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 Courbis Synthèse and others for a use 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 5 August 2021, Courbis Synthèse, Annovi S.r.l., Dansk Elastomer A/S, Durlast S.r.l., Pieffe S.r.l., Policart S.r.l., R.B.M. Italia S.r.l., Tecnocaucho S.A., Tegea S.r.l., Optibelt Urethane Belting Ltd., Productos Salinas S.A. and V.M. SPA ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of MOCA. The use for which authorisation was sought is industrial use of MOCA in the manufacture of hot cast polyurethane products.

(3) The European Chemicals Agency sent the opinions[2] on the application 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 17 August 2022, the Commission received the opinions.

(4) In its opinion, 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 therefore MOCA is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3),

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

[2] https://echa.europa.eu/documents/10162/5587a9a1-0ee5-74e4-8895-ea0225a35751

point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to MOCA, and therefore an authorisation may only be granted to that substance on the basis of paragraph 4 of that Article.

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to workers and to members of the general population who could be potentially exposed to MOCA via the environment, arising from the use described in the application. RAC noted that in different sites the use of respiratory protective equipment is not fully in line with the hierarchy of control principles and that in five sites a ventilation system to remove the particulates before they are released to external air has not been installed. RAC therefore recommended specific conditions to improve risk management measures in place, also in view of the predicted increase in the volume of MOCA used. Moreover, in order to further improve the monitoring programmes and verify the effectiveness of the measures in place, RAC recommended monitoring arrangements. Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(6) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the risks to human health arising from the use of MOCA. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have demonstrated that the socio-economic benefits of the continued use of MOCA outweigh the risk to human health arising from that use.

(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 some 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 opinion, SEAC concluded that there were no suitable alternative substances or technologies available to the applicants by the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that alternative casting technologies to MOCA exist and have been implemented in the Union, however, those technologies do not allow achieving the high level of technical performance required in specific industrial applications by the applicants' customers, and acknowledges that further research, performance testing and customer trials of alternatives are still needed. Therefore, the Commission considers that the identified alternatives cannot yet be considered technically feasible for the applicants. Consequently, the Commission agrees with SEAC's conclusion that there are no suitable alternatives for the applicants, but concludes that suitable alternatives are available in the Union.

(9) In its opinion, SEAC concluded that the substitution plan submitted by the applicants 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 applicants have discharged their 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 use of MOCA described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the conditions set out in this Decision, are fully applied. Nevertheless, the Commission considers it appropriate to align the description of the authorised use with the information included in the application for authorisation as assessed in the opinions, to ensure that only the products listed in that application are covered by the authorisation.

(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 that additional exposure and emission information is generated.

(12) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set until 31 August 2028. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the risk of the continued use of MOCA and the related socio-economic costs and benefits, as well as the ongoing substitution efforts including the time needed to carry out extensive customer trials.

(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[3] to reduce the use of a carcinogen or mutagen at the place of work,

[3] 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).

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[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7] 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 [8] or Directive 2010/75/EU[9] 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[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with any 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,

HAS ADOPTED THIS DECISION:

Article 1

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

Authorisation	Authorisation holder	Authorised use

[4] 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).

[5] 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).

[6] 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).

[7] 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).

[8] 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).

[9] 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).

[10] 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).

[11] 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).

number		
REACH/23/28/0	Courbis Synthèse	Industrial use in the manufacture of the hot cast polyurethane products listed in the Annex.
REACH/23/28/1	Annovi S.r.l.	
REACH/23/28/2	Dansk Elastomer A/S	
REACH/23/28/3	Durlast S.r.l.	
REACH/23/28/4	Pieffe S.r.l	
REACH/23/28/5	Policart S.r.l.	
REACH/23/28/6	R.B.M. Italia S.r.l	
REACH/23/28/7	Tecno-Caucho S.A.	
REACH/23/28/8	Tegea S.r.l.	
REACH/23/28/9	Optibelt Urethane Belting Ltd	
REACH/23/28/10	Productos Salinas S.A.	
REACH/23/28/11	V.M. S.p.a.	

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], as well as to the conditions set out in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 18.

2. The authorisation holders 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;

[12] https://ec.europa.eu/docsroom/documents/51134

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

(c) ensure a sufficiently low limit of quantification;

(d) comprise personal and static inhalation exposure sampling;

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

(f) be recorded so as to include contextual information about the tasks performed during sampling.

3. The authorisation holders shall carry out a monitoring programme on the presence of MOCA on surfaces with the highest potential for dust formation and with higher frequency for hands contact, at least twice per year.

4. The authorisation holders shall carry out a monitoring programme measuring the emission of MOCA to air in all sites. The measurements shall:

(a) take place at least annually, and any time changes in the process are introduced;

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

(c) be representative of the operational conditions and risk management measures at the sites where MOCA is used;

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

5. The authorisation holders shall carry out a biomonitoring programme at the sites where MOCA is used. 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 holders 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.

6. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraphs 2 to 5 and related contextual information to confirm and review, at least annually, the effectiveness of operational conditions and risk management measures in place. If needed, the authorisation holders shall introduce measures to further reduce workplace exposure to MOCA and emissions to the environment to a level as low as technically and practically possible and in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC. Moreover, if needed, the authorisation holders shall update the assessment of the combined exposure for the different groups of workers and members of the general population via the environment.

7. The authorisation holders shall document and keep the information gathered by way of the monitoring programme referred to in paragraphs 2 to 5, including the

contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any measure taken in accordance with paragraph 6. The authorisation holders shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

8. The authorisation holders shall carry out a regular cleaning and maintenance programmes of the glove boxes, which shall include checking the structural integrity of the gloves.

9. The authorisation holders shall implement local exhaust ventilation systems (LEV) at all sites and a regular cleaning and maintenance programme of all LEV systems as well as ensure that appropriate filters or other air abatement techniques, ensuring a high abatement efficiency, are installed.

10. The authorisation holders shall ensure that workers perform the fit check or sealing test of their respiratory protective equipment before taking on relevant tasks and shall provide an appropriate training to perform that test.

11. The authorisation holders shall ensure that all the working clothes are disposable, or cleaned if not disposable, after being used.

12. The authorisation holders shall not carry out workers' rotation with the aim to reduce biomonitoring levels.

13. The authorisation holders shall ensure that workers use respiratory protective equipment in accordance with the hierarchy of control principles and as follows:

    (a) near the casting benches until a LEV system is implemented;

    (b) during curing or when opening the ovens after the curing process until all sites have closed ovens with suitable exhaust ventilation located inside;

    (c) during the casting step in the sites that do not have yet a LEV system in place until a LEV system is implemented.

    The authorisation holders may no longer require workers to use respiratory protective equipment, if the monitoring programmes carried out in accordance with paragraphs 2 and 5 demonstrate that there is no exposure and the implemented measures are effective.

14. As regards working contributing scenario 6, the authorisation holders shall ensure that all the sites have LEV systems in place during the casting step.

15. As regards the authorisation bearing numbers REACH/23/28/0 and REACH/23/28/4, the authorisation holders shall install glove boxes at all casting machines.

16. As regards the authorisation bearing numbers REACH/23/28/0, REACH/23/28/3 and REACH/23/28/11 the authorisation holders shall implement a LEV system at all the casting benches.

17. As regards the authorisation bearing numbers REACH/23/28/4, REACH/23/28/5, REACH/23/28/9 and REACH/23/28/11, the authorisation holders shall ensure that curing is done in closed ovens equipped with local extraction and that ovens are opened only after the vapours have been completely exhausted.

18. As regards the authorisation bearing number REACH/23/28/6, the authorisation holder shall finalise by 15 November 2024 and afterwards when new information becomes available, a study to assess the feasibility of installing a closed mixing

chamber and shall act in accordance with the outcome of that study. The results of that study and the action taken shall be made available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 31 August 2028.

2. The authorisation shall cease to be valid on 31 August 2028 with regard to any holder of the authorisation who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 28 February 2027.

Article 4

The following monitoring arrangements shall apply: the authorisation holders shall document the steps taken to substitute MOCA in accordance with the substitution plan, including information concerning any deviations from the initial substitution plan and any contingency measures taken and shall make that documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

Where an authorisation holder submits a review report, it shall include the information referred to in Article 2(7) and 2(18), as well as in Article 4.

Article 6

Upon request, the authorisation holders 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 States where the authorised use takes place in an official language of those Member States.

Article 7

This Decision is addressed to:

(1) Courbis Synthèse, 14 rue Marie Curie, BP 251 - 26 106 Romans CEDEX, France;

(2) Annovi S.r.l. Via Degli Edili 7, 41049, Sassuolo (MO), Italy;

(3) Dansk Elastomer A/S, Snedkervænget 2, 5560 Aarup, Denmark;

(4) Durlast S.r.l., Via Fratelli Cervi, 2, 20855 Lesmo (MB), Italy;

(5) Pieffe S.r.l., Via della Cartiera, 30 – 12045 Fossano (CN), Italy;

(6) Policart S.r.l., Via Po s/n – 21043 Castiglione Olona (VA), Italy;

(7) R.B.M. Italia S.r.l., Via Nazionale 48-52, 14011 Baldichieri d'Asti (AT), Italy;

(8) Tecno-Caucho S.A., c/industria Nº5 46930 Quart de Poblet (Valencia), Spain;

(9) Tegea S.r.l., Via Busca, 5/A, 12020 Tarantasca (CN), Italy;

(10) Optibelt Urethane Belting Ltd., IDA Business & Technology Park, Lisnenan, Letterkenny, Co. Donegal, F92 XH24, Ireland;

(11) Productos Salinas S.A., Polígono Landetxe, Barrio Barrondo, 12, 48480 Zaratamo, Spain;

(12) V.M. S.p.a, Viale Pordoi, 6/8, 41049 Sassuolo (MO), Italy.

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