Department for Environment Food & Rural Affairs

Authorisation decision on AFA067-01

By Marc Casale

Deputy Director, Chemicals and International (Defra)

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

Decision date: 5 August 2026

Application ref: AFA067-01

Authorised use:

Professional use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a surfactant in the final use of In-Vitro Diagnostic Devices for clinical testing using ARCHITECT and Alinity automated analyser systems.

UK REACH authorisation number:

Authorisation number	Authorisation Holder
UKREACH/26/09/00	Abbott Laboratories Limited

Preliminary matters

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO), is listed in Annex XIV to assimilated Regulation (EC) No 1907/2006 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 UK REACH.

4-tert-OPnEO, was included in Annex XIV because it meets the criteria set out in Article 57(f) of UK REACH, that there is scientific evidence of probable serious effects to the

[1] References to EUR 2006/1907, referred to in this decision as UK REACH, are to the assimilated law available online at https://www.legislation.gov.uk/eur/2006/1907/contents

environment from its endocrine disrupting properties when it degrades into 4-tert-Octyl Phenol (4-tert-OP).

4-tert-OP presents a risk to aquatic life and can adversely affect the endocrine systems of marine vertebrates.

The review report is made by Abbott Laboratories Limited, with company number 00329102, whose registered address is at Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, England, United Kingdom, SL6 4XE.

Abbott Laboratories Limited (the 'Authorisation Holder') was granted authorisation under UK REACH on 14 July 2023 for the use of 4-tert-OPnEO in accordance with Article 60(4), with authorisation UKREACH/23/03/0 (the 'Existing Authorisation'). The Existing Authorisation expires on 30 December 2027.

On 18 December 2024, the Authorisation Holder submitted a review report in relation to the Existing Authorisation (the 'Review Report') to the Health and Safety Executive (the 'Agency'), with respect to the following continued use: professional use of 4-tert-OPnEO as a surfactant in the final use of In-Vitro Diagnostic Devices for clinical testing using ARCHITECT, and Alinity automated analyser systems.

The use takes place at 100 to 200 sites across Great Britain.

The Authorisation Holder had included the analyser platform ABBOTT PRISM in their applied-for use for this Review Report. However, this analyser platform has been discontinued by the Authorisation Holder. Therefore, following confirmation from the Authorisation Holder, it has been removed from the applied-for use.

On 13 February 2026, the Agency sent its opinion (the '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 Authorisation Holder.
2. In accordance with Article 61(1) of UK REACH, effective from 5 August 2026, the authorisation set out below shall apply instead of the Existing Authorisation.
3. For the avoidance of doubt, the Existing Authorisation will continue to apply to relevant activities which took place before 5 August 2026.
4. Authorisation is granted to the Authorisation Holder for the following use, under the following Authorisation number:
    a. **UKREACH/26/09/00**: Professional use of 4-tert-OPnEO as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT and Alinity automated analyser systems. Pursuant to Article 60(8) of UK REACH, the review period referred to in Article 60(9)(e) of UK REACH is set at 5 years from the expiry of the Existing Authorisation. The authorisation will

cease to be valid on 30 December 2032 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 30 June 2031.

5. 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 operational conditions (OCs) and risk management measures (RMMs) described in the Authorisation Holder's chemical safety report, dated 17 December 2024,[2] must be adhered to.

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

Background

7. In accordance with Article 61(1) of UK REACH, the Authorisation Holder submitted a Review Report containing updated versions of the following documents initially submitted with respect to the Existing Authorisation.

    a. the analysis of alternatives.

    b. the socio-economic analysis.

    c. the chemical safety report.

8. This decision is made pursuant to Article 61 of UK REACH and having obtained consent of the Scottish and Welsh Ministers.

9. In making this decision I have taken into account:

    a. the Existing Authorisation (including associated documentation).

    b. the Review Report submitted to the Agency.

    c. the provisions of Article 60 and Article 61 of UK REACH, including the elements referred to in Article 60(4) and the requirements of Article 60(5) (as applicable).

    d. the Opinion.

    e. any change of circumstances detailed in the Review Report, which if known at the time of granting the Existing Authorisation, would have affected the decision to grant the Existing Authorisation or the terms of the Existing Authorisation.

[2] This is a reference to the updated chemical safety report dated 17 December 2024 submitted by the Authorisation Holder as part of its Review Report. This is an updated version of the chemical safety report submitted in the application for the Existing Authorisation, as was required by Article 62(4)(d) of UK REACH. The OCs and RMMs are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

Reasons

10. In its Review Report, the Authorisation Holder did not derive predicted no-effect concentrations (PNECs).

11. In accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of UK REACH does not apply to this Review Report. 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 I. Therefore, an authorisation may only be granted on the basis of Article 60(4) of UK REACH.

12. 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 arising from the use of 4-tert-OPnEO and if there are no suitable alternative substances or technologies.

Risk to the environment

13. The degradation product of 4-tert-OPnEO, 4-tert-OP, presents a risk to aquatic life when present in water. The substance can adversely affect the endocrine systems of marine vertebrates. I note that this risk cannot be excluded even at low levels.

14. In its Review Report, the Authorisation Holder stated that, combined across all downstream user sites, 10 to 100 kg of 4-tert-OPnEO is used annually.

15. The Authorisation Holder's OCs and RMMs relating to air, water, soil and waste have not changed since the granting of the Existing Authorisation. In its Review Report, the Authorisation Holder stated that there are no releases to air during the use of 4-tert-OPnEO. This is because the process takes place indoors and in controlled areas, the substance has a low vapour pressure and all operations take place at low temperatures. Therefore, the Authorisation Holder considered that emissions to air are negligible. In its Opinion, the Agency agreed with the Authorisation Holder that releases to air are negligible, given the Authorisation Holder's OCs and the low vapour pressure of 4-tert-OPnEO. I agree with the Agency's conclusion.

16. For soil, the Authorisation Holder also considered that direct releases of 4-tert-OPnEO are negligible. In its Opinion, the Agency agreed with the Authorisation Holder that direct releases to soil are not likely and noted a 0% release factor for non-agricultural soil. However, the Authorisation Holder acknowledged in their Review Report that indirect releases to soil may arise via sewage sludge application to land.[3] Despite this, given the absence of sufficient evidence for endocrine disruption in terrestrial species, the Agency did not consider this scenario to

[3] Solid waste disposal may result in leachate generation within the landfill, and this may be directed to an on-site biogas generation facility or could migrate to nearby water bodies.

substantively affect its Opinion and therefore did not evaluate the indirect releases further. I agree with the Agency's conclusion.

17. The Authorisation Holder indicated in its Review Report that releases to water occur via the discharge of contaminated wastewater from ARCHITECT and Alinity IVD kits, which is released to the sewer for treatment at local wastewater treatment works before being discharged to surface water. The Authorisation Holder assumed that 10% to 100% of the 4-tert-OPnEO used for testing is discharged to wastewater.

18. Following the Agency's evaluation of the exposure assessment in the opinion for the Existing Authorisation, the Authorisation Holder assessed three different transformation scenarios for releases to wastewater. This included a "[redacted] transformation scenario" which assumes that [redacted] 4-tert-OPnEO supplied to downstream users is released to the wastewater stream and [redacted] to 4-tert-OP in the wastewater treatment works, with no further transformation before release to the environment. The Authorisation Holder also included a "2.5% transformation scenario" which assumes that 2.5% of 4-tert-OPnEO is degraded to 4-tert-OP during treatment, with the remaining 97.5% remaining as 4-tert-OPnEO. The Agency noted that the "[redacted] transformation scenario" is overly conservative overall, as it substantially overestimates releases of 4-tert-OP to surface water. The Agency's view is that the conversion from 4-tert-OPnEO to 4-tert-OP is likely to be much less, and the 2.5% conversion remains the best available assumption.

19. The Agency concluded that measured analyser outflow concentrations of 4-tert-OPnEO are already low and will continue to decline until substitution fully eliminates the need for on-site treatment. Accordingly, the overall environmental burden of 4-tert-OPnEO is expected to remain low and diminish further over time. In its Opinion, the Agency assessed environmental risk by comparing the surface water predicted environmental concentrations for 4-tert-OP with those of ethinylestradiol (EE2), a well characterised endocrine disruptor with the same mode of action and higher potency than 4-tert-OP. On this basis, the Agency concluded that surface water concentrations remain well below the adjusted environmental quality standard for EE2 under the more realistic 2.5% transformation scenario and therefore that the OCs and RMMs for water are effective in reducing aquatic exposure to a low level.

20. In its Review Report, the Authorisation Holder stated that, due to the high volumes of liquid waste, wastewater from ARCHITECT and Alinity high-throughput, fully automated analyser systems, containing very low concentrations of 4-tert-OPnEO, is typically discharged directly to drain. The Authorisation Holder indicated that due to the high volumes of liquid waste generated, collection and incineration of the effluent is neither economically feasible nor operationally practical. Additionally, the

Authorisation Holder clarified to the Agency in its application[4] that there is no scope to reduce flow rate or waste discharge without compromising on performance, which the Agency accepted.

21. In its Review Report, the Authorisation Holder noted that monitoring of 4-tert-OPnEO and 4-tert-OP downstream of the wastewater treatment works was not conducted. The Authorisation Holder explained that, due to the large number of downstream users operating across multiple locations, direct sampling at dispersed downstream user sites across Great Britain is impracticable. Instead, the Authorisation Holder has used specific data on sales of IVD kits containing 4-tert-OPnEO across Great Britain, to estimate the quantities used by each downstream user and model exposure using the European Chemicals Agency's Chemical Safety Assessment and Reporting Tool.[5] In its Opinion, the Agency concluded that the Authorisation Holder's methodology is consistent with the methodology used for the Existing Authorisation, with refinements introduced to improve accuracy and reflect updated operational data.

22. In its Opinion, the Agency noted that while remediation technologies are available that could significantly reduce contaminated wastewater releases, these may be logistically difficult or impractical to implement. As a result, the Authorisation Holder has prioritised source elimination through substitution rather than physical controls. Between 2021 and the end of 2024, use of 4-tert-OPnEO decreased significantly, with particularly sharp reductions at the three UK sites with the highest historical consumption. The Agency accepted that there is limited scope to address discharges from systems directly plumbed into wastewater, and that source elimination is both appropriate and fundamental to reducing emissions. I agree with the conclusions of the Authorisation Holder and the Agency.

23. For waste, the Authorisation Holder noted that the 4-tert-OPnEO left in the disposed container (and thus potentially entering landfill) is negligible and has therefore not estimated environmental releases via disposal of solid waste to landfill. In its Opinion, the Agency agrees that this pathway is expected to be insignificant relative to the mass discharged to drain during use and rinsing. I agree with the Agency's conclusion on releases to the environment via solid waste.

24. Having evaluated the Agency's assessment, I agree with its conclusion that releases of 4-tert-OPnEO to air and soil are negligible. I agree with the Agency that

[4] In clarification responses to Agency questions, the Authorisation Holder stated that the volume and the flow rate of liquid waste from ARCHITECT and Alinity analysers are fixed by their high-throughput design, processing thousands of tests per hour. Each assay follows precise, time-locked steps (sample and reagent pipetting, incubation, mixing, signal reading and multiple wash/purge cycles) to ensure accuracy and prevent cross-contamination. These programmed fluidics operations are inherent to the instruments, so there is no scope to reduce flow rate or waste discharge without compromising performance.
[5] The Chemical Safety Assessment and Reporting Tool is a software application developed by the European Chemicals Agency to help companies conduct chemical safety assessments and generate chemical safety reports.

the OCs and RMMs (dilution) for the ARCHITECT and Alinity analyser systems are not appropriate due to the release of 4-tert-OPnEO to surface waters, yet they are effective in reducing aquatic exposure to a low level. I agree with the Agency that it would be difficult and impractical for the Authorisation Holder to reduce this further as this would require the incineration of large volumes of liquid waste.

25. Overall, the Agency considers that the Authorisation Holder has demonstrated that releases to environmental compartments under current use scenarios are unlikely to cause adverse effects to aquatic organisms. I agree with the Agency's conclusion as the mass of 4-tert-OPnEO released to the environment is expected to be very low. I am therefore of the view that there has been no material change of circumstances with respect to the assessment of risks which would have affected the granting of the Existing Authorisation. Accordingly, it is appropriate that no additional conditions or monitoring arrangements are required.

Socio-economic analysis

26. In its Opinion, the Agency assessed the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. The monetised socio-economic benefits of authorisation consist of avoided producer surplus loss, avoided social costs of unemployment and avoided loss of residual value of capital. The Agency estimated this to be between £5 million to £50 million over 5 years.

27. Additional benefits, which are not included in this monetised figure, are the avoided lost jobs in the Authorisation Holder's GB operations (estimated to be greater than 150 job losses) and at least £100 million of avoided costs from delayed diagnoses due to a lack of available IVD tests.

28. 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

29. In its Opinion, the Agency concluded that the Authorisation Holder has demonstrated that the monetised socio-economic benefits of granting authorisation (between £5 million to £50 million over 5 years) are greater than the risks to the environment (release of between 10kg and 100kg of 4-tert-OPnEO to the environment between 2028 and 2032).

