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: 14 July 2023

Application Ref: AFA005 - 01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/23/03/0	Abbott Laboratories Ltd	The professional use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated as a surfactant in the final use of 'in-vitro' Diagnostic Devices (IVDs) for clinical testing in ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.

Preliminary matters

- 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (4-tert-OPnEO) is listed in Annex XIV to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals ('UK REACH')[1]. As such, 4-tert-OPnEO is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- 4-tert-OPnEO is included in Annex XIV because there is scientific evidence of probable serious effects to the environment from its endocrine-disrupting properties when it degrades.
- This application is made by Abbott Laboratories Limited of Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4XE ('the Applicant').

[1] References to EUR 2006/1907, referred to in this decision as UK REACH, are 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.

- On 6 October 2021, the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the use of 4-tert-OPnEO in the professional use as a surfactant in the final use of 'in-vitro' Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.
- Article 127GA applied to this application. The sunset date for 4-tert-OPnEO for this use was therefore 30 June 2022.
- On 20 December 2022, the Agency sent its opinion ('the Agency Opinion') to the Secretary of State for Environment, Food and Rural Affairs, and Scottish and Welsh Ministers.

Decision

1. This Decision is addressed to the Applicant.
2. An authorisation is granted in accordance with Article 60(4) of UK REACH for the following use of 4-tert-OPnEO:
    a. As a surfactant in the final use IVDs for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at 5.5 years from the sunset date for authorisation UKREACH/23/03/0. The authorisation will cease to be valid on 30 December 2027 unless the authorisation holder submits a review report in accordance with Article 61(1) by 30 June 2026.
4. The authorisation is subject to the following condition (as well as the requirement in Article 60(10) of UK REACH to ensure exposure is reduced to as low a level as is technically and practically possible):
    a. The authorisation holder and its downstream users must adhere to the risk management measures ('RMMs') and operational conditions ('OCs') described in the chemical safety report referred to in Article 62(4)(d) of UK REACH[2].
5. This authorisation is not subject to any monitoring arrangements.

[2] This is a reference to the chemical safety report submitted by Abbott Laboratories Ltd on 6 October 2021 as part of the Application. The risk management measures and operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

Background

6. This decision is made under Article 60(4) of UK REACH and having obtained the consent of Scottish and Welsh Ministers.

7. In making this decision, I have taken into account:

   a. The Application.

   b. The elements referred to in Article 60(4)(a) to (d) of UK REACH, and the aspects referred to in Article 60(5).

   c. The Agency Opinion.

Reasons

8. In the Application, the Applicant did not derive predicted no-effect concentrations (PNECs). Therefore, the Agency concluded that for the purposes of the assessment of this Application it was not possible to determine PNECs for the endocrine disrupting properties of 4-tert-OPnEO for the environment.

9. In accordance with Article 60(3)(a) of UK REACH, 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.

10. An authorisation may only be granted under Article 60(4) of UK REACH if it is shown that the socio-economic benefits outweigh the risk 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.

Risk to the environment

11. 4-tert-OPnEO presents a risk to aquatic life when it degrades in water to 4-tert-OP. When degraded, it can adversely affect the endocrine systems of aquatic organisms. I note that the risk cannot be excluded even at low levels.

12. The Applicant provided an estimate of emissions of approximately 227 kg of 4-tert-OPnEO to the environment, across more than 130 downstream users over 5.5 years. From this 227kg, the Applicant predicted the environmental concentrations of the endocrine disrupting chemical 4-tert-OP being released into fresh water. This assumed all the substance mass used by downstream users and released to water is transformed to 4-tert-OP. The Agency concluded that the use applied for will be unlikely to result in anywhere near the worst-case estimate of emissions. This is because that estimate is based on a conservative

assumption of 100% conversion from 4-tert-OPnEO whereas the conversion is likely to be much less (around 2.5%).

13. In its opinion, the Agency compared the surface water predicted environment concentrations provided by the Applicant for 4-tert-OP with the environmental quality standards proposed for ethinylestradiol, an endocrine disruptor with the same estrogenic mode of action. On the basis of this comparison, the Agency concluded that the worst-case emissions in the use applied for would not result in discernible environmental impacts on wildlife in the receiving surface waters in relation to endocrine disruption.

