EUROPEAN
COMMISSION

Brussels, 16.9.2024
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COMMISSION IMPLEMENTING DECISION

of 16.9.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Kludi GmbH & Co. KG and Kludi-Armaturen Austria Ges.m.b.H for certain uses of chromium trioxide

(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) 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), point (a), of that Regulation.

(2) On 2 May 2022, Kludi GmbH & Co. KG and Kludi-Armaturen Austria Ges.m.b.H ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are functional chrome plating with decorative character of metal and plastic substrates for sanitary applications ('use 1') and pre-treatment ("etching") of plastic substrates using chromium trioxide in electroplating processes for sanitary applications ('use 2').

(3) The European Chemicals Agency sent the opinions on the application for authorisation for use 1[2] and use 2[3] adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 10 August 2023, the Commission received the opinions.

(4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic and mutagenic properties of chromium trioxide in accordance with Section 1.4 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), point (a), of that Regulation. As a result,

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://www.echa.europa.eu/documents/10162/40d9640e-a67b-e03a-fbc5-f12c07c48db2

[3] https://www.echa.europa.eu/documents/10162/dd8cb5ed-4227-e05e-2669-bfad3963d767

Article 60(2) of Regulation (EC) No 1907/2006 does not apply to chromium trioxide and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) In its opinions on uses 1 and 2, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to human health posed by the uses of chromium trioxide described in the application. However, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing the carrying out of detailed feasibility studies as additional condition for authorisation. In addition, in order to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions as well as to strengthen the measurement data provided, RAC recommended imposing monitoring programmes for both occupational exposure to and environmental release of Cr(VI).

(6) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk values for workers are higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values taken for the purpose of carrying out a risk-benefit analysis, it considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as a condition for authorisation.

(7) In its opinions on uses 1 and 2, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the uses of chromium trioxide. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have demonstrated that the benefits of the uses outweigh the risk to human health arising from those uses.

(8) For an alternative to be suitable it needs to 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, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(9) 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 the functionality, but at some loss of 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 of performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(10) In its opinions on uses 1 and 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicants but that there were technically and economically feasible alternatives in the Union at the time of adoption of the opinions. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that the applicants have identified alternatives to substitute chromium trioxide that are commercially available, that have

already been implemented in the Union in different market segments and provide the overall functionality needed for the use for which authorisation is sought and are likely to become technically and economically feasible for the applicants in the future, but that they imply a loss of performance in terms of technical requirements such as corrosion resistance, colour consistency, adhesion proprieties and etching rate. In this regard, the Commission acknowledges that the applicants have demonstrated that they are not yet able to accommodate such loss of performance and would need more time to develop and implement one of the most promising alternatives to make it technically feasible for them. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicants.

(11) In its opinions on uses 1 and 2, SEAC concluded that the substitution plans submitted by the applicants are credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the uses for which authorisation is sought and the substitution plans submitted by the applicants, that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(12) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of chromium trioxide described in the application, provided that the risk management measures described in the chemical safety report are applied and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

(13) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holders to generate and include additional information about exposure and emissions in the review report.

(14) In its opinions on uses 1 and 2, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set until 2 May 2029. SEAC noted that the 12-year review period requested by the applicants was not warranted, taking into account that the applicants have overestimated the time required for each phase of the substitution plans and that the overlap between phases could increase, considering the research and development activities that have already been undertaken by the applicants and are ongoing in the affected sectors, but that that only 7 years were warranted. The Commission takes into account that recommendation, considering 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 to limit the risk, the socio-economic benefits of the use of the substance and the ongoing substitution efforts.

(15) Nevertheless, the Commission recalls that the aim of authorisation is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where these are available and technically and economically viable. Applicants should therefore make all efforts to achieve a complete phase-out of those substances by the end of a review period. The Commission also considers that

there is increasingly available information on substitution of Cr(VI) substances in functional chrome plating with decorative character, including from similar applications for authorisation and relevant SEAC opinions, indicating that the applicants could be able to substitute more rapidly. In order to ensure that substitution of chromium trioxide for the uses for which an authorisation is sought is achieved as early as possible, and considering the potential risks posed by the uses of chromium trioxide, the Commission considers that a shorter review period should be set for those uses.

(16) 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 uses take place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holders 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.

