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: 31 July 2024

Application Ref: AFA019-01 & AFA019-02

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/09/0	LUC (UK) Limited	Use 1: Industrial use of 2,2'-dichloro-4,4'-methylenedianiline in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors.
UKREACH/24/09/1	LUC (UK) Limited	Use 2: Industrial use of 2,2'-dichloro-4,4'-methylenedianiline in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors.

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 that Regulation.

- MOCA was included in Annex XIV because of its intrinsic carcinogenic properties (Article 57(a)).
- The application is made by LUC (UK) Limited (the 'Applicant'), Goat Mill Industrial Park (East), Dowlais, Merthyr Tydfil, CF48 3TD.
- 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 both uses was 30 June 2022.
- On 29 June 2022, the Applicant submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency') for:
    a. the industrial use of MOCA as a chain extender and curing agent in the manufacturing of hot cast high-performance polyurethane products, specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors ('Use 1')
    b. the industrial use of MOCA as a chain extender and curing agent in the manufacturing of hot-cast high-performance polyurethane products, specifically for heavy duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors ('Use 2')
- On 10 August 2023, the Agency sent its opinions (the 'Opinion for Use 1' and the 'Opinion for Use 2' respectively, together the '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. In accordance with Article 60(4) of UK REACH, authorisation is granted to the Applicant as set out under the following authorisation numbers for the following uses:
    a. UKREACH/24/09/0 Industrial use of MOCA in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors (Use 1)

[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.

b. UKREACH/24/09/1 Industrial use of MOCA in the manufacture of high-performance polyurethanes specifically for heavy duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors (Use 2)

3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years from the sunset date for authorisation numbers UKREACH/24/09/0 and UKREACH/24/09/1 (Use 1 and Use 2). These will cease to be valid on 30 June 2034, unless a review report is submitted in accordance with Article 61(1) by 30 December 2032.

4. Authorisation for Use 1 and Use 2 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. Authorisation for Use 1 and Use 2 is subject to the following monitoring arrangements:

   a. The authorisation holder must undertake measurements of personal exposures to MOCA via the inhalation route. Measurements must be taken at least every 3 years. The record of these measurements must include the number of workers potentially exposed, and it must be supported by appropriate contextual information regarding descriptions of the work activities being undertaken during each monitoring period. An air sampling survey must be conducted whenever changes are made to the local exhaust ventilation (LEV) system (e.g. planned installation of filter module and subsequent rebalancing of the system) or any other containment controls

   b. Subject to gaining consent from employees, the authorisation holder must continue the regular biological monitoring programme to confirm the holistic effectiveness of the RMMs via all routes of exposure. Monitoring requirements should include production personnel, contract maintenance personnel, and employees who do not work directly with MOCA (as appropriate), with sampling being done at least annually at the authorisation holders site

6. In the event that a review report is submitted in accordance with Article 61(1) of UK REACH, it is recommended to include the results of the measurements

[3] This is a reference to the chemical safety report dated June 2022 (Updated July 2022 with redactions removed) submitted by the Applicant as part of the Application. The RMMs and OCs are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

referred to in points 5.a and b. This recommendation is not a condition of authorisation or a condition 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 Opinions

Reasons

9. In accordance with the criteria set out in Annex XIII of UK REACH, MOCA is carcinogenic. In the Agency Opinions, the Agency concluded 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, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

10. 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 if there are no suitable alternative substances or technologies.

Risk to human health

11. For both uses, workers are directly exposed to MOCA via inhalation of vapour from molten MOCA and dust release from MOCA granules when performing tasks as described in the Agency Opinion, which contribute to a cancer risk. Airborne exposure to MOCA, and the extremely low number of estimated statistical cancer cases over the review period requested, demonstrate that the risk associated with the exposure of workers to MOCA is low.

12. Some emission of particulate MOCA via the LEV system is possible. Although MOCA has a low volatility, some air emissions may occur when MOCA is melted. LEV is provided to minimise worker exposure, but there may be releases to the atmosphere. Uncertainties remain around the volatility of molten MOCA and the potential for dust release from granules.

13. In the Agency Opinions, the Agency noted that the measured values from the Applicant's occupational exposure monitoring programmes are below the UK workplace exposure limit for MOCA and the Biological Monitoring Guidance Value for both Use 1 and Use 2.

14. The Agency concluded in the Agency Opinions that the OCs and RMMs are appropriate and effective in limiting risk to human health, via the workplace, in respect of both Use 1 and Use 2.

15. The total level of indirect human exposure via the environment is very low. The Applicant states that releases to water at the site are 0% for both Use 1 and Use 2, as they prohibit the washing of empty vessels, and apply spill protocols to ensure that MOCA does not enter the drains. Given that Use 1 and 2 are dry processes, the Agency agreed with the Applicant's conclusion that there are unlikely to be direct releases to water or wastewater.

16. The Agency agreed with the Applicant's conclusion that there is no direct release of MOCA to soil for both Use 1 and Use 2 as all contaminated materials are incinerated by a licensed waste contractor.

17. The Agency agreed with the Applicant's conclusion that air releases of MOCA are very low. The Applicant is currently installing filters in the LEV system to remove particulates from the exhaust air.

18. The total monetised risk of continued use is estimated to be £95 to £159 over 12 years for Use 1, and £45 to £75 for Use 2. This is based on 68% (by tonnage) of MOCA use being Use 1 and 32% being Use 2.

19. Having evaluated the Agency's assessment, I agree with its conclusion that RMMs and OCs as described in the Agency's Opinions are appropriate and effective, for Use 1 and Use 2 provided they are adhered to.

20. The Agency's justification for proposing personal exposure monitoring arrangements (paragraph 5.a) is that the Applicant's inhalation exposure monitoring is insufficient to characterise exposure across all similar exposure groups, or to evaluate thoroughly the impact of changes made to the containment regime. However, the Agency concluded that the current OCs and RMMs are effective in limiting risks to workers, and as such the current data is acceptable.

21. Biomonitoring campaigns are performed yearly at LUC Group level (four European sites as well as the GB site with some level of rotation). Thus, at present the UK site may not monitor on an annual frequency. As a result, there is a shortfall of adequate annual biomonitoring occurring at the Applicant's UK site, as the results provided in the Application are LUC Group results.

22. The Agency is satisfied that the Applicant is currently undertaking a regular biological monitoring programme to confirm the holistic effectiveness of the RMMs via all routes of exposure monitoring. Therefore, including that monitoring arrangement within the authorisation should not result in unreasonable additional financial burden on the Applicant.

23. I agree with the Agency that the inclusion of monitoring arrangements for both Use 1 and Use 2 (both personal exposure and regular biological monitoring) will ensure that regular monitoring will continue for the full duration of authorisation and will provide assurance that the RMMs and OCs continue to remain appropriate and effective. Such ongoing regular monitoring represents good industrial practice.

Socio-economic analysis

24. The socio-economic benefits of authorisation for Use 1 and Use 2 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 relocate the entire UK production for Use 1 and Use 2 to its other facilities in Europe and close the UK facility, resulting in the redundancy of 13 employees.

25. In the Agency Opinions, the Agency assessed both the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. In its Opinions, the Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting authorisation are estimated to be £1.44 million over 12 years for Use 1, and £0.68 million for Use 2. For both uses, this consists of avoided producer surplus loss due to ceasing the use applied for, avoided decommissioning cost, and avoided social cost of unemployment.

26. The Agency concluded that the NUS is plausible and credible, establishing the likely consequences of authorisation not being granted. Overall, the Agency considers 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

27. The Agency concluded for Use 1 that the Applicant has demonstrated that the socio-economic benefits of granting an authorisation (£1.4 million) are higher than the risk to human health (£95 to £159).

28. The Agency concluded for Use 2 that the Applicant has demonstrated that the socio-economic benefits of granting an authorisation (£0.68 million) are higher than the risk to human health (£45 to £75).

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

    a. the likely benefits in light of avoided profit losses, avoided decommissioning cost, and avoided social costs of unemployment

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

Alternatives

30. In its Opinions, the Agency concluded that there were no available alternative substances or technologies with the same function and a similar level of performance that were technically feasible for the Applicant by the sunset date.

31. The Applicant took 15 possible alternatives forward for feasibility testing, which involved assessing against a set of primary, secondary and tertiary requirements. This allowed for a conclusion to be made as to whether the alternative was a suitable alternative to the current MOCA process. None of the 15 alternatives that underwent feasibility testing was considered to be technically feasible.

32. The Applicant also considered alternative technologies, including elastomers such as rubber, on a longlist during the early research and development stages. None of the alternative technologies considered met the minimum property requirements, and so were not considered as part of this application.

33. Having evaluated the Agency's assessment, I agree with the 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

34. In the Agency Opinions, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 12 years from the sunset date for each of Use 1 and Use 2.

35. The Agency is satisfied that the Applicant demonstrated that there are no technically suitable alternatives for these uses, considering the timeline for the proposed substitution plan to be reasonable. A shorter review period than requested would mean that the Applicant would have to either prepare and submit a review report sooner or cease the use sooner (and forego the socio-economic benefits of continued use) before substitution is complete. The

Agency considers it disproportionate to trigger these events in an attempt to avoid the low risks over the review period.

36. I agree with the Agency's conclusions on these points and its recommendation for a 12-year review period from the sunset date for each of Use 1 and Use 2.

Conclusion

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

38. 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