EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002332-85-05/F Helsinki, 20 December 2012

DECISION ON TESTING PROPOSALS SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Tert-butyl perbenzoate, CAS No 614-45-9 (EC No 210-382-2), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(d) thereof for tert-butyl perbenzoate, CAS No 614-45-9 (EC No 210-382-2), by [redacted] (Registrant).

- Viscosity (OECD Test Guideline 114), Annex IX, 7.17.;
- Long-term toxicity testing on aquatic invertebrates (OECD Guideline 211 – Daphnia Magna Reproduction Test), Annex IX, 9.1.5.;
- Long-term toxicity testing on fish (OECD Guideline 210 - Fish, Early-Life Stage Toxicity Test), Annex IX, 9.1.6.;
- Pre-natal Developmental Toxicity Study (OECD Guideline 414), Annex IX, 8.7.2.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of [redacted]. This decision does not take into account any updates after 19 July 2012, 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 decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

On 4 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a consultation of third parties for the testing proposals from 16 June until 01 August 2011. ECHA did not receive information from third parties.

On 7 March 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 9 April 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision, but requesting an extension of the deadline to submit the update dossier from 18 months to 24 months.

ECHA considered the Registrant's comments received and amended the draft decision rejecting the extension requested by the Registrant because the Registrant did not substantiate the request, as explained in Section III.

On 19 July 2012 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 22 August 2012 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.

On 3 September 2012 ECHA referred the draft decision to the Member State Committee.

ECHA reviewed the proposals for amendment received and has amended the draft decision.

The Registrant did not provide comments on the proposed amendments.

After discussion in the Member State Committee meeting on 23-24 October 2012, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 23 October 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the substance subject to the present decision:

1. Viscosity (Annex IX, 7.17. ; test method: OECD Guideline 114);
2. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: OECD Guideline 211 or EU Method C.20);
3. Long-term toxicity testing on fish (Annex IX, 9.1.6.; test method: OECD 210 (Fish, Early-life Stage Toxicity Test); and
4. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2.; test method: EU B.31/ OECD 414).

Before conducting any of the tests mentioned above in points 2 and 3 the Registrant shall consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **20 June 2014** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

a) Examination of the testing proposal

1. Viscosity

Information on the viscosity of a substance is a standard information requirement as laid down in Annex IX, 7.17 of the REACH Regulation. As the information on this endpoint is not available for the substance subject to the present decision but needs to be present in the technical dossier to meet the information requirements, it is necessary to generate the data and to perform the test.

Therefore, the Registrant shall carry out the proposed viscosity test following the test method OECD 114 (Viscosity of Liquids). Furthermore, the Technical Guidance Document on *Information Requirements and chemical safety assessment* notes that "*Each determination of viscosity must be accompanied by the temperature at which the measurement was made. The determination should preferably be made at a temperature of 20°C and one other temperature approximately 20°C higher. At least two determinations should be made at each temperature*" (R.7.1.18.3, page 184).

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study on the registered substance, tert-butyl perbenzoate, using the test method of OECD Guideline 114.

2. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, 9.1.5. of the REACH Regulation. Column 2 of Section 9.1 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

ECHA notes that the Registrant has not provided any justification for the testing proposal in the technical dossier. However, in the chemical safety report, under section 7.1.1 the Registrant indicates that he wishes to use the chronic testing to verify assumptions he has made in deriving the aquatic PNEC. These were to take account of the significant degradation that occurred in the acute ecotoxicity testing.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008) Figure R.7.8-4 p. 53) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the daphnia study is to be conducted first. If based on the results of the long-term daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (test method OECD Guideline 211 or EU Method C.20) using the registered substance, tert-butyl perbenzoate.

During the 30-day commenting period, the Registrant acknowledged that the proposed time to perform the aquatic toxicity tests (18 months) is sufficient for their completion, but expressed concerns regarding their commission. The Registrant justified his request by referring to competing "time slots" for the ecotoxicological tests if the tests are to begin after 3-6 months from now, i.e. by the time the final decision will be issued. However, ECHA notes that the Registrant has not referred to technical difficulties in undertaking the studies involved, it has not provided any adequate documentation and/or substance-specific justification that could substantiate its claim for deadline extension. On the contrary, the Registrant has agreed with the draft decision that the 18 month time is adequate for the test completion. At the same time, the testing proposal examination procedure needs to follow the timeline set out in Article 51 of the REACH Regulation before a final decision is adopted and the 18 month deadline applies. For these reasons, ECHA considered the Registrant's comment but did not amend the deadline for the test completion as set in the draft decision sent to the Registrant on 7 March 2012.

3. Long-term toxicity testing on fish

Long-term toxicity testing on fish is a standard information requirement as laid down in Annex IX, section 9.1.6. of the REACH Regulation. Column 2 of Section 9.1 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

ECHA notes that the Registrant has not provided any justification for the testing proposal in the technical dossier. However, in the chemical safety report, under section 7.1.1 the Registrant indicates that he wishes to use the chronic testing to verify assumptions he has made in deriving the aquatic PNEC. These were to take account of the significant degradation that occurred in the acute ecotoxicity testing.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008) Figure R.7.8-4 p. 53) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the daphnia study is to be conducted first. If based on the results of the long-term daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted. In summary, before conducting the long-term toxicity testing on fish, the Registrant is recommended to consider the results of the test performed on aquatic invertebrates.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on fish (test method OECD 210) using the registered substance, tert-butyl perbenzoate.

For the reasons explained before in point 2, ECHA also rejects the request of the Registrant for an extention of the deadline of the submission of this test.

4. Pre-natal developmental toxicity study

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the substance subject to the present decision, but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint. The Registrant did not specify the species and route to be used for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out with the following test: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD Guideline 414) using the registered substance, tert-butyl perbenzoate.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is note, however that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studiesmust be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint Registrants. It is the responsibility of all the joint Registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed

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

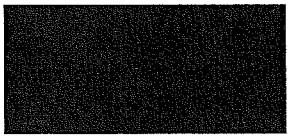
ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



Jukka Malm
Director of Regulatory Affairs