EUROPEAN CHEMICALS AGENCY

Helsinki, 21 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347316-50-01/F
Substance name: hexadecyl 3,5-bis-tert-butyl-4-hydroxybenzoate
EC number: 267-342-2
CAS number: 67845-93-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28.10.2015
Tonnage band: 100-1000 T

**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. **Flammability (Annex VII, Section 7.10; test method: UN Test N.1) with the registered substance;**

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

3. **Identification of degradation products (Annex IX, 9.2.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307);**

4. **Identification of DNEL(s) and risk characterisation (Annex I, Section 1.4. and 6.): revise long-term DNELs for workers, inhalation and dermal routes systemic effects according to ECHA Guidance R.8 for DNEL derivation using the study giving rise to the highest concern and revise the risk characterisation accordingly *or* provide a detailed justification for not using the study giving rise to the highest concern;**

5. **Revision of the life-cycle of the registered substance, exposure assessment and risk characterization (Annex VI, Section 3.5. and Annex I, Sections 5. and 6.)**

   - **Considering all stages of the life-cycle of the registered substance.**

6. **Exposure assessment and risk characterisation for environment (Annex I, Sections 5. and 6.): provide a quantitative exposure assessment and revise the risk characterisation accordingly;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **28 November 2018**. You shall also update the chemical safety report, where relevant.

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

**Appeal**

**Applicable only for the final decision:** 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, shall 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 Claudio Carlon, Head of Unit, Evaluation E2

[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**

## 1. Flammability (Annex VII, Section 7.10)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Flammability" is a standard information requirement as laid down in Annex VII, Section 7.10 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1 of the REACH Regulation. You provided the following justification of the adaptation: "*In accordance with Section 1 of REACH Annex XI, the study does not need to be performed; based chemical structure pyrophoric properties are not to be expected.*"

However, based on your justification it is not possible to identify what type of adaptation under Annex XI, Section 1, you are referring to.

In addition, ECHA notes that according to Annex VII, Section 7.10., column 2, the study for this endpoint does not need to be conducted if, among other possibilities, the substance is a solid which possesses explosive or pyrophoric properties. Therefore, since you consider your substance is not expected to have pyrophoric properties, a flammability study needs to be performed.

Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments to the draft decision, you agreed to perform a flammability test according to UN Test N.1.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Flammability (test method: UN Test N.1).

## 2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a "breeding/reproductive" study (no standard test method mentioned). However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters and exposure duration of a pre-natal developmental toxicity study. More specifically, in your study summary you have not indicated the examination of key parameters that need to be carried out on the parental animals and foetuses, and thus considered as not performed. While, according to the OECD TG 414, the pregnant animals should be exposed to the test material from implantation to one day prior of scheduled kill and then examination of the uterine content and foetal examinations (*e.g.* skeletal and soft tissue alterations; external alterations) should be carried out. Hence, the result from this study does not provide sufficient confidence to conclude that there is no prenatal developmental toxicity effect of the registered substance.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision, you agreed to perform a pre-natal developmental toxicity study according to OECD TG 414.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 414) in a first species (rats or rabbits) by the oral route.

### 3. Identification of degradation products (Annex IX, 9.2.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.3., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH annex IX, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation*".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.3., column 2 because the substance is not readily biodegradable considering the information that you provided in the registration dossier.

ECHA further notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to identify the degradation products. ECHA considers that the information is needed for the PBT/vPvB assessment (Annex XIII of the REACH Regulation) and for the compilation of safety data sheets (Annex II of the REACH Regulation).

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolites may be investigated. Based on the information provided in your registration dossier, ECHA notes that the registered substance is poorly soluble and very adsorptive. ECHA further notes that direct and/or indirect exposure to soil cannot be disregarded as the substance is expected to be used as light stabilizers in plastics which may have agricultural use. It is not clear how significant the exposure to soil could be since you have not provided a quantitative exposure assessment for the environment and you have not considered all the life-cycle of the registered substance in the uses described and the subsequent exposure scenarios developed (issues 5 and 6 of the present decision). Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is a validated standard international test laid down in the Test Methods Regulation 440/2008 (Sections C.23 and C.24) and, therefore meets the requirements of Article 13(3) of the REACH Regulation. This test shall be performed to determine the nature and rates of formation and decline of transformation products to which plants and soil organisms may be exposed.

In your comments to the draft decision, you appreciated the need for further information on simulation testing in soil and on the identification of potential degradation products. However, you proposed to perform first an inherent biodegradation test (OECD 302C: Modified MITI Test (II)) before deciding whether to perform a simulation test in soil (OECD 307).

ECHA notes that information on degradation products is required for the PBT/vPvB assessment as Annex XIII of the REACH Regulation explicitly requires that PBT/vPvB properties of degradation products need to be taken into account. Information on degradation products shall also be taken into account for the exposure assessment (Annex I 5.2.4. of the REACH Regulation) and for the hazard assessment (e.g. column 2 of Annex X 9.4 and Annex X 9.5.1 of the REACH Regulation). Finally, ECHA further points out that information on degradation products is required for the preparation of Section 12 of the safety datasheet (Annex II of the REACH Regulation).

The OECD 302 test proposed in your comments is a screening test performed under artificial conditions (i.e. artificial inoculum, high inoculum concentration, high test substance concentrations) and is not intended for the identification of degradation products, whereas the requested test is appropriate for identifying degradation products that could form in the environment because it is designed to simulate the degradation behaviour of substances in natural soil. Therefore ECHA considers that the proposed OECD 302C test would not fill-in the data gap with regard to the identification of degradation products and cannot be regarded as a valid adaptation for the requested test.

Since the purpose of the requested simulation test is the identification of potential degradation products, any mention of the test temperature of 12°C has been removed from the draft decision since a higher test temperature may be acceptable in that case. As specified in the OECD 307 test guideline, testing one soil type is generally regarded as sufficient for the evaluation of transformation pathways. Besides, for analytical reasons, higher test concentrations can be used when the purpose of the simulation test is the identification and quantification of major transformation products (see OECD guidelines for the testing of chemicals: revised introduction to the OECD guidelines for testing of chemicals, Section 3 - Part 1: principles and strategies related to the testing of degradation of organic chemicals).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Identification of the degradation products using the following test method: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307).

*Notes for your consideration*

The separate requests for soil and sediment simulation testing have been removed from this decision, because the available information indicates that the registered substance as such is not PBT/vPvB. However, as described above, the requirement to provide information on the degradation products must be fulfilled.

## 4. Identification of DNEL(s) and risk characterisation (Annex I, Section 1.4. and 6.)

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

Annex I, Section 1.1.4. of the REACH Regulation requires that the study or studies giving rise to the highest concern shall normally be used to establish the DNEL. It also requires that a robust study summary shall be prepared for that study or studies and included in the technical dossier. In addition, Annex I, Section 1.1.4. requires that if a study giving rise to the highest concern is not used, then this shall be fully justified.

In the technical dossier, you have provided the "*91 day feeding study in the rat protocol 406*" and the "*91 day feeding study in the dog*" as key studies. Further, you have identified the "*91 day feeding study in the dog*" as the study giving rise to the highest concern and consequently used to establish the DNELs.

However, ECHA notes that whilst the NOAEL for the dog study is 1000 mg/Kg bw/day, the NOAEL from the rat study is 5000 ppm which would correspond to approximately 375 mg/kg bw/day using a conventional conversion formula considering the average food intake by rats. In addition, while the effect for setting the NOAEL in the dog study is a "*statistically and biologically meaningful decrease in the body weight of the highest dose level in the females*", the effects observed in rats were liver lesions which pose a higher concern. As a consequence, the DNELs derived from the rat study would be approximately three times lower for inhalation route and 7 times lower for dermal route. ECHA notes that you have not provided an adequate justification to support why the study giving rise to the highest concern was not used, especially as this would lead to some RCR-values being higher than 1. Consequently, there are risks arising from some of the uses of your substance that might not be adequately controlled.

ECHA acknowledges that, in your comments to the draft decision you agreed to revise the DNEL derivation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise long-term DNELs for workers, inhalation route, systemic effects using the study giving rise to the highest concern and the default assessment factors and other recommendations of ECHA Guidance R.8 for DNEL derivation and to revise the risk characterisation accordingly *or* provide a detailed justification for not using the study giving rise to the highest concern.

*Notes for your consideration*
The results of the studies requested with this decision shall be taken into account when revising the DNELs.

**5. Revision of the life-cycle of the registered substance, exposure assessment and risk characterization (Annex VI, Section 3.5. and Annex I, Sections 5. and 6.)**

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

According to Article 14(4) of the REACH Regulation, the CSR must include an exposure assessment and risk characterisation in the chemical safety assessment if the substance is assessed to be a PBT or vPvB or fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1271/2008. You have classified the substance as Aquatic Chronic 4 and therefore an exposure assessment and a risk characterization need to be included in the CSR.

Pursuant to Article 10(a)(iii) of the REACH Regulation the technical dossier shall contain information on the manufacture and use(s) of the substance representing all the registrant's identified uses, as specified in Annex VI, Section 3 of the REACH Regulation. In addition, pursuant to Annex I Section 5.0, exposure assessment, which is a part of the chemical safety assessment (CSA), shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses.

ECHA observes that you have indicated the registered substance being a light stabiliser used in polymers. However, in Section 3.5 of the technical IUCLID dossier you have identified only two uses and consequently, you have described only two exposure scenarios (ES): ES1 which describes the formulation of additive blends in the production of polymers, and ES 2 which describes the manufacture of plastic products with those polymers. No end-uses have been identified.

Therefore, ECHA considers that, according to the information provided, you have not addressed all stages of the life-cycle of your substance, because it is likely that there are end-uses that you did not describe for the materials containing your substance and/or articles manufactured with those materials. Those uses could be industrial, professional and/or consumer uses. Consequently, in that situation you shall also consider the article service life.

In your comments to the draft decision, you acknowledged that further information on the life-cycle of the substance was needed and agreed to collect this information and to revise your registration dossier accordingly.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise the life-cycle of the registered substance considering all stages of the life-cycle of the registered substance and to revise the exposure assessment and risk characterisation accordingly. If further stages of the life-cycle are not considered relevant and not to be identified as uses, a justification for such a conclusion shall be given. The chemical safety report and section 3.5 of the technical IUCLID dossier shall be amended accordingly.

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

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

According to Article 14(4), the CSR must include an exposure assessment and risk characterisation in the chemical safety assessment if the substance is assessed to be a PBT or vPvB or fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1271/2008. You have classified the substance as Aquatic Chronic 4 and therefore an exposure assessment and a risk characterization need to be included in the CSR.

Annex I, Section 5.2.4. of the REACH Regulation indicates that "*an estimation of the exposure levels shall be performed for all human populations* (...) *and environmental spheres for which exposure to the substance is known or reasonably foreseeable*".

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.*"

ECHA notes that you have provided only a qualitative assessment for environment based on the following justification: "*Since CYASORB® UV-2908 may be regarded as a 'super-lipophilic' compound, a compound with a log Kow greater than 8, the potential for bioaccumulation of the substance from water can be adversely affected by a variety of factors including steric hindrance and sorption to dissolved and particulate organics in aquatic systems. Based on the predicted log Kow, the substance will likely not be soluble or bioavailable. In fact, per REACH Information Requirements, Chapter R.11 PBT Assessment guidance (ECHA 2008), the substance is believed to exhibit a BCF =< 2000 L/kg in light of the estimated log Kow of 12.33 (EPI Suite, US EPA 2011). In light of the substance's physical and chemical characteristics, and in light of the inability to generate concentrations toxic to test organisms in aquatic toxicity testing, CYASORB® UV-2908 is believed to be non-bioavailable and non-toxic to environmental receptors. Thus no quantitative environmental risk assessment has been performed as part of this Chemical Safety Assessment. Uncertainties in this assessment specifically relate to the predicted Log Kow, since per ECHA (REACH Information Requirements, Chapter R.11 PBT Assessment, ECHA 2008) the reliability of modeled Kow values greater than 10 is not known, and the extreme insolubility of the substance prevents the accurate quantification of a solubility limit (*[redacted]*)*".

