EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 6.3.2019

granting an authorisation for certain uses of sodium chromate and potassium chromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Saes Getters S.p.A.)

(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) Sodium chromate and potassium chromate are listed in Annex XIV to Regulation (EC) No 1907/2006 and are therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 13 April 2017, Saes Getters S.p.A. ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for use of sodium chromate and potassium chromate in the fabrication of alkali metal dispensers for production of photocathodes ('use 1') and use of alkali metal dispensers containing sodium chromate and potassium chromate for production of photocathodes ('use 2'). In order to align the wording of the uses with the terminology of Regulation (EC) No 1907/2006, use 1 should be referred to as the use of sodium chromate and potassium chromate "in the formulation of a mixture and filling of that mixture into alkali metal dispensers for the production of photocathodes" and use 2 should be referred to as the use of sodium chromate and potassium chromate "in alkali metal dispensers in the production of photocathodes".

(3) On 25 January 2018, 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 pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) In its opinions, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic and mutagenic properties of sodium chromate and potassium chromate in accordance with Section 6.4 of Annex I to Regulation (EC) No

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

[2] https://echa.europa.eu/documents/10162/905b7988-94cb-3ded-46c0-5c755cccf132 https://echa.europa.eu/documents/10162/1676ed2c-3dfc-0407-b863-132e770d7cc0

1907/2006 and therefore sodium chromate and potassium chromate are non-threshold substances for the purposes of Article 60(3)(a) of that Regulation. In accordance with that Article, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to those substances, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

(5) In its opinions, RAC concluded, for both uses of sodium chromate and potassium chromate, that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and to the general population that could potentially be exposed via the environment. However since some tasks and parts of the process with a potential for worker exposure to powdered form of chromates remain in use 1, RAC has recommended further risk management measures as a condition for authorisation for that use.

(6) In its opinions, SEAC concluded that the overall socio-economic benefits arising from the two uses of sodium chromate and potassium chromate applied for outweigh the risk to human health and the environment arising from those uses and that there are no suitable alternative substances or technologies for the applicant. The Commission, having evaluated RAC's and SEAC's assessments, concurs with this conclusion.

(7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of sodium chromate and potassium chromate applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report[3], as well as the conditions set out in this Decision, are fully applied.

(8) In its opinions, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years for both uses of sodium chromate and potassium chromate applied for. The Commission takes into account the relevant elements from RAC's and SEAC's assessments and, in particular, that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the conclusion that the benefits of continued use substantially outweigh the risk, the time necessary to develop and implement an alternative, including the time needed for qualification by the applicant's customers, and the likelihood that substitution would not be possible within shorter timelines. Based on these elements, the Commission concurs with SEAC's recommendation.

(9) Therefore, it is appropriate that, as regards the uses of sodium chromate and potassium chromate applied for, the review period be set at seven years.

(10) Given that the applicant submitted its application for authorisation after the latest application date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 and that the sunset date set out in Annex XIV to that Regulation has already passed at the time of the adoption of this Decision, it is appropriate to set the date of adoption of this Decision as the starting point for the review period.

(11) The language used for the description of 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 holder to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.

[3] http://ec.europa.eu/docsroom/documents/27908

(12) This Decision does not affect the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect the obligation of the authorisation holder 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 and 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[4], or to prevent and reduce exposure in accordance with Article 5 of that Directive. Furthermore, this Decision is without prejudice to the application of the 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], 98/24/EC[8] and Directive 2004/37/EC.

(13) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC[9] and 2010/75/EU[10] of the European Parliament and of the Council, as well as with emission limit values set to achieve compliance with the environmental quality standards established both by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] and in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.

(14) The measures provided for in this Decision are in accordance with the opinion of the Committee established under 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 granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of sodium chromate (EC No 231-889-5; CAS No 7775-11-3) and potassium chromate (EC No 232-140-5; CAS No 7789-00-6), provided that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, as well as the conditions laid down in Article 2 of this Decision are fully applied:

Authorisation number	Authorised use
REACH/19/14/0	Use of sodium chromate in the formulation of a mixture and filling of that mixture into alkali metal dispensers for the production of photocathodes
REACH/19/14/1	Use of potassium chromate in the formulation of a mixture and filling of that mixture into alkali metal dispensers for the production of photocathodes
REACH/19/14/2	Use of sodium chromate in alkali metal dispensers in the production of photocathodes
REACH/19/14/3	Use of potassium chromate in alkali metal dispensers in the production of photocathodes

Article 2

The authorisation for the uses bearing authorisation numbers REACH/19/14/0 and REACH/19/14/1 shall be subject to the following conditions:

(a) on the basis of the results of the air monitoring already performed, the authorisation holder shall, without undue delay, review the risk management measures in place and ensure that potential for exposure resulting from the feeding and operation of the fabrication (wiring) machine, from the application of terminals to the alkali metal dispensers, and from cleaning/maintenance operations is minimised by the risk management measures which shall be applied in accordance with the principles of the hierarchy of control;

(b) the authorisation holder shall continue to perform biomonitoring of workers with possible exposure to chromium(VI) by measuring chromium values in urine.

The authorisation holder shall use the information gathered in the measurements referred to in point (b) of the first paragraph to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate to further reduce exposure of workers to chromium (VI).

The results of the measurements referred to in point (b) of the first paragraph with the corresponding contextual information, as well as the outcome and conclusions of the review and any actions taken under the second paragraph shall be documented and, upon request, submitted to the competent authority of the Member State where the authorised use takes place.

Article 3

1. As regards the authorised uses of sodium chromate and potassium chromate, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 6 March 2026.

2. The authorisation shall cease to be valid on 6 March 2026 in case a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 6 September 2024 unless a decision to withdraw the authorisation is adopted earlier pursuant to paragraph 3 of Article 61 of that Regulation.

Article 4

The results of the measurements referred to in point (b) of the first paragraph of Article 2 shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006, together with the corresponding contextual information and the outcome and conclusions of the review, and any actions taken under the second paragraph of Article 2.

Article 5

The authorisation holder shall submit, upon request, to the competent authority of the Member State where the authorised use takes place a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report in an official language of that Member State.

Article 6

This Decision is addressed to Saes Getters S.p.A., Viale Italia 77, 20020, Lainate (MI), Italy.

Done at Brussels, 6.3.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION