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: 15 October 2024

Application Ref: AFA015-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/23/0	Bonaprene Products Limited	Use of MOCA as a reactant in the manufacture of cast polyurethanes at an industrial site.

Preliminary Matters

- 2,2'-dichloro-4,4'-methylenedianiline (MOCA) 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, MOCA is subject to the authorisation requirement referred to in Article 56(1) of UK REACH.
- MOCA was included in Annex XIV because of its intrinsic carcinogenic properties (Article 57(a) of UK REACH).

[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.

- The application is made by: Bonaprene Products Limited, Clywedog Road South, Wrexham Industrial Estate, Wrexham, LL13 9XS (the ‘Applicant’).
- Article 127GA of UK REACH applied to this application. The latest application date for MOCA for this use was therefore extended to 30 June 2022.[2] The sunset date for this use was 30 June 2022.
- On 17 June 2022, the Applicant submitted an application for authorisation (the ‘Application’) to the Health and Safety Executive (the ‘Agency’) for the use of MOCA as a reactant in the manufacture of cast polyurethanes at an industrial site. On 11 October 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. Authorisation is granted to the Applicant in accordance with Article 60(4) of UK REACH for the following use of MOCA:
    a. As a reactant in the manufacture of cast polyurethanes (PU) at an industrial site.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at 7 years from the sunset date. The authorisation will cease to be valid on 30 June 2029 unless the authorisation holder submits a review report in accordance with Article 61(1) by 30 December 2027.
4. The authorisation is subject to the following conditions (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] subject to the condition specified in paragraph 4.b.
    b. Within 3 months of the date of this authorisation, the authorisation holder must review its personal protective equipment (PPE) management system, with assistance from an appropriately qualified Occupational Hygienist, and must implement any improvements to bring its processes into compliance with

[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 Bonaprene Products Limited on 17 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).

best practice guidance. The Agency must be notified with details of any improvements made within 1 month of their implementation.

5. The following monitoring arrangements must be applied:
   a. The authorisation holder must undertake annual monitoring for airborne MOCA in its premises.
   b. Subject to gaining consent from employees, the authorisation holder must continue to monitor personal exposure of employees with biomonitoring biannually via urinary MOCA testing and compile all exposure monitoring activities into a coherent annual monitoring strategy.
6. The Agency has set out recommendations for the authorisation holder in section 10 of its Opinion, should the authorisation holder submit a review report in accordance with Article 61(1) of UK REACH. These recommendations are not conditions of this authorisation or conditions for any future review report.

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's Opinion

Reasons

9. In its Opinion, the Agency confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of MOCA and therefore MOCA is a substance for which it is not possible to determine a threshold. Therefore, 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. Therefore, authorisation may only be granted on the basis of Article 60(4) of that Regulation.
10. 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 MOCA, and there are no suitable alternative substances or technologies.

Risk to human health

11. MOCA presents a risk to human health due to its carcinogenic properties.

12. In its Application, the Applicant stated that human exposure via the environment is negligible. The Applicant explained that there is no use of water in the manufacturing or cleaning process, and accordingly no potential for releases to water or wastewater. The Applicant considers that releases to soil are zero, as all contaminated materials are disposed of as hazardous waste using a licensed waste contractor.

13. 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, the properties of the substance, and the constraint that emissions from the finished article are outside of the scope of authorisation. The Agency noted, however, that there is no monitoring data to support the exposure assessment.

14. The Applicant has identified that releases to atmosphere are possible but stated that they would be very low due to the low vapour pressure of the melted MOCA and low dustiness of the pellets. The Agency agreed that there may be some particulate emissions to atmosphere via the local exhaust ventilation (LEV) system but agreed that the quantities involved are likely to be very low.

15. Having evaluated the Agency's assessment, I agree with its conclusion that the OCs and RMMs described in the Application are likely to be appropriate and effective in limiting exposure to humans via the environment provided they are adhered to.

16. Workers are directly exposed to MOCA via inhalation of vapour from molten MOCA and dust release from MOCA granules when performing tasks, which contributes to a cancer risk. The Applicant has no inhalation exposure data to demonstrate that the LEV controls are effective at reducing exposure to below the UK workplace exposure limit (WEL).

17. The Applicant's calculation of excess cancer risk is based on their biomonitoring data. The Applicant undertakes biological monitoring of workers' exposures at intervals of approximately six months. There were reported incidences of elevated biomonitoring results, which have been attributed by the Applicant to workers' skin exposure to MOCA, caused by deficiencies in the Applicant's PPE management process. These deficiencies will be addressed via conditions in paragraph 4.b above.

18. The Agency concluded based on the Applicant's biomonitoring results that worker exposure levels are well below the UK WEL and the Biological Monitoring Guidance Value (BMGV) for MOCA. The Agency noted however that as MOCA is a non-threshold carcinogen it is not possible to define this as an acceptable risk, but merely a well-controlled risk, as there are concerns that the OCs and RMMs are not robust and too much emphasis is placed on PPE.

19. The Agency concluded that the total monetised risk of continued use is estimated to be £55 to £78 over 12 years, calculated based on the willingness-to-pay (WTP) methodology.[4]

20. The primary engineering containment measures adopted by the Applicant include a mixture of fully contained process stages, predominantly contained processes with supplied LEV where containment is opened infrequently, and partially contained processes with supplied LEV for airborne MOCA exposure reduction.

21. Due to the absence of inhalation exposure data with respect to information provided by the Applicant relating to the LEV system, air monitoring and some of the OCs and RMMs, the Agency was not able to form an opinion on the efficiency of the existing engineering controls in use at the Applicant's site and their adequacy to minimise airborne exposure.

22. The Agency also highlighted deficiencies in the Applicant's PPE management processes, and the overreliance on PPE. In its Opinion, the Agency noted that this is a concern as the process equipment lacks automation and containment, the LEV system may not be as effective as the Applicant believes it to be.

23. The Agency explained that better contained material transfer and PU mixing equipment options are commercially available and being used by other MOCA cured PU manufacturers, and the Applicant's protective equipment programme and administrative control measures are not appropriately robust for handling non threshold carcinogens like MOCA. The Agency therefore concluded that the OCs and RMMs are not appropriate or effective in limiting the risk to workers.

24. Having evaluated the Agency's assessment, I agree with its conclusion that the OCs and RMMs described in the Application are not appropriate and effective in limiting the risks to workers as the engineering control measures, PPE management system, and the administrative controls employed by the Applicant are not appropriately robust to control exposure as effectively as they could.

25. The Agency has proposed additional conditions and monitoring arrangements, which should improve the data on worker exposure and result in improved OCs and RMMs that are appropriate and effective in limiting the risk to workers, provided that they are implemented and adhered to. I agree with the Agency on this matter.

26. The Agency's justification for recommending a condition requiring the Applicant to review their PPE management system (para 4.b) is based on their conclusion

[4] Monetary valuation of health impacts is undertaken using WTP values to assess the economic value of preventing specific health endpoints (intangible costs) and opportunity costing to account for the resources spent on medical treatment and health care (treatment costs) as well as for productivity losses and other non-healthcare related costs associated with specific health endpoints.

that the Applicant's reliance on PPE as an exposure control measure is likely to be high, and its use is not adequately controlled. This is based on: the conclusions drawn by the Applicant about the likelihood of elevated urinary MOCA levels in employee samples tested, the Applicant's description of the frequency of respiratory protective equipment (RPE) equipment checks (and decontamination procedures) coupled with the uncertainty surrounding the efficiency of airborne MOCA engineering controls, and the description provided for the segregation of MOCA contaminated PPE disposal and associated hygiene facilities.

27. I agree with the Agency, and I believe the inclusion of this condition will lead to improvements in the Applicant's OCs and RMMs, and will increase worker safety, as the Applicant must implement any improvements to bring its processes into compliance with best practice guidance.

28. The Agency justified their proposed monitoring arrangement for measuring airborne MOCA, highlighting that it will assist the Applicant in determining the efficacy of their current RMMs and help to underpin modelled exposure estimates provided with any review report. If the Applicant identifies a shortfall in the efficacy of their RMMs for controlling inhalation exposure, the process specific results can be used by the Applicant to make the most efficient changes to existing process equipment and/or working practices to attain a level of control in line with industry best practice. The Agency recommended that the Applicant engages the services of a qualified Occupational Hygienist to assist with this.

29. In its Opinion the Agency recommended biomonitoring as part of several recommendations for the authorisation holder. I consider making this a monitoring arrangement is justified as the Applicant has no inhalation exposure data to demonstrate that the LEV controls are effective at reducing exposure. The data generated by this monitoring arrangement will assist with estimating the proportion of total exposure likely to be due to dermal or oral exposure. This will inform the Applicant where improvements should be focused.

