EUROPEAN
COMMISSION

Brussels, 26.8.2022
C(2022) 6036 final

COMMISSION IMPLEMENTING DECISION

of 26.8.2022

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Ariston Thermo SpA. for a use of sodium chromate

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 26.8.2022

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Ariston Thermo SpA. for a use of sodium chromate

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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 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 February 2019, Ariston Thermo SpA. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of sodium chromate. The use for which authorisation was sought is as an anticorrosion agent of the carbon steel in the sealed circuit of gas absorption appliances up to 0,70 % by weight (as hexavalent chromium (Cr(VI)) in the refrigerant solution.

(3) On 26 June 2020, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine a derived no-effect level for the carcinogenicity properties of sodium chromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore sodium chromate is a substance for 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 sodium chromate and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

---

1 OJ L 396, 30.12.2006, p. 1.

2 https://echa.europa.eu/documents/10162/2c6232e9-2c66-7413-15bb-f97901c35ac9

(5) RAC concluded that the risk management measures and operational conditions described in the application, and further detailed by the applicant at RAC's request, are expected to be appropriate and effective to limit the risk to workers and to members of the general population via the environment posed by the use of sodium chromate described in the application. However, RAC recommended imposing monitoring arrangements in order to address residual uncertainties and provide information on the trends in exposure and emissions during the authorisation period. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and the qualitative elements of the applicant's assessment of the socio-economic benefits and the monetised risks to human health and the environment associated with the future use of sodium chromate. Taking into account SEAC's assessments, RAC's conclusion that the risk management measures and operational conditions are expected to be appropriate and effective to limit the risk, the estimated excess monetised risk to workers and the general population of a few euros per year, the estimated monetised socio-economic benefits of several million euros per year due to avoided societal impacts in the form of avoided CO_2 emissions, secured energy savings and avoided profit losses, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the future use of the substance outweigh the risk to human health and the environment 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, an authorisation may be granted if the applicant for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible.

(8) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available at the time of adoption of its opinion. The Commission, having evaluated the SEAC assessment and all relevant information available, acknowledges that none of the shortlisted alternative substances provides the required corrosion inhibition, nor are the identified alternative technologies applicable for retrofit in high or medium temperature sectors, nor do they achieve the necessary levels of efficiency, energy consumption and running costs of gas absorption heat pumps. Thus, the Commission considers that the identified alternative substances and technologies do not allow the functionality needed for the use applied for. However, the Commission notes that, as reflected in RAC's and SEAC's opinions, the content of the application refers to gas absorption heat pumps only and thus the analysis of alternatives is also limited to those gas absorption heat pumps. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant as regards gas absorption heat pumps only, and considers it necessary to limit the scope of the use accordingly from 'gas absorption appliances' to 'gas absorption heat pumps' only.

(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 sodium chromate described in the application, as limited by this Decision, provided that the risk management measures and operational conditions described in the chemical safety report, and further detailed by the applicant at RAC's request, are fully applied.

(10) 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 the existence of 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 base in the future. Hence, it is appropriate to require additional exposure and emission information to be generated.

(11) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the conclusion that the risk management measures and operational conditions are expected to be effective in limiting the risk to workers and to members of the general population via the environment, the applicant's planned research and development activities, the applicant's search for alternatives, including literature review and patent search, the likelihood that substitution will not be possible within shorter timeline, as well as the conclusion that the socio-economic benefits of the use applied for significantly outweigh the risk.

(12) The language used to describe the risk management measures and operational conditions 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 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.

(13) Directive 2011/65/EU of the European Parliament and of the Council[3] restricts certain hazardous substances in electrical and electronic equipment (EEE), including Cr(VI). This Decision is without prejudice to any obligation to comply with that Directive. Gas absorption heat pumps, which are EEE and contain Cr(VI), may only be placed on the market if they are not covered by Directive 2011/65/EU or are subject of a time-limited exemption from the substance restriction pursuant to that Directive.

(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 Articles 4(1) and 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

[3] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

[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).

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 Directive 2004/37/EC, or any national 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 or other requirements 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 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 for the following use of sodium chromate (EC No 231-889-5; CAS No 7775-11-3):

Authorisation number	Authorised use
REACH/22/26/0	As an anticorrosion agent of the carbon steel in sealed circuit of gas absorption heat pumps up to 0,70 % by weight (as Cr(VI)) in the refrigerant solution

An authorisation is not granted for the use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0,70% by weight (as Cr(VI)) in the refrigerant solution other than heat pumps.

---

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 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).

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

Article 2

The review period shall expire on 26 August 2034.

The authorisation shall cease to be valid on 26 August 2034 if the review report has not been submitted by 26 February 2033.

Article 3

1. The monitoring arrangements referred to in paragraphs 2 to 6 shall apply.

2. The authorisation holder shall implement the following monitoring programmes for Cr(VI):

   (a) occupational inhalation exposure measurements. Those measurements shall:

      (i) be conducted at least annually. The first measurement in the new installation shall be performed without delay and at the latest 1 month after the start of the use of sodium chromate;

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

      (iii) ensure a sufficiently low limit of quantification;

      (iv) comprise static and personal inhalation exposure sampling;

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

      (vi) be recorded as to include contextual information about the tasks with possible exposure to Cr(VI).

   (b) measurements of emissions to wastewater and air. Those measurements shall:

      (i) be conducted at least annually. The first measurement in the new installation shall be performed without delay and at the latest 1 month after the start of the use of sodium chromate;

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

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

      (iv) ensure a sufficiently low limit of quantification;

      (v) be recorded so as to include contextual information associated with each of the measurements.

3. The authorisation holder shall use the information gathered via the measurements referred to in paragraph 2 and related contextual information to confirm and regularly review, at least annually, the effectiveness of the risk management measures and operational conditions in place and, if needed, to introduce measures to

[12] https://ec.europa.eu/docsroom/documents/42061

further reduce workplace exposure to Cr(VI) as well as Cr(VI) emissions to the environment to as low a level as technically and practically possible.

4. The authorisation holder shall ensure that the application of risk management measures at its site is in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC, including the appropriateness of respiratory protective equipment, where appropriate, and shall refine exposure assessment for workers and for humans via the environment, if necessary.

5. The authorisation holder shall document and keep the information obtained from the monitoring programmes referred to in paragraph 2, 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 3 and 4, and submit it, upon request, to the competent authority of the Member State where the authorised use takes place.

6. If the authorisation holder submits a review report, it shall include the information referred to in paragraph 5.

Article 4

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 use takes place in an official language of that Member State.

Article 5

This Decision is addressed to Ariston Thermo SpA., Viale Aristide Merloni 45, 60044 Fabriano, Italy.

Done at Brussels, 26.8.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION