



Brussels, 22.5.2019  
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**COMMISSION IMPLEMENTING DECISION**

**of 22.5.2019**

**refusing an authorisation for a use of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Hapoc GmbH & Co KG)**

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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(ONLY THE GERMAN 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 therefore subject to the authorisation requirement laid down in Article 56(1)(a) of that Regulation.
- (2) On 14 March 2016, Hapoc GmbH & Co KG ('the applicant') submitted an application for the authorisation for the use of sodium dichromate in molten bath form to modify surfaces, especially by blackening, of delicate medical products, specifically micro-surgical instruments.
- (3) On 8 June 2017, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency submitted to the applicant, pursuant to Article 64(3) of Regulation (EC) No 1907/2006, a request for additional information to bring the application into conformity with the requirements of Article 62 of that Regulation. The applicant did not submit the requested information.
- (4) On 28 March 2018, the Commission received the opinions of RAC and SEAC<sup>2</sup> on the application, pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (5) In its opinion, RAC concluded that the application did not include the necessary information specified in point (d) of Article 62(4) of Regulation (EC) No 1907/2006. The applicant did not provide exposure measurements or results of modelling related to exposure of workers to hexavalent chromium through the atmosphere or any exposure assessment for ancillary activities such as rinsing. The applicant also failed to address the reproductive toxicity of the substance in the submitted chemical safety

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

<sup>2</sup> <https://echa.europa.eu/documents/10162/1a7e62df-1c04-bdc3-4a9c-6b24da4c70d5>

report. As a consequence, RAC could not evaluate the risk to human health arising from the use of the substance as required under point (a) of Article 64(4) of that Regulation. The Commission concurs with RAC's conclusion.

- (6) In its opinion, SEAC concluded that, since the application did not include all the necessary information specified in Article 62(4)(d) of Regulation (EC) No 1907/2006 for evaluation by RAC, it could not evaluate the socio-economic factors related to the use applied for, in accordance with point (b) of Article 64(4) of that Regulation. The Commission concurs with SEAC's conclusion.
- (7) The Commission, taking into account the RAC and SEAC opinions, considers that the application for authorisation is not in conformity with the requirement laid down in point (d) of Article 62(4) of Regulation (EC) No 1907/2006. Therefore, pursuant to Article 60(7) of that Regulation, an authorisation should be refused.
- (8) 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,

HAS ADOPTED THIS DECISION:

*Article 1*

An authorisation is refused for the use of sodium dichromate (EC No 234-190-3; CAS No 7789-12-0, 10588-01-9) in molten bath form to modify surfaces, especially by blackening, of delicate medical products, specifically micro-surgical instruments.

*Article 2*

This Decision is addressed to Hapoc GmbH & Co KG, In der Neuen Welt 8, 87700 Memmingen, Germany.

Done at Brussels, 22.5.2019

*For the Commission*  
*Elżbieta BIENKOWSKA*  
*Member of the Commission*