30. I agree with the Agency that the inclusion of the above monitoring arrangements (both airborne monitoring and regular biological monitoring) will ensure that the regular monitoring will continue for the full duration of the authorisation and will provide assurance that the OCs and RMMs, amended by the conditions of this authorisation, are appropriate and effective in limiting the risk to workers.

Socio-economic analysis

31. The socio-economic benefits of authorisation are based on the cost of the most likely non-use scenario (NUS) if the Applicant was not granted authorisation. The most likely NUS is that the Applicant would cease production and supply of MOCA-related products.

32. The expected socio-economic benefits of granting authorisation are estimated to be £574,000 over 12 years, consisting of avoided profit loss due to ceasing the use applied for and avoided social cost of unemployment.

33. The Agency concluded that the NUS is plausible and credible, establishing the likely consequences of authorisation not being granted. Overall, in its Opinion the Agency concluded that the Applicant's approach to assessing the socio-economic benefits to be based on an acceptable general methodological framework. Having evaluated the Agency's assessment, I agree with this conclusion.

Conclusion on whether the benefits outweigh the risk

34. The Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting authorisation (£574,000) are higher than the risks to human health (£55 to £78).[5] The risks to human health were calculated based on the Applicant's current OCs and RMMs, and they were not calculated based on any improvements to OCs and RMMs in light of any proposed conditions or monitoring arrangements. The introduction of conditions and monitoring arrangements would only serve to reduce exposures and risks further.

35. I consider that the Applicant has shown that the socio-economic benefits of granting authorisation outweigh the risks to human health because of:

    a. the likely benefits in respect of avoided profit losses and the avoided social cost of unemployment

    b. the likely risks from the applied for use of MOCA

Alternatives

36. 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 were technically and economically feasible for the Applicant by the sunset date.

37. In its Application, the Applicant drew heavily on its experience of PU production and from lessons learnt over a 20-year period of systematically reducing its use of MOCA in the products it makes (from 97% in 2001 to around 6% in 2021). In addition, the Applicant undertook a combination of desk-based research and experimental production to analyse alternative systems available and their strengths and weaknesses. The Applicant applied its understanding of the

[5] This assessment was calculated based on the benefits and risks over the 12-year review period requested by the Applicant, and the Agency have confirmed that calculating the benefits vs risks over the shorter 7-year review period recommended by the Agency would not have materially altered the analysis.

different systems and applications and utilised potential alternative curing agents or PU systems to target the testing of the different components it produces.

38. The Applicant tested a number of different PU systems designed to give hard, cured resins. Two key parameters were used when determining the success of the different systems that were investigated: the pot-life of the resin mixture in its liquid state, and the dynamic properties of the cured resins. None of the alternatives tested performed adequately and so the Applicant concluded that there are no technically feasible alternatives available.

39. Having evaluated the Agency's assessment, I agree with its conclusion that there were no available alternatives before the sunset date, and I 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 feasibility of alternative substances already on the market. The Agency did not assess the economic feasibility and the risk of alternatives due to the alternatives not being technically feasible for the Applicant by the sunset date.

Review period

40. In its Opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 7 years from the sunset date.

41. The Applicant initially sought a review period of 7 years, which it revised to 12 years after it submitted a subsequent socio-economic analysis. The Applicant feels it meets the criteria for a 12-year review period as the risks of continued use are very low and the benefits of continued use are very high, and neither of those is expected to change in the foreseeable future.

42. However, the Applicant did not submit a substitution plan as it has been unable to identify an alternative that performs to the same standard. The Applicant also did not set out timescales for the development of a suitable alternative. In addition, the Applicant did not provide information on the expected service life of the parts nor the service life of the machinery for which the parts are supplied. The Agency concluded that not having this information introduces a degree of uncertainty on the expected future requirement for such parts.

43. Whilst the Applicant made a case for a longer review period, the Agency's uncertainty around the future demand for MOCA-based parts, concerns around the control of exposures, lack of a substitution plan, and uncertainty surrounding the service life of the parts and the machinery are such that the Agency believes a 7-year review period is warranted.

44. I agree with the Agency's conclusions on these points and its recommendation for a 7-year review period from the sunset date.

Conclusion

45. For the reasons set out above I conclude that the socio-economic benefits outweigh the risk to human health for the use of MOCA referred to in paragraph 2 and that there are no suitable alternative substances or technologies.

46. 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