ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003628-67-05/F Helsinki, 28 March 2014

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

For 2,4-di-tert-butylphenol, CAS No 96-76-4 (EC No 202-532-0), registration number [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 2,4-di-tert-butylphenol, CAS No 96-76-4, (EC No 202-532-0) submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Sections 7.14 and 8.4.1 and Annex IX, Sections 7.16, 8.6.2, 9.2., 9.4.1, 9.4.2, 9.4.3 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after 1 August 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 28 August 2012.

On 03 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

By 03 June 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 1 August 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 11 September 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide

comments on those proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and modified Section II and III of the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

By 11 October 2013 the Registrant did not provide any comments on the proposal for amendment.

After discussion in the Member State Committee meeting on 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision as amended at the meeting was reached on 5 November 2013 and ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vi) and/or (vii), 12(1)(d), 13 and Annexes VII, IX and XI of the REACH Regulation the Registrant shall submit the following information generated with the test methods as indicated on the registered substance subject to the present decision:

1. Granulometry (Annex VII, 7.14.; the Registrant is recommended to follow the Integrated Testing Strategy on granulometry, as described in the Guidance on Information Requirements, Chapter R.7a);
2. Dissociation constant (Annex IX, 7.16.; test method: OECD 112);
3. *In vitro* gene mutation study in bacteria using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. E. coli WP2 uvrA, or E. coli uvrA (pKM101), or S. typhimurium TA102 (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14./OECD 471);
4. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats;
5. Effects on terrestrial organisms – Short-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.; test method: Earthworm, acute toxicity tests, EU C.8./OECD 207)
   or, if long-term testing is considered appropriate, either
   Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)
   or
   Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Enchytraeid reproduction test, OECD 220)
   or
   Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Collembolan reproduction test in soil, OECD 232)
   and
6. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216)
   and

7. Effects on terrestrial organisms – Short-term toxicity to plants (Annex IX, 9.4.3. test method: Terrestrial plants, growth test, OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species)
   Or, if long-term testing is considered appropriate, either
   Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD 208), with at least six species tested (with as a minimum two monocotyledonous species)
   or
   Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2; test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

8. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309), as specified in Section III.8-10 below;
9. Soil simulation testing (Annex IX, 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307), as specified in Section III.8-10 below;
10. Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308), as specified in Section III.8-10 below;
11. Identification of degradation products (Annex IX, 9.2.3.) as specified in Section III.11 below.

ECHA notes that another registrant of the same substance has already been requested to carry out the test mentioned in point 4 above. In addition, that other registrant has been requested to provide the information listed above in points 1 to 3 and 5 to 11 in order to fulfil the relevant information requirements. Article 25 of the REACH Regulation establishes the general aim of avoidance of unnecessary testing. Furthermore, and in accordance with Article 53 (1) of the REACH Regulation, the Registrant shall contact the other registrants of the same substance and make every effort to reach agreement on which registrant is to carry out testing and to share the costs of such studies.

In addition, the Registrant is reminded of the obligation imposed by Article 11 of the REACH Regulation on all the registrants of the same substance to submit registrations for the same substance jointly.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **28 March 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

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

1. Granulometry (Annex VII, 7.14.)

"Granulometry" is a standard information requirement as laid down in Annex VII, Section 7.14. 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.

The Registrant waived the standard information requirement of Annex VII, section 7.14 for granulometry claiming that "*2,4-di-tert-butylphenol is transported to end users in a melted form*". ECHA views that the waiving statement cannot be accepted since the manufactured substance is a solid and worker exposure to dust of this substance cannot be excluded under certain manufacturing processes (e.g. sampling during process, cleaning of production equipment, use of substance in laboratories). ECHA concludes that there is thus a need for information on particle size of the substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Granulometry (the Registrant is recommended to follow the Integrated Testing Strategy on granulometry, as described in the Guidance on Information Requirements, Chapter R.7a).

2. Dissociation constant (Annex IX, 7.16.)

"Dissociation constant" is a standard information requirement as laid down in Annex IX, Section 7.16. 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.

The dissociation of a substance in water is of importance in assessing its impact upon the environment and it governs the form of the substance which in turn determines its behaviour and transport. It may affect the adsorption of the substance on soils and sediments.

