Department for Environment Food & Rural Affairs

Authorisation Decision

by Jo Churchill MP

Parliamentary Under Secretary of State

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

Decision date: 16 November 2021

Application Ref: ID 0173-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/21/04/0	Siemens Healthcare Diagnostics Products Ltd	Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent in the production of bead components for in-vitro diagnostic kits for an immunoassay platform.

Preliminary Matters

- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated ('4-tert-OPnEO') is listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (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] because there is scientific evidence of probable serious effects to the environment from its endocrine-disrupting properties when it degrades.
- The application is made by Siemens Healthcare Diagnostics Products Ltd of Glyn Rhonwy, Llanberis, United Kingdom, LL55 4EL ('the Applicant').

[1] References to "EUR 2006/1907" 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" are to that Regulation as it has effect in EU law.

- On 20 May 2019, the Applicant made an application for authorisation ('the Original Application') to the European Chemicals Agency (ECHA) for the use of 4-tert-OPnEO as a detergent in the production of bead components for in-vitro diagnostic (IVD) kits for an immunoassay platform. The Original Application described additional risk management measures that were not in place when it was submitted ('additional RMMs').
- The additional RMMs were described as involving the incineration of more than 99% of the liquid waste contaminated with 4-tert-OPnEO, with the rest ('remaining wastewater') being collected and transported to an industrial wastewater treatment facility before being sent to an off-site municipal sewage treatment plant.
- On 15 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, together 'the ECHA Opinion') to the European Commission.
- On 20 May 2021, the Applicant notified the Secretary of State of the Original Application in accordance with Article 127G of EUR 2006/1907.
- On 20 July 2021, the Applicant confirmed to the Secretary of State that the additional RMMs had been implemented.
- In reaching this decision I have considered the likely emissions to the environment and the likely socio-economic benefits in respect of Great Britain.

Decision

1. This Decision is addressed to the Applicant.
2. An authorisation is granted in accordance with Article 60(4) of EUR 2006/1907 for the following use of 4-tert-OPnEO as set out in the table above titled 'UK REACH authorisation No.':

   > Use of 4-tert-OPnEO as a detergent in the production of bead components for in-vitro diagnostic kits for an immunoassay platform.

3. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at 9 years. The authorisation will cease to be valid on 4 January 2030 unless the authorisation holder submits a review report in accordance with Article 61(1) of EUR 2006/1907 by 4 July 2028.
4. The authorisation is subject to the following condition (as well as the requirement in Article 60(10) of EUR 2006/1907 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 EUR 2006/1907[3]

5. The following monitoring arrangement(s) must be applied:

a. The authorisation holder must measure the concentration of 4-tert-OPnEO and 4-tert-octylphenol (4-tert-OP) in remaining wastewater before it is released to the on-site holding tanks, and immediately before it is removed from the on-site holding tanks to be transported off-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 takes place. The first measurements for each substance must be taken within three months of the date of this decision.

c. If any measurements show a significant change in the concentrations of either substance compared to previous measurements (e.g. due to changes or operational fluctuations in the process), 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 EUR 2006/1907.

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

e. The authorisation holder must record the following in respect of all measurements: details of the sampling point(s), the analytical method(s) chosen, the reasons for choosing those analytical method(s), the concentrations detected and the corresponding environmental release values, and the associated contextual information. The authorisation holder must also record any necessary further steps identified in accordance with subparagraph (c) to ensure compliance with Article 60(10) of EUR 2006/1907.

f. The authorisation holder must also carry out a mass balance analysis to determine the effectiveness of the implemented RMMs (including the additional RMMs) and OCs, and to confirm whether emissions are reduced to as low a level as is technically and practically possible. The methodology and results of the calculations carried out for the purpose of

[3] This is a reference to the updated chemical safety report dated 16 September 2020, which replaced the chemical safety report submitted by the Applicant as part of the Original Application. The risk management measures and operational conditions are described in sections 9 (introduction) and 10 (risk characterisation related to combined exposure).

[4] 4-tert-OP is formed when 4-tert-OPnEO degrades in the environment.

this analysis, any assumptions made, and the corresponding environmental release values must be recorded. This mass balance analysis must be carried out within 3 months of the date of this decision.

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

6. In the event that a review report is submitted in accordance with article 61(1) of EUR 2006/1907 it should include:

a. The information referred to in paragraph 5(g) relating to the monitoring programme and mass balance analysis.

b. The authorisation holder's assessment of the feasibility of collecting the remaining wastewater for adequate treatment, and an explanation of any actions the authorisation holder has taken on the basis of that assessment.

Background

7. This decision is made under Article 64(8) of EUR 2006/1907.

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 EUR 2006/1907, and the aspects referred to in Article 60(5).

c. The RAC Opinion and the SEAC Opinion.

d. Further information provided by the Applicant confirming that the additional RMMs have been successfully implemented and are working as expected.

e. That the use applied for takes place in Llanberis, so all the data and analysis supplied in the Original Application and the ECHA Opinions is in relation to that site. Therefore, that information is all relevant to Great Britain.

Reasons

9. In the Original Application, the Applicant did not derive predicted no-effect concentrations (PNECs). The 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 Regulation (EC) No 1907/2006. 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 for 4-tert-OPnEO in accordance with Section 6.4 of Annex 1 to Regulation (EC) No 1907/2006.

