EUROPEAN
COMMISSION

Brussels, 15.11.2023
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COMMISSION IMPLEMENTING DECISION

of 15.11.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Limburgse Urethane Castings NV for certain uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

(Only the English text is authentic)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) 2,2'-dichloro-4,4'-methylenedianiline (MOCA) is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a) of that Regulation.

(2) On 20 May 2020, Limburgse Urethane Castings NV ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of MOCA. The uses for which authorisation was sought are 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') and 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 European Chemicals Agency sent the opinions on the application for authorisation for use 1[2] and use 2[3], adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the Agency, to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 10 August 2021, the Commission received the opinions.

(4) In its opinions, RAC confirmed that it is not possible to determine a derived no-effect level for the carcinogenic properties of MOCA in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore MOCA is a substance for

[1] OJ L 396, 30.12.2006, p. 1.

[2] https://echa.europa.eu/documents/10162/f7921b81-e27b-e5a5-36c9-e23bfb23f998

[3] https://echa.europa.eu/documents/10162/c22c1dd9-4b2a-e807-78cb-44818a08a5f6

which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to MOCA and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) In its opinions, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and to the members of the general population who could be potentially exposed to MOCA via the environment, arising from the use described in the application. However, RAC noted that the main uncertainty in the worker exposure assessment was related to the expected increased volumes of MOCA to be used in the future. Therefore, it recommended some monitoring arrangements aimed at ensuring that the exposure level will remain the same regardless of the increased volumes. Furthermore, RAC recommended the performance of a study on the feasibility of implementing the best available techniques (i.e. machine casting) in all casting lines to minimise workers' potential exposure to MOCA. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) In its opinions, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the socio-economic benefits and the risks to human health resulting from the continued uses of the substance. Taking into account SEAC's assessment, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the estimated monetised risk of cancer associated with the continued uses of MOCA, the estimated quantitatively assessed benefits due to avoided profit loss, relocation cost and job losses, the additional qualitatively assessed socio-economic benefits of the continued uses of that substance due to possible business rearrangement costs and impacts for the end user, the potential environmental impacts, as well as any relevant distributional impact, the Commission notes that the monetised benefits of continued uses of MOCA outweigh the monetised risk by a factor of at least 500 and concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of that substance outweigh the risk to human health or the environment arising from those uses.

(7) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required to submit a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible. Certain potential alternatives may provide the functionality but at some loss to performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(8) In its opinions, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the time of adoption of the opinions. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that alternative casting systems to MOCA exist and have been implemented in the Union. However, those systems have a lower performance and do

not achieve the required range of desired properties. Further research, performance testing and customer trials of alternatives are needed to achieve the high level of performance required by the applicant's customers. Therefore, the Commission considers that the identified alternatives cannot yet be considered technically feasible for the applicant. Consequently, the Commission agrees with SEAC's conclusion that there are no suitable alternatives for the applicant but concludes that suitable alternatives are available in the Union.

(9) In its opinions, SEAC concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and, taking into account the availability of suitable alternatives in the Union and the obligation to submit a substitution plan, considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(10) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of MOCA described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.

(11) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require additional exposure and emission information to be generated.

(12) SEAC recommended in its opinions that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 31 December 2030 for use 1 and at 31 December 2032 for use 2. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the socio-economic costs and benefits, the high customer requirements for the applicant's products, the ongoing substitution efforts, as well as the fact that an alternative for use 1 requires less time for market implementation than an alternative for use 2.

(13) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language(s) of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(14) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible, or the obligation of the employer

under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[4] to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7] and 98/24/EC[8], and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive 2010/75/EU[10] of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(16) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

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4 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

5 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

6 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

7 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

8 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

9 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

10 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

11 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

12 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) (EC No 202-918-9; CAS No 101-14-4):

Authorisation number	Authorised use
REACH/23/27/0	Industrial use in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors
REACH/23/27/1	Industrial use 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

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13].

Article 2

1. As regards the authorisation bearing number REACH/23/27/0, the review period shall expire on 31 December 2030.

   The authorisation shall cease to be valid on 31 December 2030 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2029.

2. As regards the authorisation bearing number REACH/23/27/1, the review period shall expire on 31 December 2032.

   The authorisation shall cease to be valid on 31 December 2032 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2031.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 9 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to MOCA. The measurements shall:

   (a) take place at least annually. The frequency of the measurements shall be sufficient to capture any potential increase in exposure of workers to MOCA;

   (a) be based on relevant standard methodologies or protocols;

   (b) ensure a sufficiently low limit of quantification;

[13] https://ec.europa.eu/docsroom/documents/50637

(c) comprise personal and static inhalation exposure sampling;

(d) be representative of all the tasks with possible exposure to MOCA, including maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers who are potentially exposed;

(e) be recorded so as to include contextual information about the tasks with possible exposure to MOCA.

3. The authorisation holder shall carry out a biomonitoring programme. The analysis shall be conducted with a sufficiently low limit of detection, and the samples collected with contextual information necessary to identify the relevant working contributing scenarios, risk management measures in place and changes in the process. The measurements shall be carried out at least twice per year and be based on samples collected at the end of a 5-day working week.

The authorisation holder can reduce the frequency of the biomonitoring measurements referred to in the first subparagraph, to once per year, if the level of MOCA detected is below the limit of detection for at least two consecutive measurements. Afterwards, the frequency shall be increased if the level of MOCA is detected again in a measurement.

4. The authorisation holder shall carry out a monitoring programme on the presence of MOCA on surfaces with the highest potential for dust formation, at least twice per year. The authorisation holder can reduce the frequency of the monitoring to once per year, under the same conditions as those referred to in paragraph 3, second subparagraph.

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2, 3, and 4 related contextual information to review, at least annually, the appropriateness and effectiveness of the operational conditions and risk management measures in place. If needed, the authorisation holder shall introduce measures to further reduce workplace exposure to MOCA in accordance with the hierarchy of control principles to a level as low as technically and practically possible.

6. The authorisation holder shall finalise by 15 November 2024, and afterwards when new information becomes available, a study to assess the feasibility of implementing machine casting in all casting lines and shall act in accordance with the outcome of that study.

7. The authorisation holder shall install filters or implement other air abatement techniques, ensuring a high abatement efficiency, on the local exhaust ventilation (LEV) systems at all sites and implement a regular cleaning and maintenance programme of all LEV systems and their filters or other air abatement techniques. These shall be followed by a measurement of emissions to validate the effectiveness of the applied technical improvements.

8. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2, 3 and 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraphs 5, 6 and 7, and shall make it available, upon request, to the competent authority of the Member State where the authorised uses take place.

9. The authorisation holder shall document the steps taken to substitute MOCA in accordance with the substitution plan, including information on any deviations from the initial substitution plan and information on any contingency measures taken, and shall make that documentation available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 4

Where the authorisation holder submits a review report, it shall include the information referred to in Article 3 (8) and (9).

Article 5

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised uses take place in an official language of that Member State.

Article 6

This Decision is addressed to Limburgse Urethane Castings NV, Slakweidestraat 18, B-3630, Maasmechelen, Belgium.

Done at Brussels, 15.11.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION