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: AFA017-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/04/0	Becton, Dickinson U.K. Limited	Use of an imported polymer containing UV-328 as an additive for UV stabilisation in the manufacture of a mechanical separator component used in Barricor™ blood collection tubes.

Preliminary Matters

- UV-328 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, UV-328 is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- UV-328 was included in Annex XIV because of its persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties (Article 57(d) and Article 57(e)).
- The application is made by: Becton, Dickinson U.K. Limited of 1030 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5TS ('the Applicant').

[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.

- Article 127GA of UK REACH applied to this application. The latest application date for UV-328 for this use was therefore extended to 30 June 2022.[2] The sunset date for this use was 27 November 2023.
- On 24 June 2022, the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the use of an imported polymer containing UV-328 as an additive for UV stabilisation in the manufacture of a mechanical separator component used in Barricor™ blood collection tubes.
- On 20 September 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. An authorisation is granted to the Applicant in accordance with Article 60(4) of UK REACH for the following use of UV-328:
    a. as an additive for UV stabilisation in the manufacture of a mechanical separator component used in Barricor™ blood collection tubes.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at four years from the sunset date. The authorisation will cease to be valid on 27 November 2027 unless the authorisation holder has submitted a review report in accordance with Article 61(1) by 27 May 2026.
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.[3]
5. The authorisation is not subject to any monitoring arrangements.

Background

6. This decision is made under Article 60(4) of UK REACH and having obtained the consent of Scottish and Welsh Ministers.
7. In making this decision, I have taken into account:

[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] The chemical safety report referenced in this provision of UK REACH was submitted by Becton, Dickinson U.K. Limited and is dated 20 June 2022. The RMMs and OCs are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure) of that document.

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 Opinion.

Reasons

8. In accordance with the criteria set out in Annex XIII of UK REACH, UV-328 is PBT and vPvB. Therefore, and in accordance with Article 60(3)(b) of UK REACH, this means that Article 60(2) of that Regulation does not apply to this Application. Therefore, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

9. 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 UV-328 and if there are no suitable alternative substances or technologies.

Risk to the environment

10. 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 PBT and vPvB properties of UV-328 for the environment.

11. As a PBT and vPvB substance, UV-328 poses a risk to the environment due to its persistence and ability to accumulate in living organisms.

12. In its Opinion, the Agency concluded that the OCs and RMMs described in the Application are appropriate and effective in limiting the risk to the environment. In reaching this decision, the Agency considered that the Applicant's assessment that environmental releases to water and soil will be zero is reasonable, given the OCs and RMMs and the properties of UV-328.

13. In its Opinion, the Agency considered whether the heating of the thermoplastic elastomer resin[4] could potentially indirectly release a relatively small quantity of airborne "hot rubber fume" into the working environment, at the point where each separator comes out of the injection moulding machine. The Agency concluded that any airborne releases of UV-328 relating to the heating of the TPE resin could find its way outside the factory via the general ventilation system for the factory, but that it is unlikely there will be measurable airborne releases of UV-328 to the general environment outside the factory. The Agency estimated on a worst-case basis that the quantities involved are not expected to exceed 200g per year. The Agency concluded

[4] UV-328 is imported by the Applicant having already been fully incorporated into a thermoplastic elastomer (TPE) resin (small, rubber-like pellets).

this will likely not be measurable in practice, and that the risk from the applied for use of UV-328 is considered negligible.

Risk to the humans via the environment

14. In its Opinion, the Agency concluded that the OCs and RMMs are appropriate and effective in limiting risk to the environment, therefore the Agency also concluded that human exposure via the environment is likely to be insignificant. The Agency therefore concluded that a quantitative risk assessment for humans via the environment was not relevant.

Risk to workers

15. In its Opinion, the Agency concluded that with respect to UV-328's T criterion (toxicity) relating to risk to human health, UV-328 has a no observed adverse effect level (NOAEL). The Agency therefore included the assessment of worker exposures in this Opinion.

16. UV-328 is considered toxic to humans as it may cause damage to organs (primarily the liver and kidneys) through prolonged or repeated exposure and can cause adverse effects upon repeated exposure in specific target organs.

17. In its Opinion, the Agency concluded that the OCs and RMMs described in the Application are appropriate and effective in limiting risk to workers. The Agency accepted all of the Applicant's exposure estimates and agreed that they are likely to be conservative in nature and probably represent the likely worst-case rather than the expected actual exposures to UV-328.

