disposed off as waste,
- in soil, with the justification that there is no direct release to soil and no indirect release from sewage.

However, ECHA notes that you have not provided any information on RMM applied and any actual data (e.g. monitoring data) to support your claim that no releases occur at the production site.

Secondly, for exposure scenarios ES 2 to ES 8, you have applied release factors cited in chapter 12 (UV and other weathering stabilisers) of the OECD Emission Scenario Document number 3 on plastic additives[4]. This document presents different scenarios for this use: 'raw materials' handling', 'compounding', 'conversion', 'service life', 'disposal'.

ECHA notes that for exposure scenarios ES 2 to ES 8, you have used release factors only from OECD emission scenario 'compounding' assuming a low volatility (0.0001 Pa) and a particle size >40 µm. However, from your CSR it is not clear whether OECD scenario 'compounding' is actually applicable to exposure scenarios ES 2 to ES 8:

- As indicated in chapter 12 of the above-mentioned OECD Scenario Document, this emission scenario only applies to solids whereas the registered substance is a liquid.

- For exposure scenarios ES 2, ES 3, ES 4, ES 6, and ES 7, handling and transfer of the substance does occur (as suggested by the PROC codes you have reported in those exposure scenarios for workers' exposure) and therefore should be taken into account in those exposure scenarios and in the estimation of the corresponding release factors. However, OECD emission scenario 'compounding' does not take into account the handling and transfer of the substance.

- For exposure scenario ES7 ("Formulation of HALS in articles: "[redacted]", resulting in inclusion

[4] OECD Series on Emission Scenario Documents - Number 3. Emission Scenario Document on Plastic Additives ENV/JM/MONO(2004)8/REV1. 09-Jul-2009.

into a matrix, including application in adhesives and plastics"), OECD emission scenario 'conversion' as described in the OECD document seems to be more relevant. OECD emission scenario 'conversion' indeed specifically covers the following uses:

- closed processes: extrusion, injection moulding, compression moulding, extrusion blow moulding, injection blow moulding
- partially-open processes: film extrusion, paper and textile coating
- open processes: thermoforming, calendering, fibre reinforced plastic fabrication

ECHA considers that your CSR does not provide sufficient description of the different industrial uses (in particular RMMs and OCs) to assess whether OECD emission scenario 'compounding' is applicable to exposure scenarios ES 2 to ES 8 and therefore whether the corresponding release factors applied in your assessment are relevant.

Finally, for exposure scenarios ES 9 to 12, ECHA notes that you have applied a release factor of 1% for wastewater, whereas the value of 5% is recommended in the current version of ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (version: 3.0, February 2016). Indeed, Table R-16-7 of the latest version of the guidance, provides that the release factor to wastewater for environmental release categories ERC 8c and ERC 8f is 5% for uses in paints, coatings, adhesives, plastics.

In your comments during the 30-day commenting period to the draft decision, you indicated that you agree with the information requirement in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, you are requested to revise the release factors for exposure scenarios ES 1 to ES 12 in order to ensure that either the default release factors recommended in the latest version of ECHA Guidance R.16 are used or that any non-default release factors are adequately justified (e.g. based on RMMs, OCs, monitoring data). You shall revise your CSR accordingly.

The dilution factor used for the exposure assessment in scenario ES1 shall not exceed 1000

Pursuant to Annex I, Section 5.2.4. of the REACH Regulation, exposure estimation shall take account of the dilution in the receiving environmental compartment.

By default, the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (version: 3.0, February 2016) recommends using a generic dilution factor of 10 for the freshwater environment. However, it also indicates that a higher dilution factor can be applied if this can be supported by site-specific information, as long as this dilution factor does not exceed 1000.

Indeed, in the receiving environment, dilution is in practice not complete near the point of discharge. In the mixing zone, higher concentrations will occur. The distance from the point of discharge where complete mixing may be assumed will vary between different locations. For situations with very high dilution factors, the mixing zones may be very long and the overall area that is impacted by the effluent before it is completely mixed can be

considerable. For this reason, ECHA Guidance recommends that dilution factors above 1000 should never be used for the assessment (Section R.16.2.2.7. of ECHA Guidance, version: 3.0, February 2016).

However, ECHA notes that for exposure scenario ES 1, you have used a dilution factor of approximately [redacted]. This value largely exceeds the limit of 1000 recommended in ECHA guidance.

In your comments during the 30-day commenting period to the draft decision, you indicated that you agree with the information requirement in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, you are requested to amend your exposure assessment for the aquatic compartment for exposure scenario ES 1 by using a dilution factor that does not exceed 1000 so that incomplete mixing in the environment could be taken into account. You shall revise your CSR accordingly.

