EUROPEAN CHEMICALS AGENCY

Helsinki, 5 September 2016

Addressee [redacted]

Decision number: CCH-D-2114343509-45-01/F
Substance name: Potassium Titanium Oxide
EC number: 432-240-0
CAS number: 12056-51-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19.08.2013

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. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5; test method: Daphnia magna reproduction test, EU C.20/OECD TG 211) with the registered substance;**

2. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

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 **12 June 2018**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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

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.

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Appendix 1: Reasons

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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 waived testing on aquatic invertebrates using the following justification: *'Long-term toxicity to aquatic invertebrate testing would only be required if the chemical safety assessment indicates the need to investigate further the effects of aquatic organisms. The chemical safety assessment does not show this need. Notable environmental emissions of the substance from human activities are not expected to occur under the conditions defined in the exposure scenarios that are described in the attached CSR. Potential release of the substance to the environment is minimised through exposure controls as described in the exposure scenarios and through the form of final articles produced from mixtures containing the substance. Negligible emissions of the substance into the environment are anticipated with the water phase of articles if these are disposed of in appropriate landfills. It is concluded that emissions of the substance from human activities do not pose environmental risks and that a detailed assessment of environmental exposure to the substance need not be conducted'.*

ECHA points out, as also explained in the second introductory paragraph of Annex IX, that long-term toxicity testing on aquatic invertebrates is a standard information requirement at the current tonnage level.

Furthermore, concerning exposure, ECHA notes that the Chemical Safety Report includes the risk management measure 'Do not discharge directly into the environment', however, this does not take into account the use of the substance as a wear-resistant material in brake disc-pads and brake-linings for cars, trains and industrial machines. ECHA considers that environmental emissions from the wearing of brake linings may be possible. In the absence of an environmental exposure assessment or risk characterisation for this substance, there is insufficient information to conclude on the acceptability of your waiving justification.

Consequently, your justification for waiving does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.1, or the general adaptation rules of Annex XI. Therefore, the adaptations 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 requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that in your comments to the Draft Decision, you have committed to provide the requested data.

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: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) 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. In such case, 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 the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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.

"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. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have waived testing on fish using the following justification: *'Long-term toxicity to fish testing would only be required if the chemical safety assessment indicates the need to investigate further the effects of aquatic organisms. The chemical safety assessment does not show this need. Notable environmental emissions of the substance from human activities are not expected to occur under the conditions defined in the exposure scenarios that are described in the attached CSR. Potential release of the substance to the environment is minimised through exposure controls as described in the exposure scenarios and through the form of final articles produced from mixtures containing the substance. Negligible emissions of the substance into the environment are anticipated with the water phase of articles if these are disposed of in appropriate landfills. It is concluded that emissions of the substance from human activates do not pose environmental risks and that a detailed assessment of environmental exposure to the substance need not be conducted'*.

ECHA points out, as also explained in the second introductory paragraph of Annex IX, that long-term toxicity testing on fish is a standard information requirement at the current tonnage level.

Furthermore, concerning exposure, ECHA notes that the Chemical Safety Report (CSR) includes the risk management measure 'Do not discharge directly into the environment', however, this does not take into account the use of the substance as a wear-resistant material in brake disc-pads and brake-linings for cars, trains and industrial machines.

ECHA considers that environmental emissions from the wearing of brake linings may be possible. In the absence of an environmental exposure assessment or risk characterisation for this substance, there is insufficient information to conclude on the acceptability of your waiving justification.

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.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as appropriate and suitable.

ECHA notes that in your comments to the Draft Decision, you agree to perform the long-term fish test if, based on the results of the long-term Daphnia study and the application of a relevant assessment factor, a risk is observed.

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: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Before conducting any of the tests mentioned above in points 1-2 you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 2.0, November 2014)*, 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.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), 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. In such case, 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 the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

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 22 October 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, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment(s).
As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2017.

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

3. 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.

4. In carrying out the test(s) 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 test(s) 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 test(s) to be assessed.