14. The Applicant stated there are no releases to the environment from one of the analysers (ABBOTT PRISM). However, there are releases to water from the other 2 analysers because they are plumbed directly to the drain. The Applicant has remarked that all aqueous waste cannot practically be incinerated due to the high volume of wastewater generated (around 10 to 100 million litres per year), which would result in a high cost of incineration to downstream users. In addition, there are issues regarding the practicality of installing separate collection and storage facilities for wastewater from these analysers and physical space constraints in downstream user sites.

15. The Agency concluded that the OCs and RMMs in the chemical safety report have been shown to be appropriate and effective at limiting risk and that the Applicant has demonstrated that exposure to the environment has been reduced to as low a level as is technically and practically possible. Therefore, the Agency did not propose any additional conditions or monitoring arrangements.

16. Having evaluated the Agency's assessment, I agree with its conclusion that the use applied for will have no adverse environmental impacts in relation to endocrine disruption.

Socio-economic analysis

17. The Agency Opinion concluded that the Applicant's socioeconomic analysis is considered proportionate, and the evidence in the Application sufficient for the Agency to reach a definitive conclusion.

18. In its opinion, the Agency concluded that the Applicant has demonstrated that the socioeconomic benefits of granting the authorisation are over ten million pounds. This figure accounts for the avoided profit losses and the avoided social costs of unemployment.

19. The Agency concluded that many major benefits of continued use are not monetised. These qualitative benefits consist of:

    a. Continued use of high-precision IVD tests to carry out tests necessary for the diagnosis and monitoring of serious health conditions

b. Ensuring that blood and plasma donations continue to be tested in Great Britian so that results are shared with patients in a timely manner

c. Avoided impacts on human health and the public health system

20. Having evaluated the Agency's assessment, I agree with its conclusions on the quantitative and qualitative benefits.

Conclusion on whether the benefits outweigh the risk

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

a. The likely quantitative benefits in respect of avoided job and profit losses;

b. The likely qualitative benefits in respect of avoided negative impacts on the IVD market, affected industries and human health; and

c. The likelihood of low emissions in Great Britain and no discernible environmental impacts in relation to endocrine disruption.

Alternatives

22. The Agency concluded in its opinion that there were no available alternative substances or technologies with the same function and a similar level of performance that were safer and technically and economically feasible for the Applicant by the sunset date.

23. The Applicant provided a clear substitution plan in their Application. The Applicant began preparation for substitution in 2014, during which they conducted an initial data mining step, carried out data searches and a literature review. Following this, an internal consultation was carried out seeking out information on different surfactants already in use within the company. These activities resulted in the Applicant agreeing on 20 potential alternatives. Following a screening process, the Applicant agreed to proceed with the alternative of secondary alcohol ethoxylates. This alternative is suitable, and the Applicant is on track to finalise the relevant tests within the review period requested. The Applicant has stated that they are committed to the removal of the 4-tert-OPnEO from the final use of IVDs for clinical testing.

24. Having evaluated the Agency's assessment, I agree with that conclusion and consider that the Applicant has discharged their burden of proof in demonstrating the current absence of suitable alternatives. In reaching this conclusion, I have considered the Agency's assessment of the technical and economic feasibility of alternative substances already on the market.

Review period

25. In its opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 5.5 years.

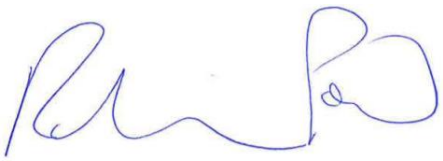
26. The Applicant has requested 5.5 years to coincide with their substitution plan. The substitution plan outlines the process which began in 2014. The Agency concluded that so far, the testing is proceeding well, and the alternative is deemed to be technically suitable. Later stages such as implementation and customer conversion are scheduled to be completed by 2027. The Agency concluded that the substitution plan is credible for the review period requested and is consistent with the analysis of alternatives and the socio-economic analysis.

27. I agree with the Agency's conclusions on these points and its recommendation for a review period of 5.5 years.

Conclusion

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

29. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of UK REACH.



Rebecca Pow MP

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