A proper justification for the number of emission days applied for exposure scenarios ES 3 to ES 5 shall be provided or the generic number of release days recommended in the latest version of ECHA Guidance R.16 shall be used

Pursuant to Annex I, Section 5.2.4. of the REACH Regulation, exposure estimation shall take account of the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems.
The number of release days per year is used to estimate the daily use amount from the annual tonnage for the use. For exposure scenarios ES 3 to ES 5, you have assumed a number of release days of [redacted] days/year. These three exposure scenarios are about industrial uses (Environmental Release Category 5: "Industrial use resulting in inclusion into or onto a matrix") and for tonnages below 1000 tonnes/year. The default number of release days recommended in the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (version: 3.0, February 2016) is 20 days/year for industrial uses and for tonnages below 1000 tonnes/year (Table R.16-2 of the guidance). The underlying assumption behind those default values is that, for uses in industrial sites, low tonnages are more likely to be used for short periods of time.

The ECHA guidance also indicates that it is possible to refine the daily and annual use amount by using suitable and specific data if available, for example on the basis of site-specific information or information provided by the downstream users.

You have provided the following justification for using [redacted] days/year as the number of release days:
"*based on assumptions laid down in the OECD Series on Emission Scenario Documents Number 3 - Emission Scenario Document on Plastic Additives – and in the Technical Guidance Document on Risk Assessment (Table B3.9 of Appendix I) the release days were set to* [redacted]".

The OECD Scenario Document states that "*if the number of days of emission ($T_{emission}$) for the process are known, the local emissions can also be estimated on a daily basis.*

Alternatively, Table B3.9 of Appendix I of the TGD can be used to estimate $T_{emission}$ for this purpose".

ECHA notes that the number of release days you have used for your assessment of exposure scenarios ES 3 to ES 5 has been actually calculated from Table B3.9 of the Technical Guidance Document (TGD) using the following formula: [redacted]

ECHA notes that the TGD was developed for pieces of legislation prior to the adoption of the REACH Regulation. It is no longer applicable and has been superseded by ECHA Guidance. ECHA further notes that the methodology proposed in the TGD to estimate the number of release days does not constitute site specific information or information provided by downstream users.

In your comments during the 30-day commenting period to the draft decision, you indicated that you agree with the information requirement in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to use the default number of release days in accordance with the recommendations of the latest version of ECHA Guidance R.16 or to provide adequate justification for any deviation from these recommendations, for example site specific information or information provided by downstream users. You shall revise your CSR accordingly.

> *Information on the "fraction used at the main source" shall be provided and justified for exposure scenarios ES 6 to ES 8 or by default shall be set in accordance with the recommendations of the latest version of ECHA Guidance R.16.*

Pursuant to Annex I, Section 5.2.4. of the REACH Regulation, exposure estimation shall take account of spatial variations in the exposure pattern.

For point sources, a protective estimation of the emissions requires that the capacity of the largest point source for the particular stage of the life cycle be estimated. If this information is not known, it has to be estimated from the registered total annual tonnage. ECHA Guidance R.16 recommends that, for an industrial site, the annual use at the site be set by default to 100% of the total annual tonnage for the use, i.e. that the fraction of the main source be set to 100%. This default value of 100% is a worst case to cover situations where the total registered tonnage is processed at a single site. The ECHA guidance specifies that the default value of 100% can be replaced by site-specific information or by information on the actual amount used by the largest downstream user (See chapter R16.2.2.1.1.).

ECHA notes that no information on the fraction used at the main source is provided for exposure scenarios ES 6 to ES 8.

In your comments during the 30-day commenting period to the draft decision, you indicated that you agree with the information requirement in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, you are requested to provide in your CSR the "fraction of the main source" used for exposure scenarios ES 6 to ES8. In accordance with the recommendations of ECHA Guidance R.16, for industrial sites, you shall set by default the fraction of the main source to 100%, i.e. the annual use at the site shall be set to 100% of the total annual tonnage for the use. Alternatively, you can use site-specific data from the largest downstream user, in accordance with the recommendations of the latest version of ECHA Guidance R.16. You shall revise your CSR accordingly.

Note for your consideration

ECHA notes that exposure scenarios ES 6, 7 and 8 describe very similar uses (i.e. "Formulation of HALS in articles"). These uses may take place at the same sites. If so, you should perform a combined assessment for these uses.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 14 December 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.