18. The Agency accepted the Applicant's final risk characterisation calculations for exposures to UV-328. The Applicant's final risk characterisation calculations were based on long-term systemic derived no-effect levels (DNELs) which were calculated by the Agency. The Agency concluded that as each risk characterisation ratio (RCR) was significantly below 1, with an overall combined RCR of 0.5, all worker exposures to UV-328 are being adequately controlled[5] with respect to the T criterion. The Agency consequently concluded that the monetised human health impacts are zero.

19. Having evaluated the Agency's assessment, I agree with the Agency's conclusions on the negligible risk to the environment and that exposures to workers are adequately controlled. Therefore, I agree with the Agency that the OCs and RMMs described in the Application are appropriate and effective in limiting the risk to the environment as well as to humans via the environment and to workers. The Agency did not recommend any additional conditions or monitoring arrangements and I agree with this conclusion.

[5] 'Adequately controlled' is a term typically used in applications, opinions and decisions in accordance with Article 60(2) in which the substance being applied for and decided on has a threshold. Whilst the T criterion for UV-328 has a NOAEL, Article 60(2) does not apply to this Application for reasons outlined in paragraph 8.

Socio-economic analysis

20. The Agency concluded that the Applicant's socio-economic analysis is based on a suitable general methodological approach, is proportionate, and the evidence and information included accounting for uncertainties in the Application sufficient for the Agency to reach a definitive conclusion. The Agency also concluded the non-use scenario is acceptable, such that it establishes the likely general situation for the Applicant in the event of not being granted an authorisation.

21. The socio-economic benefits of granting the authorisation were calculated by the Agency to be in the order of £1 million to £5 million. This figure accounts for avoided profit losses. Additional socio-economic benefits of granting an authorisation have been assessed qualitatively by the Agency but have not been monetised. These consist of avoided profit losses of the downstream users, and end users' healthcare benefits.

22. 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

23. The Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting an authorisation outweigh the risk to human health and to the environment.

24. The Agency concluded that the Applicant has demonstrated that environmental risk has been effectively and appropriately limited such that no negative impacts are foreseen from the intrinsic properties for which UV-328 is listed in Annex 14 of UK REACH, and that the Applicant has demonstrated that the risk to workers is adequately controlled.

25. I consider that the Applicant has shown that the socio-economic benefits of granting authorisation outweigh the risk to human health and the environment because of:

    a. The likely quantitative benefits in respect of avoided profit losses;

    b. The likely qualitative benefits in respect of avoided profit losses for the downstream users, and end users' healthcare benefits; and

    c. The risk from the applied for use of UV-328 is considered negligible.

Alternatives

26. The Agency concluded in its Opinion that there were no available alternative substances or technologies with the same function and similar level of performance that were technically and economically feasible for the Applicant by the sunset date.

27. The Applicant and its USA supplier of the thermoplastic elastomer raw material containing UV-328 worked together to identify potential alternatives and the Applicant conducted its own desk research, identifying 24 UV

absorbers from publicly available information. At the time of submitting its Application, the supplier had identified a single promising alternative and the Applicant was engaged in a validation process to confirm its feasibility. As this was expected to be completed only after the sunset date for UV-328, the identified alternative for use in the mechanical separator had therefore not yet been confirmed to be technically feasible. The Agency agreed that although there are other UV stabilisers/absorbers on the market, these would first need to be validated for use in the Applicant's products, and therefore agreed that there were no available alternatives before the sunset date.

28. In its Opinion, the Agency concluded that implementing the identified alternative would lead to an overall reduction of overall risk. The Agency noted that the alternative may have similar hazard properties to UV-328, however, the hazard profile has not been fully evaluated so cannot be confirmed and it is not currently subject to any regulatory measures. The Agency concluded that, should the alternative become subject to regulatory restrictions at a later stage, and even if it had the same hazard properties, it would similarly be expected to pose negligible risks.

29. Having evaluated the Agency's assessment, I agree with the conclusion that there were no available alternatives before the sunset date 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, and the Agency's assessment of whether these would result in a reduced risk to human health and the environment, taking into account the appropriateness and effectiveness of the RMMs.

Review period

30. In its Opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 4 years from the sunset date.

31. The Applicant's substitution plan corresponded with the requested review period which will enable the Applicant to complete validation testing of the identified alternative. The Agency concluded that the Applicant's substitution plan is based on logical stepwise testing of their product and the timings seem reasonable. The Agency also concluded that whilst substitution may be achieved sooner, a four-year review period allows for unexpected issues and also negates the need to apply for a precautionary review report almost immediately should a shorter review period be granted.

32. I agree with the Agency's recommendation for a 4-year review period from the sunset date.

Conclusion

33. For the reasons set out above I conclude that the socio-economic benefits outweigh the risk to human health for the use of UV-328 referred to in

paragraph 2 and that there are no suitable alternative substances or technologies.

34. 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