Department for Environment Food & Rural Affairs

Authorisation Decision

by Robbie Moore, Parliamentary Under Secretary of State

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

Decision date: 3 July 2024

Application Ref: AFA018-01 and AFA018-02

UK REACH authorisation Numbers:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/06/0 [4-(1,1,3,3 tetramethylbutyl) phenol, ethoxylated]	Siemens Healthcare Diagnostics Products GmbH	**Use 1:** Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (4-tert-OPnEO) in *in-vitro* diagnostic (IVD) kit reagents on diagnostic analyser systems used in controlled settings by professional users such as hospitals and pharmacies.
UKREACH/24/06/1 [4-(1,1,3,3 tetramethylbutyl) phenol, ethoxylated]	Siemens Healthcare Diagnostics Products GmbH	**Use 2:** Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (4-tert-OPnEO) as a cleaning surfactant in IVD wash solutions on diagnostic analyser systems to ensure their continued accuracy in controlled settings by professional users such as hospitals and pharmacies.

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.
- The Application is made by Siemens Healthcare Diagnostics Products GmbH, Park View, Watchmoor Park, Camberley, Surrey, United Kingdom, GU15 3YL ('the Applicant').
- Article 127GA applied to the Application. The latest application date for 4-tert-OPnEO for these uses was therefore 30 June 2022.[2] The sunset date for these uses was 30 June 2022.
- On 24 June 2022 the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the professional use of 4-tert-OPnEO by professional users such as hospitals or commercial laboratories:

  Use 1: In IVD kit reagents on diagnostic analyser systems used in controlled settings by professional users such as hospitals and pharmacies; and

  Use 2: As a cleaning surfactant in IVD wash solutions on diagnostic analysers system to ensure their continued accuracy in controlled settings by professional users such as hospitals and pharmacies**.**
- On 13 October 2023 the Agency sent its opinions for Use 1 and Use 2 respectively ('the Agency Opinion for Use 1' and 'the Agency Opinion for Use 2' respectively, together 'the Agency Opinions') 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. Authorisations are granted to the Applicant in accordance with Article 60(4) of UK REACH for the following uses of 4-tert-OPnEO:

[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.

[2] This provided time for applicants to submit their application under UK REACH following the transition from EU REACH, where certain criteria were met.

a. Use 1: In IVD kit reagents on diagnostic analyser systems used in controlled settings by professional users such as hospitals and pharmacies; and

b. Use 2: As a cleaning surfactant in IVD wash solutions on diagnostic analysers system to ensure their continued accuracy in controlled settings by professional users such as hospitals and pharmacies**.**

3. Authorisation UKREACH/24/06/0 (Use 1) is time limited. This authorisation will cease to be valid and the time-limited review period will end on 31 December 2032 unless the authorisation holder submits a review report in accordance with Article 61(1) by 31 June 2031.

4. Authorisation UKREACH/24/06/1 (Use 2) is time limited. This authorisation will cease to be valid and the time-limited review period will end on 31 December 2025 unless the authorisation holder submits a review report in accordance with Article 61(1) by 31 June 2024.

5. The authorisations are 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 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]

6. The authorisations are not subject to any monitoring arrangements.

Background

7. This decision is made under Article 60(4) of UK REACH and 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).

   c. The Agency Opinions.

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.

[3] This is a reference to the chemical safety report submitted by Siemens on 24 June 2022 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).

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, authorisations 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 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

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 explained that, for Use 1, 1 million to 10 million litres of liquid waste is generated per year across all downstream users. For Use 2, this figure is 10 million to 100 million litres. The Applicant went on to explain that, for both uses, liquid waste from all instrument IVD kits is released to sewer for treatment at the local sewage treatment plants (STPs) where it is discharged to surface water.

14. The Applicant gave an estimated breakdown of the worst-case scenario releases over the review period up to the end of 2032, for Use 1, and the end of 2025, for Use 2. These were between 10 – 500 kg and 100 – 500 kg releases of 4-tert-OP respectively.

15. For Use 2, the Applicant conducted a survey of their downstream users in 2023, in which they gathered data relating to the number of products containing 4-tert-OPnEO that were still in use. The Agency has clarified that, based on the results of this survey together with the results of additional modelling, overall (annual) emissions for 2023 are expected to be approximately half of the original emissions stated above. This is due to the Applicant's ongoing replacement of analysers using 4-tert-OPnEO leading to a reduction in downstream user sites at which these uses take place from 77 to 36.

16. The Agency Opinions assessed environmental risk by reference to a well-characterised endocrine disruptor with the same mode of action; ethinylestradiol (EE2), which is more potent than the degradation product 4-tert-OP. For Use 1, on the basis of the comparison with EE2, the Agency concluded that the use applied for may present a potential risk via endocrine disruption, although the magnitude of risk is likely to be low. For Use 2, on the basis of the comparison with EE2, the Agency concluded that the risk to aquatic species through endocrine disruption cannot be excluded but is likely to be low.

17. The Applicant explained that it is not economically feasible or practical for downstream users to collect and incinerate the wastewater containing 4-tert-

OPnEO due to the very high volume of wastewater and the associated costs. The Applicant also explained that alternative methods of disposal, such as the separation of 4-tert-OPnEO from liquid waste, would not be technically and economically feasible.

18. The Agency Opinions agreed with the Applicant's explanation, and therefore concluded that, for both uses, the Applicant has demonstrated that the OCs and RMMs are appropriate and effective at limiting 4-tert-OPnEO emissions to the environment. The Agency also concluded that the implementation of additional RMMs and OCs would not be practical or reasonable given the volumes of liquid waste generated, the practicalities of liquid waste collection, transport and incineration and the proposed substitution plan. Therefore, the Agency did not propose any additional conditions or monitoring arrangements.

19. Having evaluated the Agency's assessment, I agree with its conclusion that the uses applied for will likely have no adverse environmental impacts in relation to endocrine disruption and that no additional conditions or monitoring arrangements are appropriate for the uses applied for.

Socio-economic analysis

20. The Agency Opinions concluded that the Applicant's socio-economic analysis is considered proportionate, and that the evidence in the Application is sufficient for the Agency to reach a definitive conclusion for both uses.

21. The Agency Opinions concluded that the Applicant has demonstrated that the socio-economic benefits of granting the authorisations are greater than £1 million for Use 1, and greater than £0.1 million for Use 2. These figures account for avoided costs to downstream users having to prematurely replace instruments as well as forgone returns to downstream users from other potential investments if authorisations were not granted.

22. The Agency concluded that many major benefits of continued use are not monetised for both uses. These qualitative benefits consist of:

    a. Avoided social cost of unemployment;

    b. Avoided producer surplus loss for the applicant;

    c. Avoided disruption to public health provision;

    d. Avoided impacts from reduced market competition.

23. Having evaluated the Agency's assessment, I agree with its conclusions on the quantified and non-quantified benefits for both uses.

Conclusion on whether the benefits outweigh the risk

24. For both uses, I consider that the Applicant has shown that the socio-economic benefits of granting the authorisations outweigh the risk to the environment because of:

    a. The likely quantitative benefits, in respect of avoided costs to downstream users;

    b. The likely significant qualitative benefits, in respect of avoided negative impacts to the IVD market; and

    c. The likelihood of low risk to aquatic species through endocrine disruption.

Alternatives

25. The Agency Opinions concluded 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. For Use 1, The Applicant initially listed key physicochemical properties of any potential replacement, including budget and resourcing considerations, before four surfactants were identified as potential alternatives.

27. For Use 2, The Applicant has two remaining wash solutions that contain 4-tert-OPnEO. These will be reformulated or phased out by the end of 2025, with a year-on-year decrease in volume up to that point. The products covered under this use are original equipment manufacturer (OEM) formulations. Therefore, the Applicant noted that the testing information of alternative wash solutions is proprietary, and it will be informed of a replacement once testing has been completed.

28. Having evaluated the Agency's assessment, I agree with their conclusion and consider that the Applicant has discharged their burden of proof in demonstrating the absence of suitable alternatives for both uses. 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 for either use due to the alternatives not currently being technically feasible for the Applicant by the sunset date.

Review period

29. The Agency Opinions recommended the review period referred to in Article 60(9)(e) of UK REACH should end on 31 December 2032 for Use 1 and 31 December 2025 for Use 2. These review periods were requested by the Applicant in order to achieve substitution of 4-tert-OPnEO from their IVD products.

30. The Applicant provided a clear substitution plan in their Application for each use:

a. Use 1: the Applicant currently has four products containing 4-tert-OPnEO due to be retired, and three products at the very early stages of substitution. The applicant estimates the investment costs of substitution to be between £10 million to £25 million.

b. Use 2: The Applicant is seeking an alternative wash solution that does not contain 4-tert-OPnEO and that meets several technical requirements. Furthermore, the Applicant is seeking alternatives that are unlikely to be subject to future restrictions or require authorisation under UK REACH, for both uses.

31. I agree with the Agency's conclusions on these points and its recommendations for the respective review periods until 31 December 2032 for Use 1, and until 31 December 2025 for Use 2.

Conclusion

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

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

Robbie Moore

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