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: AFA016-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/03/0	Custom Moulded Polyurethane Limited	Industrial use of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) as a curing agent/chain extender in hot cast polyurethane elastomer production.

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 carcinogenicity (category 1B, 'may cause cancer').
- This application is made by: Custom Moulded Polyurethane Limited, of Unit 144E, Lydney Industrial Estate, Harbour Road, Lydney, Gloucestershire, GL15 4EJ ('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 MOCA for this use was therefore extended to 30 June 2022.[2] The sunset date for this use was 30 June 2022.
- On 20 June 2022, the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the industrial use of MOCA as a curing agent/chain extender in hot cast polyurethane elastomer production.
- On 18 August 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 MOCA:
    a. Industrial use as a curing agent/chain extender in hot cast polyurethane elastomer production.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years from the sunset date. The authorisation will cease to be valid on 30 June 2034 unless the authorisation holder submits a review report in accordance with Article 61(1) by 30 December 2032.
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 following monitoring arrangements must be applied:
    a. The authorisation holder must undertake at least annual personal inhalation exposure measurements in order to characterise exposures across all MOCA processing, equipment maintenance and cleaning activities. When the authorisation holder has generated at least three samples for each similar exposure group, and if these measurements

[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 Custom Moulded Polyurethane Limited on 20 June 2022 as part of the Application. The risk management measures and operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

are consistently below the Workplace Exposure Limit (WEL),[4] then frequency of testing should be reduced to once every three years, or to coincide with any changes the authorisation holder makes to either the process or exposure reduction equipment if this comes earlier.

b. Subject to gaining appropriate consent from employees, the authorisation holder must continue its annual biomonitoring programme to confirm the effectiveness of the RMMs via all routes of exposure. This must include incidentally exposed employees and ensure that activities characterised by the inhalation monitoring programme are also captured.

6. The Agency has set out recommendations for the authorisation holder in section 10 of the Agency Opinion, should the authorisation holder submit a review report in accordance with Article 61(1) of UK REACH. The Agency also recommended that the authorisation holder should include the results of the measurements referred to in paragraph 5.a. as well as any available data from 5.b. These recommendations are not conditions to 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 Opinion.

Reasons

9. In accordance with the criteria set out in Annex XIII of UK REACH, MOCA is carcinogenic. In the Agency 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 in accordance with Section 6.4 of Annex I of UK REACH.

10. Therefore, and in accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of UK REACH does not apply to this Application. Therefore, an authorisation may only be granted on the basis of Article 60(4) of UK REACH.

[4] The UK WEL for MOCA is 5 µg/m^3 TWA (time weighted average).

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 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

12. In its Application, the Applicant explained that MOCA is received into the company in sealed containers. Prior to use it is stored in a dedicated storage facility in sealed drums, in low dust pelletised form which releases no significant dust during handling and transfer. The material is transferred from the containers to a sealed system by vacuum transfer. Local Exhaust ventilation (LEV) is used at all points of the process from initial opening of the containers through to casting to minimise inhalation risks to workers. The LEV system extracts air from the rear of the building where the MOCA is used and ensures that any fugitive releases of MOCA into the air are not transferred to other parts of the factory.

13. The Agency concluded that the biological monitoring results provided a strong indication that the OCs and RMMs identified to address exposure (by all routes) are effective and provide assurance of low exposure across all routes (oral/dermal/inhalation), provided that they are followed correctly. In its Opinion, the Agency noted that the measured values from the Applicant's occupational exposure monitoring programmes are below the WEL for MOCA and the Biological Monitoring Guidance Value. However, the Agency concluded that there were too many uncertainties in the Applicant’s air measurement analysis to be able to come to any firm conclusion other than that the results are indicative of a low level of airborne MOCA in the workplace.

14. Additionally, the Agency noted that the Applicant has not undertaken any dermal exposure measurements and that there is a degree of uncertainty about whether the conclusion that worker exposure is likely to remain well controlled and that engineering controls are well maintained would apply to workers during equipment maintenance and cleaning, for example under breakdown conditions. While the Agency acknowledged that it would be impractical to expect that the Applicant could monitor unplanned breakdown maintenance events, the Agency concluded that there is scope for the Applicant to characterise exposure potential by conducting air sampling / biomonitoring concurrently with planned maintenance activities that involve the breaking of equipment containment. The Agency agreed this would be an acceptable compromise, and recommended monitoring arrangements which will address the uncertainties above.

15. The Applicant used modelled exposure concentrations to calculate excess lifetime cancer risk for each worker contribution scenario via inhalation and dermal exposure routes. The Agency then used these to estimate the excess cancer cases and monetised health risks, which the Agency calculated as £23 to £33 for exposed workers for the 12-year assessment period. The Agency

therefore concluded that the Applicant is reducing risks to workers by employing appropriate and effective OCs and RMMs to limit exposures to MOCA.