(17) This Decision does not affect the obligation of the authorisation holders to ensure that the 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 holders 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 Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[4] to reduce the use of carcinogens, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, 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 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], 98/24/EC[8] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

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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, mutagens or reprotoxic substances 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, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

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, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

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, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

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, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

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, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

(18) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive 2010/75/EU[10] of the European Parliament and of the Council, 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[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(19) 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 to the following persons for the following uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/23/32/0	Kludi GmbH & Co. KG	Functional chrome plating with decorative character of metal and plastic substrates for sanitary applications
REACH/23/32/1	Kludi Armaturen Austria Ges.m.b.H.	
REACH/23/32/2	Kludi GmbH & Co. KG	Pre-treatment ("etching") of plastic substrates using chromium trioxide in electroplating processes for sanitary applications

[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, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

[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, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[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, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[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, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13], and to the conditions set out in Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 6.

2. By 16 September 2025 and afterwards each time when new relevant information becomes available, the authorisation holders shall carry out studies to assess the feasibility of implementing the following measures:

   (a) the installation of a physical segregation between the plating areas and the loading/unloading areas;

   (b) the replacement of solid chromium trioxide flakes by a liquid solution of chromium trioxide, or the installation of a closed or automated system to perform the dilution of solid chromium trioxide and any subsequent (re-) filling of the baths with liquid solutions;

   (c) the installation of a closed or automated system to perform bath sampling tasks.

   The authorisation holders shall act in accordance with the outcome of those studies.

3. The authorisation holders shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide. The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to Cr(VI);

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

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal and static inhalation exposure sampling;

   (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;

   (f) be recorded so as to include contextual information about the tasks performed during exposure sampling.

4. The authorisation holders shall continue to conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

5. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraphs 3 and 4 to review, at least annually, the appropriateness and effectiveness of risk management measures and operational conditions in place. While doing so, the authorisation holders shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this review, the authorisation holders shall introduce measures to further reduce to a level as low as technically and

[13] https://ec.europa.eu/docsroom/documents/55699

practically possible occupational exposure to Cr(VI). Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

6. The authorisation holders shall document and maintain the information from the monitoring programmes referred to in paragraph 3 and 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and studies and any measure taken in accordance with paragraphs 2 and 5, and shall make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 3

1. The review period shall expire on 31 December 2028.

2. The authorisation shall cease to be valid on 31 December 2028 with regard to an authorised use in relation to any holder of the authorisation who has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2027.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.

2. The authorisation holders shall continue conducting their monitoring programme measuring the environmental releases of Cr(VI) to the wastewater and carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air. The programmes shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

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

   (c) ensure a sufficiently low limit of quantification;

   (d) be representative of the operational conditions and risk management measures used at the sites where the authorised uses take place;

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

3. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraph 2 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holders shall also review and, if needed, update its assessment of the exposure of the general population via the environment. If needed, based on the outcome of this review, the authorisation holders shall introduce measures to further reduce to a level as low as technically and practically possible Cr(VI) emissions to the environment.

4. The authorisation holders shall document and maintain the information 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 reviews and any measure taken in accordance with paragraph 3,

and shall make that information available upon request, to the competent authority of the Member State where the authorised uses take place.

5. The authorisation holders shall document the steps taken to substitute chromium trioxide, including information on the efforts to convince the authorisation holders' customers to accept alternative Cr(VI)-free solutions and justification in case their customers do not accept alternative Cr(VI)-free solutions. Information on contingency measures taken shall also be documented. The authorisation holders shall make such documentation available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 5

If a review report is submitted, it shall include the following:

(a) the information referred to in Article 2(6) and Article 4(4) and (5);

(b) a detailed justification as to why a complete phase-out of chromium trioxide is not expected to be achieved by the end of the review period;

(c) figures detailing the reduction of the quantity of chromium trioxide, as part of the substitution plan to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006.

Article 6

Upon request, the authorisation holders 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 uses take place. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to:

1. Kludi GmbH & Co. KG, Am Vogelsang 31-33, 85706, Menden, Germany;

2. Kludi-Armaturen Austria Ges.m.b.H, Neufelder Straße 17, 7053 Hornstein, Austria.

Done at Brussels, 16.9.2024

For the Commission
Margrethe VESTAGER
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION