



Brussels, 11.9.2023  
C(2023) 6014 final

**COMMISSION IMPLEMENTING DECISION**

**of 11.9.2023**

**withdrawing an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Gruppo Colle S.r.l. for a use of sodium dichromate in the context of a review and repealing Implementing Decision C(2017) 8331**

(Only the English text is authentic)

# COMMISSION IMPLEMENTING DECISION

of 11.9.2023

**withdrawing an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Gruppo Colle S.r.l. for a use of sodium dichromate in the context of a review and repealing Implementing Decision C(2017) 8331**

(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<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) Sodium dichromate 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 15 December 2017, by Commission Implementing Decision C(2017) 8331<sup>2</sup>, an authorisation was granted to Gruppo Colle S.r.l. for a use of sodium dichromate as mordant in wool dyeing with dark colours (authorisation number REACH/17/27/0). The review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use of sodium dichromate expired on 15 December 2021.
- (3) On 14 August 2020, Gruppo Colle S.r.l. submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation for the use of sodium dichromate as mordant in wool dyeing with dark colours. Upon request by Gruppo Colle s.r.l., the Commission acknowledged that a late submission of that report was justified by *force majeure*, namely the COVID-19 pandemic.
- (4) On 16 September 2021, the Commission received the opinions on the review report adopted by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)<sup>3</sup> and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

---

<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> Commission Implementing Decision of 15 December 2017 granting an authorisation for a use of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Gruppo Colle s.r.l.) (C(2017) 8331).

<sup>3</sup> <https://echa.europa.eu/documents/10162/7a444152-a19d-e1f7-ddc2-96e5e1ade98a>

- (5) In its opinion, RAC confirmed that it is not possible to determine a derived no-effect level for the carcinogenic properties of sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore sodium dichromate 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 that substance and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.
- (6) In its opinion, RAC concluded that the risk management measures and operational conditions described in the chemical safety report are appropriate and effective to limit the risk to workers and to members of the general population who could potentially be exposed to sodium dichromate via the environment. However, in order to address minor shortcomings related to measurement of exposure and emissions, RAC recommended monitoring programmes for both occupational exposure and environmental release of hexavalent chromium (Cr(VI)), the hazardous component of sodium dichromate. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendation.
- (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 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. Similarly, in order to be considered economically feasible, the use of the alternative should not lead to a negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use applied for.
- (8) In its opinion, SEAC concluded that by the expiry date of the authorisation there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the authorisation holder. SEAC further concluded there were clear indications from the information provided in the review report and by third parties that suitable alternatives are available in the Union for all types of wool. SEAC also noted that the alternatives are being implemented by Gruppo Colle S.r.l. in 65 % of its dye formulations. For the remaining 35 % of the dye formulations for special wools, SEAC concluded that it is not clear that no suitable alternatives exist, as claimed by Gruppo Colle S.r.l.. SEAC also pointed out that Gruppo Colle S.r.l. did not sufficiently justify the lack of progress in identifying and implementing alternatives for those formulations as only the commitment to initiate research and development projects, contained in the original application, was repeated in the review report. SEAC had reservations on the human resources deployed to carry out substitution activities and on the sequence of such activities, highlighting that a parallel implementation of certain reformulation and substitution activities would bring efficiency gains that have not been exploited. The

Commission, having evaluated SEAC's assessment and all information available, concludes that there are suitable alternatives available in the Union but that those alternatives are not yet technically and economically feasible for the applicant.

- (9) Moreover, SEAC concluded that the substitution plan has significant shortcomings and that it is therefore not credible. In particular, for the 35 % of dye formulations where sodium dichromate is used, it does not sufficiently justify the 7-year period needed according to the authorisation holder to substitute chrome-based dyes. SEAC also noted that the part of the substitution plan concerning those formulations is non-committal and incomplete, as neither a list of actions to be carried out nor a corresponding timetable with milestones have been provided.
- (10) Having evaluated SEAC's assessment, the Commission agrees with SEAC's conclusions and, taking into account the availability of suitable alternatives in the Union and that the substitution plan is not credible, considers that Gruppo Colle S.r.l. has not discharged its burden of proof in demonstrating the absence of suitable alternatives for the applicant.
- (11) Consequently, as Gruppo Colle S.r.l. failed to fulfil one of the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is unnecessary to assess whether socio-economic benefits outweigh the risk to human health or the environment arising from the use of sodium dichromate for which authorisation is sought.
- (12) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to withdraw the authorisation for the use of sodium dichromate as mordant in wool dyeing with dark colours.
- (13) 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.
- (14) The authorisation granted by Implementing Decision C(2017) 8331 should therefore be withdrawn as provided for in Article 61(3) of Regulation (EC) No 1907/2006. Consequently, Implementing Decision C(2017) 8331 should be repealed.
- (15) 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 withdrawn for the use of sodium dichromate (EC No 234-190-3; CAS No 10588-01-9 (anhydrous); CAS No 7789-12-0 (dihydrate)) as mordant in wool dyeing with dark colours.

#### *Article 2*

Implementing Decision C(2017) 8331 is repealed.

*Article 3*

This Decision is addressed to Gruppo Colle S.r.l., Via G. Di Vittorio 3/5, 59025 Usella, Cantagallo, Prato, Italy.

Done at Brussels, 11.9.2023

*For the Commission*  
*Thierry BRETON*  
*Member of the Commission*