16. The Applicant has identified that the total level of human exposure via the environment is possible but would be negligible.

    a. The Applicant states that there is no release of MOCA to water at the site as they do not use of water as part of the process and there is no release to water directly or via drains. Given that the use applied for is a dry process, the Agency considers that there are unlikely to be direct releases to water or wastewater.

    b. There is no direct release of MOCA to soil as all contaminated materials are sent for disposal as hazardous waste by a licensed waste contractor. All solid waste is collected for off-site incineration. This position is accepted by the Agency.

    c. Air releases of MOCA are stated to be very low because of the low vapour pressure when it is melted and due to the low dustiness of the MOCA pellets. The Agency concluded that whilst the Applicant has not conducted any monitoring of stack emissions for MOCA, the Applicant's workplace air monitoring supports their analysis that emissions to the atmosphere are very low. Although MOCA has a low volatility, some air emissions may occur when MOCA is melted. However, the Agency agreed with the Applicant that whilst there may be some emissions to the atmosphere, the quantities involved are likely to be very low and are unlikely to be readily detectable.

17. The Applicant did not estimate the risk related to local and regional exposures to indirectly exposed workers and the general population because the Applicant expects such exposures to be minimal given the very low risks to directly exposed workers. The Agency agreed with the Applicant’s approach on this, therefore the Agency did not calculate any monetised health risks for humans via the environment and concluded that the OCs and RMMs are appropriate and effective in limiting risk to humans via the environment.

18. Having evaluated the Agency’s assessment, I agree with the Agency’s conclusion that the Applicant is reducing risks to workers by employing appropriate and effective OCs and RMMs to limit exposures to MOCA. I agree with the Agency’s recommended monitoring arrangements and conclude that both personal exposure and regular biological monitoring (subject to employee consent) will ensure that regular monitoring will continue for the full duration of the authorisation and will provide assurance during planned equipment maintenance and cleaning activities that the RMMs continue to remain appropriate and effective. I also agree with the Agency’s conclusion that the Applicant’s OCs and RMMs are appropriate and effective in limiting risk to humans via the environment.

Socio-economic analysis

19. 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 use before substitution is complete which would result in the loss of the vast majority of the Applicant's business and consequently closure of the company, resulting in the redundancy of eight employees.

20. In its Opinion, the Agency assessed both the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. The expected socio-economic benefits of granting an authorisation were calculated by the Agency to be at least £923,000 over 12 years. This is the avoided cost of closing the business and consists of avoided profit losses (£396,910), avoided social cost of unemployment (£615,697), minus the value of Applicant's assets that could be sold off (-£90,000).

21. 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 its conclusion on the quantified benefits.

Conclusion on whether the benefits outweigh the risk

22. The Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting an authorisation (£923,000) are higher than the risk to human health (£23 to £33).

23. 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 quantitative benefits in respect of avoided profit losses and the avoided social cost of unemployment; and

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

Alternatives

24. The Agency concluded in its Opinion that currently 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.

25. The Applicant took four possible alternatives forward for feasibility testing, which involved testing different polyurethane systems, as well as conducting tests involving the different end products varying from wheels and rollers to engine mounts and railway maintenance equipment, taking into consideration their varying technical requirements. This allowed for a conclusion to be made as to whether the alternative was a suitable alternative to the current MOCA process.

26. In the small number of cases where the alternative substances produced usable parts, the number of products produced with defects was too high. Therefore, the alternatives failed for technical and economic reasons. However, the tests have shown promising results which suggests some products (those with lower technical requirements) could be substituted sooner than the 12-year period. If a suitable replacement for MOCA was to become available, the Applicant could switch to it relatively quickly for some, but not all, of its products. Therefore, as discussed in paragraph 31 below, granting a shorter review period than the 12 years is not considered proportionate.

27. The Agency agreed with the Applicant's approach to assessing and shortlisting alternatives and concluded that none of the four alternatives were considered to be technically and/or economically feasible. Therefore, the Agency did not evaluate the risk of alternatives.

28. In its Application, the Applicant volunteered to provide the Agency with an update report on its search for alternatives every three years. The Agency recommended instead that five years would be more suitable, as this is approximately halfway through the recommended review period and because it is unlikely that the Applicant will find any alternatives before then because of the reasons outlined above. I agree that the Agency's recommendation is appropriate in the circumstances.

29. Having evaluated the Agency's assessment, I agree with its conclusion 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. The Agency did not evaluate the risk of alternatives due to the alternatives not being technically feasible for the Applicant by the sunset date.

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 12 years.

31. The Agency is satisfied that the Applicant demonstrated that there are no technically and/or economically suitable alternatives for the uses. A shorter review period than requested would likely mean that the Applicant would have to either prepare and submit an application sooner or cease the use sooner 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.

32. I agree with the Agency's conclusions on these points and its recommendation for a 12-year review period and agree with the Agency's recommendations for any future review report.

Conclusion

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