The Registrant waived the standard information requirement of Annex IX, section 7.16 for dissociation constant claiming that "*2,4-Di-tert-butylphenol is a solid substance which is practically not soluble in water. It contains functional groups with weak potential for dissociation*". ECHA views that the waiving statement cannot be accepted since the registered substance contains a phenol group. Therefore, a partial dissociation of the neutral form of the registered substance to form a charged molecule cannot be excluded at environmentally relevant pH.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Dissociation constants in water (test method: OECD 112).

3. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.)

"*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

The Registrant has in the Section 7.6.1 of the technical dossier sought to justify the adaptation for genetic toxicity *in vitro* information requirements with the following arguments: *"Read-across to the closest structural analogue -2,6-di-tert-butylphenol (CAS 128-39-2; EC: 204-884-0): No genotoxic potential"* and *"No data on genotoxicity of 2,4-di-tert-butylphenol in humans were located."* However, the Registrant has not provided in the technical dossier a robust study summary for the reference substance to adequately and reliably cover the key parameters addressed by *in vitro* gene mutation study in bacteria.

ECHA therefore notes that the adaptation provided by the Registrant is not appropriate as it does not provide adequate and reliable documentation. ECHA concludes that the adaptation argument does not fulfil the requirements of Annex XI or introductory paragraph 4 of Annex VII of the REACH Regulation. As the data is insufficient even for the proposed read-across substance, ECHA does not need to assess whether the conditions for applying the group concept have been justified by the Registrant.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14./OECD 471) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. E. coli WP2 uvrA, or E. coli uvrA (pKM101), or S. typhimurium TA102.

4. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.)

"Sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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.

The Registrant has in the Section 7.5.1 of the technical dossier sought to justify the adaptation for genetic toxicity in vitro with the following argument: *"2,4-di-tert-butylphenol is a non volatile solid substance with low water solubility and low vapour pressure. It is an industrial chemical which is not available to general public (consumers) as such."*

ECHA notes that the adaptation provided by the Registrant does not fulfil the requirements of Annex XI or introductory paragraph 4 of Annex VII of the REACH Regulation.

As explained above, the information available 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 light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is most appropriate.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

5. – 7. Effects on terrestrial organisms (Annex IX, 9.4.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, section 9.4.1.), effects on soil micro-organisms (Annex IX, section 9.4.2.), and short-term toxicity to plants (Annex IX, section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

5. Short-term or long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.)

The Registrant has waived testing on terrestrial invertebrates using the following justification:

"The QSAR estimated data may exceed the limit of water solubility of 2,4-di-tert-butylphenol and, therefore, cannot be used in the CSA.
2,4-di-tert-butylphenol is a non volatile solid substance which is insoluble in water. The value for soil organic carbon-water partition coefficient calculated using KOCWIN v. 2.0 (logKoc = 3.96) suggests that 2,4-di-tert-butylphenol has some potential to adsorb onto soil and sediment.

In the absence of ecotoxicity data for soil organisms, the PNEC soil is calculated using the equilibrium partitioning method (EPM) as follows (in accordance with ECHA Guidance on Information Requirements, PartB):

PNECsoil =(0.174 + 0.0104 x Koc) x PNEC water.

Estimated Koc for 2,4-di-tert-butylphenol =9010 -9127 L/kg (by following a precautionary approach, the lowest estimated Koc value of 9010 L/kg will be used in the calculation); PNEC water =0.002 mg/L.

Therefore, PNECsoil= 0.188 mg/kg is calculated for 2,4-di-tert-butylphenol."

ECHA notes that, according to the evidence presented within the Registration dossier, exposure of the soil compartment is likely. The use pattern of the registered substance as a fuel additive suggests that direct or indirect exposure of soil is likely. Direct soil exposure of fuels from consumer (and probably professional) use can be expected. Indirect exposure of soils via application of sludge from a sewage treatment plant can be expected. In the Chemical Safety Assessment, the PNECsoil is derived using the equilibrium partitioning method (EPM). The registrant does not present any risk characterisation ratios for the soil

compartment but states in Section 10.2 relating to environmental risk characterisation: *"Because of its chronic aquatic toxicity, overall conclusion on risks of 2,4-di-tert-butylphenol to environment is summarized as follows:· conclusion (iii) applies: There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account."*

ECHA notes that, according to the evidence presented within the Registration dossier, the registered substance possesses intrinsic properties indicating a high hazard potential to soil organisms. The registered substance is predicted to be not readily biodegradable (QSAR predictions provided show 'does not biodegrade fast' and 'ready biodegradability: no') and is considered by the registrant to meet the criteria for persistent/very persistent. The predicted LogKoc is 3.96 which indicates a potential for adsorption to soil.

