EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 10.1.2020

granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Doosan Electro-Materials Luxembourg SARL and Doosan Energy Solution Kft)

(Only the English and Hungarian texts are 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) Chromium trioxide 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)(a) of that Regulation.

(2) On 18 May 2018, Doosan Electro-Materials Luxembourg SARL and Doosan Energy Solution Kft (together referred to as 'the applicants') submitted an application, in accordance with Article 62 of Regulation (EC) No 1907/2006, for authorisation for use of chromium trioxide in the industrial formulation of a chromium trioxide solution below 0.1 % weight by weight concentration for the passivation of copper foil used in the manufacture of lithium ion batteries for motorised vehicles.

(3) On 24 January 2019, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] on the application sent pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine a Derived No-Effect Level (DNEL) for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. Pursuant to Article 60(3)(a) of Regulation (EC) No 1907/2006, Article 60(2) of that Regulation does not apply to that substance, and therefore an authorisation may only be granted in accordance with Article 60(4) of Regulation (EC) 1907/2006.

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

[2] https://echa.europa.eu/documents/10162/44f7c3a1-4a4f-6b92-bdd8-66bb9b73c721

(5) In its opinion, RAC also concluded that the risk management measures and operational conditions described in the application are expected to be appropriate and effective in limiting the risk to workers and to members of the general population who could potentially be exposed to the substance through the environment, provided that they are implemented and adhered to. However, in order to improve the assessment of emissions and of workers' exposure, RAC recommended monitoring arrangements. Having evaluated RAC's assessment, the Commission agrees with the conclusions and recommendations made by RAC.

(6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of chromium trioxide covered by the application outweigh the risk to human health arising from that use. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.

(7) An alternative should be able to provide the level of technical performance functionally necessary for the use applied for to be considered technically feasible. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, the Commission should not consider a potential alternative technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers it must be possible to depart from this approach where justified by particular circumstances, including the specific function of the substance for the use applied for, the public interests at stake, or a low net balance of the socio-economic benefits and the risk to human health or the environment. The Commission also considers that no particular factors justify less strict technical feasibility requirements in this case. Where the Commission is able to conclude on lack of technically feasible alternatives to the substance, it is unnecessary to consider economic feasibility of substitution.

(8) In its opinion, SEAC also concluded that there are no suitable alternative substances or technologies. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the uses applied for and has discharged its burden of proof in demonstrating the absence of suitable alternatives.

(9) 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 chromium trioxide covered by the application, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006, are fully applied. However, for the sake of legal clarity, the description of the use authorised by this Decision should be expressed in a way that is consistent with the way terminology is used in Regulation (EC) No 1907/2006 and should therefore refer to the "production", not the "manufacture", of lithium ion batteries.

(10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more

robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional exposure and emission information.

(11) In its opinion, SEAC recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessements and, in particular, the conclusion that the risk management measures and operational conditions are expected to be appropriate and effective in limiting the risk to workers and to members of the general population, the uncertainties linked to the use, the very long investment cycle associated with the use and with the investment in the new plant, the fact that the active research and development efforts have not been able to identify any technically feasible alternative, the likelihood that substitution will not be possible within a shorter timeframe, the conclusion that the socio-economic benefits arising from the use would significantly outweigh the monetised risk to human health, as well as the expected considerable socio-economic benefits of the use.

(12) It is, therefore, appropriate to set a review period of 12 years from the date of adoption of this Decision.

(13) The language used to describe the risk management measures and operational conditions included in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the authorisation holders to submit, on 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 holders to ensure that the authorised use 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, it does not affect either the obligation of the authorisation holders to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible pursuant to Article 60(10) of Regulation (EC) No 1907/2006 or the obligation of the employer 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 in accordance with Article 4(1) of Directive 2004/37/EC of the European Parliament and of the Council[3], or to prevent and reduce exposure in accordance with Article 5 of that Directive. This Decision also 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], 98/24/EC[7] and Directive 2004/37/EC, as well as any national

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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).

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).

binding occupational limit values which may be stricter than the applicable Union limit values.

(15) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], 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 other emission limit values or environmental quality standards under 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 for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/20/13/0	Doosan Electro-Materials Luxembourg SARL	Use in industrial formulation of a chromium trioxide solution below 0.1 % weight by weight concentration for the passivation of copper foil used in the production of lithium ion batteries (LiB) for motorised vehicles
REACH/20/13/1	Doosan Energy Solution Kft	

The authorisation is granted subject to the full application of the risk management measures and operational conditions described in the chemical safety report[12].

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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).

12 https://ec.europa.eu/docsroom/documents/34024

Article 2

1. The review period shall expire on 10 January 2032.

2. The authorisation shall cease to be valid on 10 January 2032 with respect 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 10 July 2030.

Article 3

1. The monitoring arrangements specified in paragraphs 2 to 7 shall apply.

2. The authorisation holders shall implement the following monitoring programmes for chromium (VI):

   (a) occupational exposure measurements. These measurements shall:

      (i) be conducted at least annually. The first measurement shall be conducted, without undue delay, after commissioning and start-up of each plant where the authorised use takes place;

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

      (iii) comprise both static and personal inhalation exposure sampling;

      (iv) be representative of the range of tasks undertaken where exposure to chromium (VI) is possible, including tasks involving maintenance workers, and representative of the operational conditions and risk management measures typical for each of those tasks and of the number of workers potentially exposed;

      (v) include contextual information about the tasks with possible exposure to chromium (VI).

   (b) measurements of emissions to wastewater and air from local exhaust ventilation. These measurements shall:

      (i) be conducted at least annually. The first measurement shall be conducted, without undue delay, after commissioning and start-up of each plant where the authorised use takes place;

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

      (iii) be representative of the operational conditions and risk management measures used at each plant where the authorised use takes place.

3. The authorisation holders shall use the information gathered from the measurements conducted under paragraph 2 and the related contextual information in order to confirm the effectiveness of the risk management measures and operational conditions as well as to carry out a review to check whether the risk management measures and operational conditions remain effective. If needed, the authorisation holders shall introduce risk management measures or operational conditions to further reduce workers' exposure to chromium (VI), and emissions of chromium (VI) to the environment, to as low a level as is technically and practically feasible.

4. The authorisation holders shall ensure that the application of the risk management measures at their plants is in accordance with the hierarchy of control provisions set out in Article 5 of Directive 2004/37/EC.

5. The authorisation holders shall document the information obtained from the monitoring programmes referred to in paragraph 2, including the contextual information associated with each set of measurements, and the outcome and conclusions of the reviews carried out, and any action taken, in accordance with paragraph 3. The authorisation holders shall keep that information and make it available, upon request, to the competent authority of each Member State where the authorised use takes place.

6. The authorisation holders may reduce the frequency of the measurements required by paragraph 2 for each plant where the authorised use takes place once they can clearly demonstrate to the competent authority of the Member State where that use takes place that exposure to humans and emissions to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions function appropriately.

7. The authorisation holders shall include the information documented in accordance with paragraph 5 in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 4

Upon request, the authorisation holders shall submit a brief summary of the applicable risk management measures and operational conditions to the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 5

This Decision is addressed to:

1. Doosan Electro-Materials Luxembourg SARL, 19 Rue de Bitbourg, L 1273 Luxembourg, Luxembourg;

2. Doosan Energy Solution Kft, Váci út 76, HU1133 Budapest, Hungary.

Done at Brussels, 10.1.2020

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION