Department for Environment Food & Rural Affairs

Authorisation Decision

by Marc Casale, Deputy Director, Chemicals, Pesticides and Hazardous Waste (Defra)

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

Decision date: 31 July 2024

Application Ref: AFA021-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/10/0	Beckton, Dickinson UK Ltd	Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) for the lysis of different types of cells in order to release the cell contents for subsequent analysis in diagnostics.

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. There is scientific evidence of probable serious effects to the environment from its endocrine-disrupting properties when it degrades into 4-tert-OP. There are no known associated risks to human health.

[1] References to regulation (EC) No 1907/2006, 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.

- This application is made by: Becton, Dickinson U.K. Ltd, 1030 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5TS, United Kingdom (the 'Applicant').
- Article 127GA of UK REACH applied to this application. The latest application date for 4-tert-OPnEO for this use was therefore extended to 30 June 2022.[2] The sunset date for this use was 30 June 2022.
- On 30 June 2022, the Applicant submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency') for the use of 4-tert-OPnEO for the lysis of different types of cells in order to release the cell contents for subsequent analysis in diagnostics in their *In Vitro* Diagnostics (IVD) products by 60 to 80 downstream user sites in Great Britain (GB). The IVD products are for use on diagnostic analysers and point-of-care (PoC) testing.
- On 11 December 2023, 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 Applicant.
2. In accordance with Article 60(4) of UK REACH, authorisation is granted to the Applicant as set out under the following authorisation number for the following use:
    a. UKREACH/24/10/0 for the use of 4-tert-OPnEO for use of lysis of different types of cells in order to release the cell contents for subsequent analysis in diagnostics
3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years from the sunset date. The authorisation will cease to be valid on 30 June 2034 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 30 January 2033.
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.[3]

[2] This provided time for applicants to submit their application under UK REACH following the transition from EU REACH, where certain criteria were met.
[3] This is a reference to the chemical safety report submitted by the Applicant on 30 June 2022 as part of the application. The risk management measures and operational conditions are described in sections 3 (exposure assessment) and 4 (risk characterisation).

5. In the event that a review report is submitted in accordance with Article 61(1) of UK REACH, it is recommended to include a downstream user survey for GB-based customers which confirms the waste streams used for liquid waste containing 4-tert-OPnEO, for the above-mentioned use. This recommendation is not a condition of authorisation or a condition for any review report.

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

Background

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

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

   a. the Application submitted to the Agency

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

   c. the Agency's Opinion

Reasons

9. 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.

10. In accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of UK REACH does not apply to this Application. 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 UK REACH.

11. An authorisation may only be granted under Article 60(4) of UK REACH if it is shown that 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

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

13. The Applicant estimated under a worst-case scenario, based on their knowledge of use by 60 high-volume downstream users, that 70% of waste containing 4-tert-OPnEO will be disposed of via solid clinical waste for incineration and thus there will be no emissions through the solid waste route. The remaining 30% will be

disposed of as liquid waste which may be discharged into wastewater systems and will subsequently degrade to 4-tert-OP in sewage treatment plants (STPs). On this basis, the Applicant estimated 1 to 20 kg per year of 4-tert-OPnEO releases to wastewater, and thus assuming 100% conversion, a 1 to 10 kg per year release of 4-tert-OP. This equates to a release of 10 to 50 kg of 4-tert-OP over a 12-year period. The Agency considers these calculations to be conservative and believes a 2.5% conversion rate of 4-tert-OPnEO to 4-tert-OP represents a reasonable worst-case release of 4-tert-OP.[4]

14. In its Opinion, the Agency assessed environmental risk by reference to a well-characterised endocrine disruptor with the same mode of action; ethinylestradiol (EE2), which is known to be more potent than the degradation product 4-tert-OP. Taking into account differences in potency, the Agency were of the opinion that the use applied for presents a potential risk to aquatic species via endocrine disruption if inadequate disposal of waste occurs. However, the Agency, concluded that the predicted environmental concentrations (PECs) provided are overestimated and these estimations are unlikely to be realistic if the OCs and RMMs are implemented and adhered to.

15. In their Application, the Applicant outlines RMMs and OCs in its chemical safety report which they already have in place, including updated guidelines to its downstream users in GB on the disposal of 4-tert-OPnEO containing liquid waste. These guidelines were updated in response to a condition in the EU REACH decision in March 2023 on a parallel application for authorisation for the same use within the EU.[5] The updated guidelines instruct downstream users to collect their liquid waste and adequately dispose of it as biohazardous waste.

16. The Applicant believes that the updated disposal guidelines in the safety data sheet (SDS) will be 100% effective in reducing emissions via liquid waste because disposal of biohazardous waste (via incineration) in the UK is already in place for downstream users, and so the collection of liquid waste for disposal via the biohazardous waste route should not induce significant costs on the downstream users. The Agency agreed that the updated disposal guidelines in the SDS will be effective in reducing 4-tert-OPnEO emissions if they are fully adhered to by downstream users. However, the Agency accepted that there is uncertainty surrounding the data used in reaching this conclusion as no downstream user survey was conducted for this Application.

17. The Applicant did not conduct a downstream user survey for this Application to assess how its downstream users in GB are disposing of waste containing 4-tert-OPnEO. Instead, the Applicant relied on the survey results from its EU REACH application, which received 31 responses with only one response from a UK

[4] This is based on the report: The Environmental Risk Evaluation Report: 4-tert-Octylphenol, available here: Water cover.qxd (publishing.service.gov.uk)

[5] The Commission decision report is available here: Commission Implementing Decision (20.3.2023) - Becton Dickinson (4-tert-OPnEO) (europa.eu)

based company. It is unclear whether the disposal methods used by this company are representative of GB based companies. Therefore, to improve the certainty of downstream users' liquid waste disposal compliance, I have included a recommendation in paragraph 5 for any possible review report.

18. The Agency proposed no additional conditions and no monitoring arrangements for the authorisation. I agree with the Agency on this.

19. Having evaluated the Agency's assessment, I agree with its conclusion that there is a potential risk to aquatic species through endocrine disruption, however as the exposure assessment is conservative, the actual release of 4-tert-OP to surface waters is likely to be markedly less than is modelled. I also agree with the Agency's conclusion that the OCs and RMMs will be effective in reducing the risk if these updated disposal guidelines are fully adhered to.

Socio-economic analysis

20. In its Opinion, the Agency concluded that the Applicant's socio-economic analysis was proportionate, transparent, and well complemented by qualitative information, and that the evidence in the Application is sufficient for the Agency to reach a definitive conclusion.

21. In its Opinion, the Agency assessed both the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. The Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting the authorisation are at least £1 million to £10 million. This figure accounts for avoided producer surplus loss.

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

    a. avoided costs to healthcare providers

    b. avoided delays in healthcare provision

    c. impacts of reduced market competition.

23. The Agency is confident that the socio-economic benefits are higher than the associated risks, therefore the granting of the authorisation would be of net benefit. I agree with its conclusions on the quantitative and qualitative benefits.

Conclusion on whether the benefits outweigh the risk

24. 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 Agency's satisfaction that the conservative assumptions made throughout the Application account for uncertainties in environmental risks

    b. the likely quantitative benefits in respect of avoided producer surplus loss, and avoided costs to downstream users

c. the likely significant qualitative benefits, in respect of avoided delays to healthcare and avoided negative impacts to the IVD market

d. the likelihood of low risk to aquatic species through endocrine disruption

Alternatives

25. 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 are technically and economically feasible for the Applicant by the sunset date.

26. In its Opinion, the Agency noted the Applicant's extensive search for alternative chemicals. The Applicant has stated that due to the number of IVD products in which 4-tert-OPnEO is used, and the different biochemistries required for these IVD products, it may not be possible to have one alternative for all IVD products. Initial studies based on a robust set of key criteria required for the IVD products identified four potential alternatives from a pool of 29 substances initially identified as potential alternatives. The Applicant is conducting validation studies with the two potential alternatives which have shown the most promise, however no alternatives have been found to be suitable for the Applicant's PoC testing kits. The Agency concluded that there were no alternatives that were technically or economically feasible for the Applicant prior to the sunset date.

27. Having evaluated the Agency's assessment, I agree with its conclusion and consider that the Applicant has discharged their burden of proof in demonstrating the 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. The Agency did not evaluate the risk of alternatives due to the alternatives not currently being technically feasible for the Applicant by the sunset date.

Review period

28. In its Opinion, the Agency recommend the review period referred to in Article 60(9)(e) of UK REACH should be set at 12 years from the sunset date (as requested by the Applicant).

29. The Applicant submitted a substitution plan in which they state that they can run two to three substitutions in parallel. The Agency calculated that a best-case scenario would mean the substitution plan could be completed in 10.5 years. The Applicant highlighted that this would mean some long-term stability studies for some IVD products could not be completed, and therefore requested 12 years as a more reasonable timeframe. The Agency concluded that the substitution plan is credible for the review period requested.

30. I agree with the Agency's conclusion on these points and its recommendation for a 12-year review period from the sunset date.

Conclusion

31. 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.

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

Marc Casale

Deputy Director, Chemicals, Pesticides and Hazardous Waste

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