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: 16 December 2022

Application Ref: 0181-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/22/06/0	DiaSorin Italia S.p.A.	Industrial use of 4-tert-OPnEO as a non-ionic surfactant, employed in the purification of antigens in in vitro diagnostics tests for infectious diseases, auto-immunity markers, bone metabolism, hepatitis and retrovirus, oncology and endocrinology.

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 was included in Annex XIV to Regulation (EC) No 1907/2006[2] ('EU REACH') because there is scientific evidence of probable serious effects to the environment from its endocrine-disrupting properties when it degrades.
- The sunset date for 4-tert-OPnEO for this use was 4 January 2021.

[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.
[2] References to Regulation (EC) No 1907/2006, referred to in this decision as EU REACH, are to that Regulation as it has effect in EU law.

- The application is made by: DiaSorin Italia S.p.A.[3] of Central Road, Dartford, Kent DA1 5LR ('the Applicant').
- On 8 May 2019, DiaSorin S.p.A. ('the EU REACH Applicant') made an application for authorisation ('the Original Application') to the European Chemicals Agency (ECHA) for the use of 4-tert-OPnEO as a non-ionic surfactant employed in the purification of antigens in in vitro diagnostics tests for infectious diseases, auto-immunity markers, bone metabolism, hepatitis and retrovirus, oncology and endocrinology.
- The technical function of 4-tert-OPnEO in the use is in cell lysis, removal of contaminants from cells and storage of antigens. The Applicant's final reagent kits are 4-tert-OPnEO-free, so there is no potential for emissions from the final products.
- The Original Application related to the use of 4-tert-OPnEO in respect of two sites: one in Saluggia, Italy, ('the Saluggia site') and one in Dartford, Great Britain ('the Dartford site').
- On 10 September 2020, 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 12 July 2022, the Applicant notified the Secretary of State of the Original Application in accordance with Article 127G of UK REACH.
- In reaching this decision I have considered the likely emissions to the environment and the likely socio-economic benefits in respect of the Applicant's site in Great Britain.

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 non-ionic surfactant, employed in the purification of antigens in in vitro diagnostics tests for infectious diseases, auto-immunity markers, bone metabolism, hepatitis and retrovirus, oncology and endocrinology.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at twelve years. The authorisation will cease to be valid on 4 January 2033 unless the authorisation holder has submitted a review report in accordance with Article 61(1) by 4 July 2031.

[3] Since the Original Application, DiaSorin S.p.A. (the EU REACH applicant) has changed its legal name and UK registration number to DiaSorin Italia S.p.A., BR024555 (transfer effective from 1 July 2022). 'DiaSorin Italia S.p.A. - UK Branch' is a UK permanent establishment of the Italian company DiaSorin Italia S.p.A.

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 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[4].

5. The following monitoring arrangements must be applied:

   a. The authorisation holder must measure the concentration of 4-tert-OPnEO and 4-tert-octylphenol (4-tert-OP[5]) in the wastewater prior to release to the local sewage treatment plant at the Dartford site.

   b. These measurements must be taken at least once every three months for each substance, with no more than three months between measurements, while the authorised use (buffer preparation and buffer application) takes place[6]. The first measurements for each substance must be taken within three months of the use first taking place.

   c. If any measurements show a significant change in the concentrations of either substance (e.g. due to changes or operational fluctuations in the process) compared to previous measurements, the authorisation holder must take additional measurements. Those additional measurements must be taken frequently enough to allow the authorisation holder to understand the reasons for the change and identify any necessary further steps to ensure compliance with Article 60(10) of UK REACH.

   d. When taking measurements, the authorisation holder must use an analytical method capable of adequately characterising 4-tert-OPnEO and 4-tert-OP at an appropriately low level of quantification, by reference to the level of anticipated emissions.

   e. The authorisation holder must record details of the sampling point, the analytical method(s) chosen, the reasons for choosing those analytical method(s), the concentrations detected and the corresponding environmental release values, as well as the contextual information associated with all measurements and any necessary further steps identified in accordance with subparagraph (c) to ensure compliance with Article 60(10) of UK REACH.

   f. The authorisation holder must make the information referred to in subparagraph (e) available to the UK REACH Agency (the Health and Safety Executive) on request.

[4] This is a reference to the chemical safety report dated 9 September 2020 submitted by DiaSorin S.p.A. on 10 September 2020 as part of the Original Application. The risk management measures and operational conditions are described in sections 7 (exposure assessment) and 8 (environmental releases and measures of risk management).
[5] 4-tert-OP is formed when 4-tert-OPnEO degrades in the environment.
[6] Buffer preparation and buffer application are the two environmental exposure scenarios presented by the applicant.

6. In the event that a review report is submitted in accordance with Article 61(1) it should include:

    a. The information referred to in paragraph 5(e) relating to the monitoring activities.

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 Original 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 RAC Opinion and the SEAC Opinion.

    d. That the Original Application was for two sites: the Saluggia site, and the Dartford site. The Original Application contained details on the Dartford site's RMMs and OCs including waste treatment via incineration, as well as expected emissions of 4-tert-OPnEO.

    e. Additional information provided by the Applicant to the Secretary of State, indicating the likely quantified benefits for Great Britain and confirming expected emissions of 4-tert-OPnEO at the Dartford site.

Reasons

9. In the Original Application, the EU REACH Applicant did not attempt to derive predicted no-effect concentrations (PNECs). The EU REACH 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 EU REACH. Therefore, the RAC Opinion concluded that for the purposes of the assessment of this application it was not possible to determine PNECs for the endocrine disrupting properties for the environment of 4-tert-OPnEO in accordance with Section 6.4 of Annex I to EU REACH.

10. In accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of that Regulation 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 I. Therefore, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

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 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 EU REACH Applicant 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 first wash of non-disposable contaminated glassware is collected for incineration. The subsequent glassware washes containing 4-tert-OPnEO are not collected for incineration.

13. RAC accepted the EU REACH Applicant's modelled worst-case estimate of emissions at the Dartford site, which would result in very low yearly emissions of 4-tert-OPnEO to the environment.

14. 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 subsequent glassware washes containing 4-tert-OPnEO at the Dartford site are likely to be very low. Having evaluated RAC's assessment, I conclude that releases to environmental compartments at the Dartford site have been prevented or minimised as far as technically and practically possible. In reaching this conclusion, I also note the Applicant's responses to my request for additional information which confirmed the expected emissions of 4-tert-OPnEO at the Dartford site.

15. RAC concluded that the EU REACH Applicant's RMMs and OCs are expected to be appropriate and effective in limiting the risk, provided that they are adhered to. Therefore, RAC did not propose any additional conditions. Based on the described RMMs and OCs, RAC concluded that the EU REACH Applicant has demonstrated 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 for both sites are appropriate. Therefore, RAC did not propose any monitoring arrangements but did recommend, in the event a review report was submitted, a monitoring programme to confirm the estimated releases.

16. Having evaluated RAC's assessment and the RMMs and OCs described in the Original Application, I agree that no additional conditions are required. In reaching this conclusion, I note that all of the RMMs and OCs referred to in the Original Application and RAC Opinion take place at the Dartford site in Great Britain.

Monitoring Arrangements

17. In its opinion, RAC noted that, ideally, the EU REACH Applicant would have presented measured data to corroborate the release estimates. Instead, the EU REACH Applicant provided release estimates based on experimental data of an analytical investigation. The EU REACH Applicant informed RAC that it is developing a method to detect 4-tert-OPnEO and to measure its

degradation products in releases. The EU REACH Applicant stated that it will use this method once validated to implement periodic monitoring. The authorisation holder should use this method to carry out its monitoring obligations under paragraph 5.

18. RAC considered that the EU REACH Applicant's release estimates are appropriate and effective in limiting risk to the environment. However, to address the uncertainty of the release estimates due to the absence of monitoring data, RAC recommended quarterly monitoring. RAC recommended the results of this monitoring should be included in any subsequent review report.