The registered substance is very toxic to aquatic organisms, based on its predicted acute toxicity to fish, invertebrates and green algae (all L/EC50s<1 mg/l) and is classified by the registrant as hazardous to the aquatic environment, Aquatic Chronic 1 and Aquatic Acute 1.

The registered substance meets the criteria for hazard category 4 according to Table R.7.11-2 in Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) since it is considered as very persistent in soil and is very toxic to aquatic organisms. For these substances, screening assessment based on EPM is not recommended since the intrinsic properties indicate a high hazard potential to soil organisms. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Annex IX, Section 9.4., column 2 states that for substances with a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is likely to be very persistent and therefore the registrant shall consider long-term toxicity testing for this endpoint.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Earthworm, acute toxicity test (test method: EU C.8./OECD 207)

Or, if long-term testing is considered appropriate, either

Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)
or
Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Enchytraeid reproduction test, OECD 220)
or
Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Collembolan reproduction test in soil, OECD 232).

6. Effects on soil micro-organisms (Annex IX, 9.4.2.)

The Registrant has waived testing on effects on soil microorganisms using the identical justification as presented above under '5. Short-term or long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.)'.

ECHA notes that, according to the evidence presented within the Registration dossier, exposure of the soil compartment is likely. The use pattern of the registered substance as a fuel additive suggests that direct or indirect exposure of soil is likely. Direct soil exposure of fuels from consumer (and probably professional) use can be expected. Indirect exposure of soils via application of sludge from a sewage treatment plant can be expected. In the Chemical Safety Assessment, the PNECsoil is derived using the equilibrium partitioning method (EPM). The registrant does not present any risk characterisation ratios for the soil compartment but states in Section 10.2 relating to environmental risk characterisation: *"Because of its chronic aquatic toxicity, overall conclusion on risks of 2,4-di-tert-butylphenol to environment is summarized as follows:· conclusion (iii) applies: There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account."*

ECHA considers that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R.7C, R.7.11.3.1. p112, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Soil microorganisms: nitrogen transformation test (test method : EU C.21./OECD 216).

7. Short-term or long-term toxicity to terrestrial plants (Annex IX, 9.4.3.)

The Registrant has waived testing on effects on terrestrial plants using the identical justification as presented above under '5. Short-term or long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.)'.

ECHA notes that, according to the evidence presented within the Registration dossier, exposure of the soil compartment is likely. The use pattern of the registered substance as a fuel additive suggests that direct or indirect exposure of soil is likely. Direct soil exposure of fuels from consumer (and probably professional) use can be expected. Indirect exposure of soils via application of sludge from a sewage treatment plant can be expected. In the Chemical Safety Assessment, the PNECsoil is derived using the equilibrium partitioning method (EPM). The registrant does not present any risk characterisation ratios for the soil compartment but states in Section 10.2 relating to environmental risk characterisation: *"Because of its chronic aquatic toxicity, overall conclusion on risks of 2,4-di-tert-butylphenol to environment is summarized as follows:· conclusion (iii) applies: There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account."*

ECHA notes that, according to the evidence presented within the Registration dossier, the registered substance possesses intrinsic properties indicating a high hazard potential to soil organisms. The registered substance is predicted to be not readily biodegradable (QSAR predictions provided show 'does not biodegrade fast' and 'ready biodegradability: no') and is considered by the registrant to meet the criteria for persistent/very persistent. The predicted LogKoc is 3.96 which indicates a potential for adsorption to soil.

The registered substance is very toxic to aquatic organisms, based on its predicted acute toxicity to fish, invertebrates and green algae (all L/EC50s<1 mg/l) and is classified by the registrant as hazardous to the aquatic environment, Aquatic Chronic 1 and Aquatic Acute 1.

The registered substance meets the criteria for hazard category 4 according to Table R.7.11-2 in Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) since it is considered as very persistent in soil and is very toxic to aquatic organisms. For these substances, screening assessment based on EPM is not recommended since the intrinsic properties indicate a high hazard potential to soil organisms. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Annex IX, Section 9.4., column 2 states that for substances with a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is likely to be very persistent and therefore the registrant shall consider long-term toxicity testing for this endpoint.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For

short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Terrestrial plants, growth test (test method: OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species).