10. In accordance with Article 60(3)(a) of EUR 2006/1907, 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.

11. An authorisation may only be granted under Article 60(4) of EUR 2006/1907 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 Applicant has 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 materials potentially in contact with 4-tert-OPnEO are collected and sent for incineration. For liquid wastes, RAC noted that the additional RMMs would involve the collection of more than 99% of liquid wastes contaminated with 4-tert-OPnEO for transportation to an incineration facility.

13. The Applicant explained to RAC that the remaining wastewater comes from cleaning the surface of the bead washing and coating equipment. The remaining wastewater is collected in on-site holding tanks and is then transferred by road to an industrial wastewater treatment facility before being sent to an off-site municipal sewage treatment plant (STP). The Applicant estimated that the capital costs of reducing the remaining emissions to zero would increase treatment costs by more than 20%. RAC recommended that in any review report the Applicant should further assess the feasibility of collecting the remaining wastewater for adequate treatment. I agree with this recommendation.

14. All release estimates in the Original Application and the ECHA Opinion were calculated on the basis that the additional RMMs would be implemented successfully. Before making a decision on this application, I confirmed with the Applicant that they have been successfully implemented and are working as expected. Having evaluated RAC's assessment, I agree with its conclusion that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. In reaching this conclusion, I note that all of the environmental releases referred to in the Original Application and RAC Opinion take place in Great Britain.

15. 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 the remaining wastewater are low.

Conditions

16. The RAC Opinion concluded that the RMMs and OCs as described in the Original Application (including the additional RMMs) are appropriate and therefore RAC did not propose any additional conditions. RAC concluded that releases to environmental compartments would be prevented or minimised as far as technically and practically possible, provided that the additional RMMs are implemented and adhered to. The Applicant has confirmed that they have been successfully implemented.

17. 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 would take place in Great Britain.

Monitoring arrangements

18. The RAC Opinion recommended that the Applicant should monitor, at least quarterly (during time of operation), the remaining wastewater prior to release to the on-site holding tanks and prior to its removal to the off-site municipal STP. RAC recommended that the Applicant should use an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. I agree with RAC that monitoring arrangements are required to ensure the effectiveness of the additional RMMs.

19. 4-tert-OPnEO is included in Annex 14 due to the impacts of 4-tert-OP, which forms when 4-tert-OPnEO degrades in the environment. I therefore take RAC's reference to 'principal degradation products' to mean '4-tert-OP'. I consider that it is appropriate to require the concentration of both 4-tert-OPnEO and 4-tert-OP in the remaining wastewater to be monitored to ensure the effectiveness of the additional RMMs.

20. The additional RMMs had not been implemented when the Original Application was submitted. Therefore, the RAC Opinion recommended that, after implementation of the additional RMMs, the Applicant should conduct a mass balance analysis. RAC recommended that the results of the mass balance analysis and the monitoring programme should be provided in any review report. RAC explained that these would confirm the predicted effectiveness of the additional RMMs.

21. The Applicant has since confirmed to me that the additional RMMs have been successfully implemented. Having evaluated RAC's assessment, I agree that the effectiveness of these RMMs should be monitored. I agree with RAC that this should be done through a one-off mass balance analysis and the monitoring programme referred to in paragraph 18.

22. I consider that the authorisation holder should make the information collected from the monitoring programme and mass balance analysis 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

23. The SEAC Opinion concluded that SEAC has no substantial reservations on the Applicant's assessment of the benefits and the risks to the environment associated with the continued use of 4-tert-OPnEO. Specific analysers are used to process the IVD kits that are the subject of this application. SEAC concluded that the quantified estimated benefits due to avoided profit losses, job losses and costs associated with the premature replacement of those analysers are in the range of millions to tens of millions of euros[5]. I agree with SEAC's conclusion on the quantified benefits and consider them to be applicable to the benefits and risks in respect of Great Britain.

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 significant quantified benefits such as avoided profit losses, job losses, and costs associated with the premature replacement of analysers; and

    b. The likely low level of emissions.

Alternatives

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

26. The analysis of alternatives was carried out by Siemens Healthineers (the Applicant's parent company). They focused their analysis of 4-tert-OPnEO-free alternatives on those IVD products within their wider product portfolio that are anticipated to have the longest remaining lifetime and that use the largest volumes of 4-tert-OPnEO. SEAC concluded that the search for alternatives carried out by Siemens Healthineers appeared to be comprehensive, and that the rationale for the approach they took is clearly explained. SEAC concluded that the methodology for identifying alternatives to the use of 4-tert-OPnEO, based on clearly described criteria, is adequate.

27. SEAC also found it credible that even if potential alternatives were identified prior to the sunset date, their successful implementation across the range of impacted IVD kits would take longer than the requested 9-year review period.

[5] The Original Application was submitted to ECHA while the UK was still an EU member state and therefore provided all monetary calculations in euros. On 12 November 2021, the Bank of England exchange rate was EUR/GBP = 0.8545

28. 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 assessment of the technical feasibility of alternative substances already on the market and I consider it to be applicable to Great Britain.

Review period

29. The SEAC Opinion recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 9 years. I agree with that recommendation, noting the typical life span of the analysers that use the IVD kits relevant to this application. SEAC found the Applicant's substitution plan, in which the use of 4-tert-OPnEO is expected to decline and eventually cease at the end of the requested 9-year review period, to be justified and credible. I agree with SEAC's assessment and consider it to be applicable to Great Britain.

Conclusion

30. 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.

31. Scottish and Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of EUR 2006/1907.

Jo Churchill MP

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