19. I conclude the monitoring recommended by RAC for the review report should be included as a monitoring arrangement. This will corroborate the exposure estimates and demonstrate the effectiveness of the OCs and RMMs in place, prior to the submission of any review report.

20. I also conclude that the authorisation holder should make the information collected from monitoring available to the UK REACH Agency on request. This information should also be provided to the UK REACH Agency in the event of a review report being submitted.

Socio-economic analysis

21. The SEAC Opinion concluded that SEAC has no substantial reservations on the quantitative and qualitative elements of the EU REACH Applicant's assessment of the socio-economic benefits and the risk to the environment associated with the continued use of 4-tert-OPnEO. These benefits included:

    a. avoided short term and medium-term profit losses aggregated for both sites;

    b. avoided job losses and avoided social costs of unemployment aggregated for both sites;

    c. avoided costs of waste disposal due to the premature return of working equipment; and

    d. avoided health impacts on patients through increased prices and disrupted availability of test kits.

22. Some of the quantified benefits in the Original Application had not been disaggregated by site. I therefore requested further information from the Applicant on the likely benefits to Great Britain. In response to my request, the Applicant provided estimated annual quantified benefits for the Dartford site only. These included the avoided short term and medium-term profit losses, and avoided social costs of unemployment with a total benefit value of tens of millions of pounds sterling. The Applicant confirmed that the costs associated with waste disposal were only relevant to the Saluggia site.

23. I have considered the Applicant's quantified costs, as well as the associated impacts on patient health, in making a decision on this application.

Conclusion on whether the benefits outweigh the risks

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

    a. The likely benefits such as avoided profit losses and avoided job losses in Great Britain.

    b. The likely avoided negative health impacts on some patients in Great Britain.

    c. The likelihood of very low emissions in Great Britain.

Alternatives

25. The SEAC Opinion concluded that no available alternative substances or technologies with the same function and a similar level of performance that are safer and economically feasible for the EU REACH Applicant would be available by the sunset date.

26. The EU REACH Applicant's assessment of alternative substances was desk based at the time the Original Application was submitted. The EU REACH Applicant had identified five alternative non-ionic and water-soluble surfactants but had not yet commenced testing these for their technical feasibility.

27. As the testing of alternative substances had not been conducted, SEAC was unable to assess the technical feasibility of alternative substances. Nevertheless, SEAC agreed with the EU REACH Applicant that, even if any of the identified alternatives was found to be technically feasible, the EU REACH Applicant would need time to implement it, including obtaining regulatory re-approval. Therefore, SEAC agreed with the EU REACH Applicant that no technically feasible alternatives would be available before the Sunset Date.

28. SEAC concluded that the EU REACH Applicant's approach overall was reasonable and the substitution plan credible and detailed and agreed with the EU REACH Applicant's steps and timelines needed to substitute 4-tert-OPnEO with an alternative surfactant.

29. Having evaluated SEAC's assessment, I agree with its conclusions 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 conclusion on the time it would take to implement a technically feasible substance. I consider SEAC's assessment to be applicable to Great Britain.

Review period

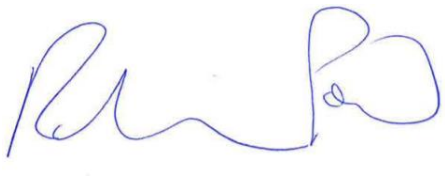
30. The SEAC Opinion recommended the review period referred to in Article 60(9)(e) of EU REACH should be set at 12 years. I agree with that recommendation and set the review period at 12 years under Article 60(9)(e) of UK REACH. In reaching this conclusion, I have considered SEAC's conclusion that the substitution plan proposed by the EU REACH Applicant

was credible and detailed and clearly outlined the steps and timelines needed to substitute 4-tert-OPnEO with an alternative surfactant. I consider that SEAC's assessment is applicable to Great Britain.

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 Articles 4A and 64(8) of UK REACH.



Rebecca Pow MP

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