30. I consider that the Authorisation Holder has shown that the socio-economic benefits outweigh the risk to the environment because of:

    a. the likely quantitative benefits in respect of the avoided producer surplus loss and avoided social costs of unemployment to the Authorisation Holder.

b. the assessed risks from the use of 4-tert-OPnEO, including the Agency's conclusion that releases to environmental compartments under current use scenarios are unlikely to cause adverse effects to aquatic organisms.

Alternatives

31. The Agency concluded in its Opinion that there are no available alternative substances or technologies with the same function and a similar level of performance that will be technically and economically feasible for the Authorisation Holder by the expiry date of the Existing Authorisation (30 December 2027).

32. The Authorisation Holder uses 4-tert-OPnEO as a surfactant in the production of a component of In-Vitro Diagnostic Medical Devices, which are distributed by their German distribution centre for use by healthcare professionals in Great Britain.

33. In the original analysis of alternatives submitted for the Existing Authorisation, the Authorisation Holder identified a suitable alternative which could fulfil the technical function of 4-tert-OPnEO. During the Existing Authorisation, the Authorisation Holder successfully substituted or discontinued a significant proportion of their products. However, circumstances arose that extend the Authorisation Holder's substitution timeline beyond the existing review period. These circumstances are:

    a. the EU legislation applicable to IVDs changed.[6] This change altered the requirements for new or modified assays (investigative laboratory test methods carried out by the analyser systems). This meant that changes to existing assays needed more validation, and assessment times by the relevant regulatory authorities increased. EU and GB marketed devices are identical, and so the change in EU legislation also impacted GB marketed devices.

    b. the COVID-19 pandemic led to a shortage of suitable biological materials that were required. This resulted in reduced testing and caused delays in the Authorisation Holder's timeline.

    c. the Authorisation Holder had underestimated the number of assays requiring further optimisation for the alternative surfactants when calculating the substitution plan for the Existing Authorisation.

34. The Authorisation Holder noted that the information provided for the Existing Authorisation in the original analysis of alternatives has not changed. Therefore, the potential alternative identified for the Existing Authorisation is still being evaluated for use in the products containing 4-tert-OPnEO. The Authorisation Holder noted in its Review Report that a small proportion of their products require further optimisation to meet expected performance to be considered technically feasible.

[6] The EU legislation moved from the In Vitro Diagnostic Medical Device Directive to the In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746).

35. Technical feasibility testing must be carried out on each individual product to ensure that substitution will be successful. The Authorisation Holder noted that this testing is progressing well, with the alternative considered technically suitable for a large proportion of products. The latter stages, including regulatory approvals, implementation, and customer conversion, are currently underway. These steps were originally scheduled for completion by 2027 during the Existing Authorisation. However, due to delays (as discussed in paragraph 33), completion is now expected in 2032.

36. The Authorisation Holder provided an updated substitution plan in its Review Report. In its Opinion, the Agency concluded that the substitution plan was sufficiently detailed to conclude on the suitability of the requested review period. The requested review period is 5 years from 30 December 2027 (the date the Existing Authorisation expires). Furthermore, the Agency concluded that the Authorisation Holder has demonstrated convincingly that they are making good progress towards substitution in accordance with their updated substitution plan. I agree with the Agency's conclusions.

37. Having evaluated the Agency's assessment, I agree with the conclusion that there will be no available alternatives to the Authorisation Holder by the expiry date of the Existing Authorisation (30 December 2027).

Review period

38. In its Opinion, the Agency recommended the review period referred to in Article 60(8) of UK REACH should be set at 5 years.

39. In its Review Report, the Authorisation Holder requested a 5-year review period. The Agency believes that this review period is realistic when considering that:

    a. the Authorisation Holder has demonstrated in its Review Report that they are actively trying to substitute the use of 4-tert-OPnEO in their products, providing updated numbers of products that have already been substituted or discontinued since the Existing Authorisation was granted.

    b. the Agency accepts the Authorisation Holder's justification for the delays in the Existing Authorisation's substitution plan.

    c. the socio-economic benefits identified have been shown to be robust under conservative assumptions.

40. Having evaluated the Agency's assessment, I agree with the Agency's conclusions on these points and its recommendation for a 5-year review period.

Conclusion

41. 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 4 and that there are no suitable alternative substances or technologies.

42. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with the requirements of UK REACH.

43. In accordance with the provisions of Article 61(1), the Existing Authorisation is amended and replaced with this decision, effective from 5 August 2026.

M Casale

Marc Casale

Deputy Director, Chemicals and International

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