Or, if long-term testing is considered appropriate, either

Terrestrial plants, growth test (test method: 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 (test method: ISO 22030).

8.- 10. Simulation testing in surface water, soil and sediment (Annex IX, 9.2.1.2.; 9.2.1.3.; 9.2.1.4.)

8. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.)

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, 9.2.1.2 of the REACH Regulation. Column 2 of Section 9.2.1.2 of Annex IX further indicates that the study does not need to be conducted if the substance is highly insoluble in water or if the substance is readily biodegradable. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI, including QSAR (Qualitative or Quantitative structure-activity relationship) based adaptation governed by Section 1.3. of that Annex. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waives the requirement for water simulation testing with the following justification:
"2,4-Di-tert-butylphenol is a non volatile solid substance which is almost insoluble in water. The environmental fate of 2,4-di-tert-butylphenol in water and sediment will be determined by biotic and abiotic transformation.

The QSARs estimated half-lives for biodegradation of 2,4-di-tert-butylphenol in water and sediment based upon BIOWIN Ultimate Biodegradation are 900 hours (37.5 days) and 8100 hours (337.5 days), respectively. Whereas the half-lives of 2,4-di-tert-butylphenol for

volatilization from water are estimated as 11.19 days (for a river) and 127 days (for a lake) using EPI Suite software.

The QSAR models predicts timeframe within days -weeks for primary biodegradation of 2,4-di-tert-butylphenol and weeks-months for its ultimate degradation.

The following information is taken into account for the hazard / risk / persistency assessment: Overall ready biodegradability prediction provided by a number of BIOWIN (v.4.10) models suggests that 2,4-di-tert-butylphenol is not ready biodegradable in the environment."

Regarding the adaptation based on QSARs referred to by the Registrant, ECHA points out that the conditions of the use of QSARs as set out by Annex XI, 1.3, of the REACH Regulation are not fulfilled. In particular, no adequate and reliable documentation of the applied method was provided. Whether or not the other conditions of Annex XI, 1.3, of the REACH regulation are fulfilled cannot be assessed by ECHA without such documentation.

Furthermore, ECHA considers that, based on information provided in the registration dossier and notwithstanding whether the QSARs used by the Registrant meet the criteria of Annex XI, Section 1.3 or not, the registered substance is not readily biodegradable within the meaning of Column 2 of Section 9.2.1.2 of Annex IX. This is evidenced by QSAR predictions for ready biodegradability in the registration dossier and concluding, as also presented above, that "*The following information is taken into account for the hazard / risk / persistency assessment: Overall ready biodegradability prediction provided by a number of BIOWIN (v.4.10) models suggests that 2,4-di-tert-butylphenol is not ready biodegradable in the environment.*" ECHA notes that there is no other data provided by the Registrant that would show that the registered substance is readily biodegradable.

In addition, in ECHA's view the registered substance cannot be considered as highly insoluble within the meaning of Column 2 of Section 9.2.1.2 of Annex IX. Notwithstanding whether the QSARs used by the Registrant meet the criteria of Annex XI or not, QSAR predictions for water solubility provided in the registration dossier indicate a water solubility of 5-32 mg/l. Furthermore, direct and indirect exposure of the aquatic compartment is likely based on the use pattern as a fuel additive and stabilizer. ECHA notes that there is no other data provided by the Registrant that would show that the registered substance is highly insoluble in water.

For the above reasons, the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2.1.2, or the general adaptation rules of Annex XI.

Therefore, the adaptation cannot be accepted and there is an information gap in the registration dossier.

As for the test method, ECHA considers that the test method "Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309" is suitable and appropriate.

9. Sediment simulation testing (Annex IX, 9.2.1.4.)

"Sediment simulation testing" is a standard information requirement according to column 1, Section 9.2.1.4 of Annex IX of the REACH Regulation. Column 2 of Section 9.2.1.4 of Annex

IX further states that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of sediment is unlikely. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI, including QSAR based adaptation governed by Section 1.3. of that Annex. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waives the requirement for sediment simulation testing using the same justification as for surface water simulation testing above. As discussed above, the Registrant concludes that "*2,4-di-tert-butylphenol is not ready biodegradable in the environment.*" In addition, direct and indirect exposure of sediment is likely based on the use pattern as a fuel additive and stabilizer. The estimated Log Koc values of 3.9547 and 3.9627 provided in the registration dossier indicate that the registered substance has potential for adsorption onto soil and sediment.

