Department for Environment Food & Rural Affairs

Authorisation Decision

by Rebecca Pow MP

Parliamentary Under Secretary of State

On behalf of the Secretary of State for Environment, Food and Rural Affairs

Decision date: 26 July 2021

Application Ref: ID 0139-01

UK REACH authorisation No:

Authorisation number	Authorisation holder	Authorised use
UKREACH/21/01/0	Ortho Clinical Diagnostics	Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) for use in the manufacture of in vitro diagnostic VITROS® products used for infectious disease screening, endocrinology, and oncology testing.

Preliminary Matters

- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (hereinafter referred to as 4-tert-OPnEO) is listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)[1]. As such, 4-tert-OPnEO is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.

[1] This is a reference to the retained version of Regulation (EC) No 1907/2006, as amended. The retained version of that Regulation is available online at https://www.legislation.gov.uk/eur/2006/1907/contents

- 4-tert-OPnEO was included in Annex XIV to Regulation (EC) No 1907/2006[2] because there is scientific evidence of probable serious effects to the environment from its endocrine-disrupting properties when it degrades.
- The application is made by Ortho-Clinical Diagnostics of Felindre Meadows, Pencoed, Bridgend, Wales, CF35 5PZ ('the Applicant').
- On 13 February 2019, the Applicant made an application for authorisation ('the Original Application') to the European Chemicals Agency (ECHA) for the use of 4-tert OPnEO in the formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) for use in the manufacture of in vitro diagnostic VITROS® products used for infectious disease screening, endocrinology, and oncology testing.
- On 11 October 2019, ECHA sent the Consolidated Opinion of the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) ('the RAC Opinion' and 'the SEAC Opinion' respectively) to the European Commission.
- On 27 January 2021, the Applicant notified the Secretary of State of the Original Application in accordance with Article 127G of EUR 2006/1907.

Decision

1. This decision is addressed to the Applicant.
2. An authorisation is granted in accordance with Article 60(4) of EUR 2006/1907 for the following use of 4-tert-OPnEO:

   Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) for use in the manufacture of in vitro diagnostic VITROS® products used for infectious disease screening, endocrinology, and oncology testing
3. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at 12 years. The authorisation will cease to be valid on 4 January 2033 unless the authorisation holder submits a review report in accordance with article 61(1) by 4 July 2031.
4. The authorisation is subject to the following condition (as well as the requirement in Article 60(10) of EUR 2006/1907 to ensure exposure is reduced to as low a level as is technically and practically possible):

[2] This is a reference to Regulation (EC) No 1907/2006 as it has effect in EU law.

a. The authorisation holder must adhere to the risk management measures and operational conditions described in the chemical safety report referred to in Article 62(4)(d) of EUR 2006/1907[3].

5. In the event a review report is submitted in accordance with article 61(1) it should include the following information:

   a. An assessment of the feasibility of collecting for adequate treatment the remaining liquid wastes released through rinsing reusable stainless steel vessels, pumps and tubing.

6. This authorisation is not subject to any monitoring arrangements.

Background

7. This decision is made under Article 64(8) of EUR 2006/1907.

8. In making this decision I have taken into account: -

   a. The Original Application.

   b. The elements referred to in Article 60(4)(a) to (d) of EUR 2006/1907, and the aspects referred to in Article 60(5).

   c. The RAC Opinion and the SEAC Opinion compiled by ECHA ('the ECHA Opinions').

   d. That the use applied for takes place in Wales, so all the data and analysis supplied in the Original Application and the ECHA Opinions is in relation to that site. Therefore, that information is all relevant to Great Britain.

Reasons

9. In the Original Application, the Applicant did not derive predicted no-effect concentration(s) (PNEC(s)). The Applicant therefore treated 4-tert-OPnEO as a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of Regulation (EC) No 1907/2006. The RAC Opinion concluded that for the purposes of the assessment of this application, it was not possible to determine PNEC(s) for the endocrine disrupting properties for the environment of 4-tert-OPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006.

10. In accordance with Article 60(3)(a) of EUR 2006/1907, this means that Article 60(2) of that Regulation does not apply. Article 60(2) does not apply to substances for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex 1. Therefore, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

[3] The risk management measures and operational conditions are described in sections 9 (exposure assessment (and related risk characterisation)) and 10 (risk characterisation related to combined exposure) of the chemical safety report submitted to ECHA.