ECHA acknowledges that because of the substance properties (e.g. log Kow >12 and very low water solubility), the exposure assessment may not be reliable or realistic (e.g. EUSES uses a ceiling value of 10 for log Kow and log Kow for the substance is above 10). However, ECHA notes that you have been able to calculate $PEC_{regional}$ values. In particular, ECHA notes that freshwater $PEC_{regional}$ exceeds $1/100^{th}$ of the water solubility and this is considered to be the case for $PEC_{local}$ as well. According to ECHA guidance, when $PEC_{regional}$ or $PEC_{local}$ exceeds $1/100^{th}$ of the water solubility then the absence of risk is not guaranteed and the assessment needs to be refined.

In addition, ECHA notes that, as already described in in section 7 above, the exposure assessment and the risk characterisation shall cover all stages of the life-cycle of the substance resulting from the manufacture and identified uses.

In your comments to the draft decision, you proposed to remove the classification as aquatic chronic 4 from the dossier since this classification was triggered only by the high log Kow value whereas an actual bioaccumulation study indicated a low bioaccumulation potential of the substance. If the substance is not classified, then an exposure assessment and risk characterisation need not be conducted. You indicated that you could conduct a *Daphnia magna* Reproduction Test (OECD 211) in order to have more conclusive information on the chronic aquatic toxicity of the substance. Also, you proposed to remove exposure driven waiving currently invoked for terrestrial endpoints and to perform Earthworm Reproduction Test (OECD 222) either with the registered substance or the potential degradation products, if relevant. You proposed to conduct those tests either on the registered substance itself or on the degradation products, whichever is the most relevant for the chemical safety assessment.

ECHA takes note of your proposed strategy and points out that, pursuant to Annexes IX and X of the REACH Regulation, you shall not conduct those tests without ECHA prior approval but you would need to submit to ECHA formal testing proposals. Pursuant to Article 40 of the REACH Regulation, ECHA would examine those testing proposals and decide whether the tests should be conducted or not. However, ECHA further notes that information on the degradation products (requested in point 3 of the decision) needs to be available before deciding which substance to test. Therefore, if you intend to submit testing proposals, you should do so only after information on degradation products is available.
Pursuant to Article 14(4) of the REACH Regulation, an exposure assessment is required if the substance meets the criteria for a classification. An exposure assessment is also required to justify any exposure-based adaptations from information requirements.

Where there is no full knowledge of the properties of the substance but there is an indication that there could be a hazard to human health or the environment, the approach to self-classify, is in line with the precautionary principle. A self-classification in-turn implies that an exposure assessment and a risk characterisation need to be conducted, as described above, and in line with the precautionary principle.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to provide a quantitative exposure assessment for environment and revise the risk characterisation accordingly.

However, ECHA acknowledges that, depending on the new information generated, you may consider revising the self-classification of your substance.

**Deadline to submit the requested information in this decision**

In the draft decision communicated to you the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 18 months. You sought to justify this request by indicating that experience with testing laboratories for other testing shows that lead times for starting testing are increasing and that you believe that 18 months would be a more appropriate timescale than 12 months. You have not provided any evidence for such lead times. ECHA notes that the deadline needs to be adjusted to accommodate for the possible sequential testing of the biodegradation simulation tests. Therefore, ECHA has set the deadline to 24 months.

**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 8 December 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

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

ECHA took into account your comments and amended the requests and the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

ECHA received proposal(s) for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-50 written procedure and ECHA took the decision according to Article 51(6) 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 request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.