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2.1.2, or the general adaptation rules of Annex XI since the substance is not readily biodegradable and direct and indirect exposure of sediment is likely and since there is no valid adaptation in line with Annex XI presented for this endpoint in the dossier.

Therefore, the adaptation cannot be accepted and there is an information gap in the registration dossier.

As for the test method, ECHA considers that the test method "Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308" is suitable and appropriate.

10. Soil simulation testing (Annex IX, 9.2.1.3.)

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, 9.2.1.3 of the REACH Regulation. Column 2 of Section 9.2.1.3 of Annex IX further indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI, including QSAR based adaptation governed by Section 1.3. of that Annex. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waives the requirement for soil simulation testing with the following justification:
"*QSAR models developed and used by the US EPA (i.e. BIOWIN (v.4.10) software) predict that 2,4-di-tert-butylphenol is not ready biodegradable in the environment. QSARs estimated half-life for biodegradation of 2,4-di-tert-butylphenol in soil based upon BIOWIN Ultimate Biodegradation Model is 1800 hours (75 days) (refer Appendix 1).*
The following information is taken into account for the hazard / risk / persistency assessment: QSAR predicted T50 for biodegradation of 2,4-di-tert-butylphenol in soil is 1800 hours (75 days).."

Regarding the validity of the QSARs referred to by the Registrant, ECHA refers to the argumentation presented under the point concerning *simulation testing on ultimate*

degradation in surface water above and concludes that the conditions of the use of QSARs as set out by Annex XI, 1.3, of the REACH Regulation are not fulfilled.

As also discussed above, the Registrant concludes that "*2,4-di-tert-butylphenol is not ready biodegradable in the environment.*" In addition, direct and indirect exposure of soil is likely based on the use pattern as a fuel additive and stabilizer. The estimated Log Koc values of 3.9547 and 3.9627 provided in the registration dossier indicate that the registered substance has potential for adsorption onto soil and sediment.

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2.1.3, or the general adaptation rules of Annex XI since the substance is not readily biodegradable and direct and indirect exposure of soil is likely and since there is no valid adaptation in line with Annex XI presented for this endpoint in the dossier.

Therefore, the adaptation cannot be accepted and there is an information gap in the registration dossier. As for the test method, ECHA considers that the test method "Aerobic and anaerobic transformation in soil, EU C.23/OECD 307" is suitable and appropriate.

Conclusion on the simulation tests 8. -10.
Therefore, pursuant to Article 41(1)(a) and(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309);

and

Soil simulation testing (Annex IX, 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307);

and

Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308).

Before conducting any of the tests mentioned above the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2, November 2012), Chapter R7b, Sections R.7.9.4 and R.7.9.6 and Chapter R.11.1.3 on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all three simulation tests. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance. The Registrant retains the right to include fully justified adaptations for simulation testing.

11. Identification of degradation products (Annex IX, 9.2.3.)

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. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI, including QSAR based adaptation governed by Section 1.3. of that Annex.

In the present dossier, ECHA notes that the information on this endpoint is not available. The technical dossier does not either contain acceptable adaptation for this standard information requirement in accordance with Column 2 of Section 9.2.1.4 of Annex IX or Annex XI to the REACH Regulation for this standard information requirement.

Regarding an 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 metabolite may be investigated.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products using an appropriate and suitable test method, as explained above in this section.

Before conducting the above test, the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2, November 2012), Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

In accordance with Annex I, Section 4, of the REACH Regulation the Registrant should revise the PBT assessment when results of the tests 8-11 detailed above are available. The Registrant is also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

Deadline for submitting the information required under Section II

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In follow-up to the proposals for amendment additional tests were included amongst the tests requested by the decision. ECHA considered that 9 months may not suffice to conduct the additional testing. ECHA considers an additional 15 months are adequate for sequential testing as outlined above. Therefore the timeline was extended to 24 months. The decision was amended accordingly.

IV. Adequate identification of the composition of the tested material

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/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