11. An authorisation may only be granted under Article 60(4) of EUR 2006/1907 if it is shown that the socio-economic benefits outweigh the risks to human health or the environment and there are no suitable alternative substances or technologies. A suitable alternative should be safer, available, and technically and economically feasible.

Risks to the environment

12. The RAC Opinion concluded that the Applicant has demonstrated that releases to environmental compartments (air, water and soil) have been prevented or minimised as far as technically and practically possible. In reaching this conclusion, RAC noted that all solid waste and the majority of 4-tert-OPnEO in liquid waste is collected for incineration. The only liquid waste containing residual 4-tert-OPnEO that is not incinerated results from rinsing reusable stainless steel vessels, pumps and tubing. RAC accepted the applicant's position that it is not proportionate to collect, store and incinerate this volume of rinse water containing a small amount of 4-tert-OPnEO.

13. 4-tert-OPnEO presents a risk to aquatic life when it degrades in water. When degraded, it can adversely affect the endocrine systems of aquatic organisms. I note that these risks cannot be excluded even at low levels. However, I conclude that the risk is low because the emissions arising from the rinse water containing 4-tert-OPnEO are low. Having evaluated RAC's assessment, I agree with its conclusion that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. In reaching this conclusion, I note that all of the environmental releases referred to in the Original Application and RAC Opinion take place in Great Britain.

14. The RAC Opinion concluded that the risk management measures and operational conditions as described in the application are appropriate and therefore did not propose any additional conditions. RAC concluded that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. RAC also concluded that the exposure estimates provided by the applicant are appropriate. Therefore, RAC did not propose any monitoring arrangements. Having evaluated RAC's assessment and the risk management measures and operational conditions described in the application, I agree that no additional conditions and no monitoring arrangements are required. In reaching this conclusion, I note that all of the risk management measures and operational conditions referred to in the Original Application and RAC Opinion would take place in Great Britain.

Socio-economic analysis

15. The SEAC Opinion concluded that SEAC has no substantial reservations on the quantitative and qualitative elements of the Applicants' assessment of the socio-economic benefits and the risk to the environment associated with the continued use of 4-tert-OPnEO. SEAC concluded that the quantified estimated benefits due to avoided profit losses and job losses are over one

hundred million euros.[4] I note that all of these quantitative benefits would take place in Great Britain.

16. SEAC also concluded that the Applicant's assessment of the qualitatively assessed additional socio-economic benefits of avoided lag in the availability of in vitro diagnostic tests were justified. SEAC concluded that it is not clear if alternative products would remain available at all or in sufficient quantities in the EEA. I conclude that these qualitatively assessed socio-economic benefits and the potential lack of alternative products also apply in Great Britain.

Conclusion on whether the benefits outweigh the risks

17. I consider that the Applicant has shown that the socio-economic benefits outweigh the risk to the environment because of:

    a. The likely low level of emissions.

    b. The likely significant quantitative benefits such as avoided profit losses and job losses.

    c. The likely significant qualitative benefits in respect of healthcare.

Alternatives

18. The SEAC Opinion concluded that there are no available alternative substances or technologies with the same function and a similar level of performance that are safer and technically and economically feasible for the Applicant by the sunset date. SEAC agreed with the Applicant that alternative substances already on the market would not be technically or economically feasible for the Applicant due to the internal testing and validation required for obtaining the external approvals for the global market.

19. Having evaluated SEAC's assessment, I agree with that conclusion and consider that the Applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion I have considered SEAC's assessment of the technical feasibility of alternative substances already on the market and I consider this to be applicable to Great Britain.

Review period

20. The SEAC Opinion recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 12 years. I agree with that recommendation. In reaching this conclusion, I have considered SEAC's Opinion that the substitution timelines proposed by the Applicant are reasonable considering the resources and time period needed for the substitution. I consider that SEAC's assessment is applicable to Great Britain.

[4] The Original Application was submitted to ECHA while the UK was still an EU member state and therefore provided all monetary calculations in euros. On the date of decision, the Bank of England exchange rate was EUR/GBP = 0.8554.

Conclusion

21. For the reasons set out above, I conclude that, for the use of 4-tert-OPnEO referred to in paragraph 2, the socio-economic benefits outweigh the risk to the environment and that there are no suitable alternative substances or technologies.

22. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with Article 4A and Article 64(8) of EUR 2006/1907.

Rebecca Pow MP

On behalf of the Secretary of State for Environment, Food and Rural Affairs.