EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 10.7.2019

granting an authorisation for certain uses of pentazinc chromate octahydroxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Indestructible Paint Ltd.)

(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) Pentazinc chromate octahydroxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and is therefore subject to the authorisation requirement laid down in Article 56(1)(a) of that Regulation.

(2) On 21 July 2017, Indestructible Paint Ltd. ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of pentazinc chromate octahydroxide in the formulation of mixtures (‘use 1’) and in stoved epoxy primer for corrosion protection of aircraft engine components in aerospace and aeroderivative applications (‘use 2’).

(3) On 6 September 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] (‘the Agency’) 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 properties of pentazinc chromate octahydroxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore pentazinc chromate octahydroxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. Pursuant to Article 60(3)(a), Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance, and therefore an authorisation may only be granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006.

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

[2] https://echa.europa.eu/documents/10162/324d3aaa-ec03-ec9b-dba3-bcf127e1be2f

(5) In its opinions on uses 1 and 2, RAC concluded that the risk management measures and operational conditions as described in the application together with the recommended conditions and monitoring arrangements, are appropriate and effective in limiting the risk to workers and to members of the general population who could potentially be exposed via the environment. Considering the uncertainties relating to the risks and due to the lack of details about the risk management measures and operational conditions in worker contributing scenarios as well as the uncertainties related to workplace air concentration of chromium (VI), RAC recommended additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with its conclusion.

(6) In its opinions, SEAC concluded that the overall socio-economic benefits from uses 1 and 2 outweigh the risk to human health arising from those uses and that there are no suitable alternative substances or technologies. The Commission, having evaluated SEAC's assessment, concurs with its conclusion.

(7) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of pentazinc chromate octahydroxide covered by the application, provided that the risk management measures and operational conditions described in the application and in the chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006, 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 12 years for uses 1 and 2. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the fact that the substance has no independent function at the stage of formulation and any substitution for use 1 is interlinked with the substitution of use 2, the conclusion that the risk management measures and operational conditions, together with the conditions and monitoring arrangements set out in this Decision, are appropriate and effective in limiting the risk, the likelihood that substitution would not be possible within a shorter period, the time necessary to develop, implement and industrialise possible alternatives, should they become available, the time necessary for qualification and regulatory certification in relation to safety and airworthiness, the very long investment cycles within the aircraft and military naval industry, as well as the conclusion that the socio-economic benefits of continued use outweigh the risk by several orders of magnitude.

(9) It is, therefore, appropriate to set a review period of 12 years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006 for uses 1 and 2.

(10) 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 compliance with 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.

(11) 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 having regard to the principle set out in 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 or 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[3], or to prevent and reduce exposure in accordance with Article 5 of that Directive. 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[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7], and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

(12) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC[8] or Directive 2010/75/EU[9] of the European Parliament and of the Council, nor 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 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 other emission limit values or environmental quality standards under Union law, as those may include further or more onerous requirements.

(13) On 29 March 2017, the United Kingdom submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. The Treaties will cease to apply to the United Kingdom from the date of entry into force of a withdrawal agreement or failing that, two years after that notification, unless the European Council, in agreement with the United Kingdom, unanimously decides to extend that period.

(14) This Decision is addressed to a legal entity established in the United Kingdom. Unless otherwise provided for in a withdrawal agreement, this Decision can therefore only

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3 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).

4 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).

5 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).

6 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).

7 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).

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).

apply to that addressee until the Treaties cease to apply to and in the United Kingdom notwithstanding the end of the validity laid down in this Decision.

(15) 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

Authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of pentazinc chromate octahydroxide (EC No 256-418-0; CAS No 49663-84-5):

Authorisation number	Authorised use
REACH/19/26/0	Formulation of mixtures
REACH/19/26/1	Use in stoved epoxy primer for corrosion protection of aircraft engine components in aerospace and aeroderivative applications

The authorisation is granted subject to full application of the risk management measures and operational conditions described in the chemical safety report[12], and once available, to the full application of the risk management measures and operational conditions described in the specific exposure scenarios to be developed pursuant to Article 2, as well as the conditions set out in Articles 2 and 3.

Article 2

1. The authorisation bearing number REACH/19/26/0 shall be subject to the following condition: at the latest on 10 July 2021, and thereafter annually, the authorisation holder shall validate and verify the exposure scenarios by making an analysis of the tasks, conducting occupational exposure measurements referred to in Article 3(2) and by measuring environmental releases. The authorisation holder shall revise the exposure scenarios where the validation and verification indicates that exposures and releases are not reduced to as low a level as technically and practically possible;

2. The authorisation bearing number REACH/19/26/1 shall be subject to the following conditions:

   (a) the authorisation holder shall develop more detailed worker contributing scenarios as a part of the exposure scenarios included in the chemical safety report referred to in Article 1, describing detailed risk management measures and operational conditions to control workers' exposure to pentazinc chromate octahydroxide and emissions to the environment together with resulting exposure levels. The worker contributing scenarios shall contain more detailed descriptions of tasks and of ways of performing them. The selection of worker contributing scenarios shall be duly documented and justified and made available to the competent authority upon request. The objective of these scenarios shall be the progressive reduction of exposure and releases to as low a level as technically and practically possible. The progressive reduction of

[12] https://ec.europa.eu/docsroom/documents/31664

exposure and releases shall be documented and the reports made available to the competent authority upon request. The authorisation holder shall communicate the revised exposure scenarios to its downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 ('downstream users'), in an updated safety data sheet, at the latest on 10 October 2019.

The authorisation holder shall validate and verify the exposure scenarios referred to in the first subparagraph at the latest on 10 July 2021 and thereafter yearly, by making an analysis of tasks, related contextual information and conducting occupational exposure measurements referred to in Article 3(2). Where the validation and verification indicates that exposure and releases are not reduced to as low as technically and practically possible, the authorisation holder shall revise the exposure scenarios and, without undue delay, make the revised exposure scenarios available to its downstream users;

(b) the downstream users shall ensure that the access to the area in which the spray painting activities and machining activities are carried out is restricted during the performance of these activities either physically by means of barriers, signage or through strict procedure during the activity and for a specified time after the operation;

(c) the downstream users shall implement effective procedures to avoid surface contamination and adequate cleaning practices in the vicinity where the spraying and machining activities referred to in point (b) take place.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 9 shall apply.

2. The authorisation holder and its downstream users shall conduct regular occupational exposure measurements of chromium (VI), related to the uses referred to in Article 1. Those measurements shall:

   (a) take place at least annually;

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

   (c) ensure a sufficiently low detection limit;

   (d) be representative of the range of tasks with possible exposure to chromium (VI), the operational conditions and risk management measures typical for these tasks and of the total number of workers that are potentially exposed;

   (e) include contextual information about the tasks with possible exposure to chromium (VI).

3. The authorisation holder shall draw up recommendations and guidelines to assist downstream users in conducting the occupational exposure measurements referred to in paragraph 2 and shall develop a report template for submission of monitoring data by downstream users according to paragraph 8. The report template shall be supplied to the downstream users together with the updated safety data sheet referred to in Article 2.2(a).

4. As regards the authorisation bearing number REACH/19/26/0, the authorisation holder shall measure the emissions of chromium (VI) into the air. Those measurements shall:

   (a) take place at least annually;

   (b) be undertaken according to standard methodologies or protocols;

   (c) ensure a sufficiently low detection limit.

5. The authorisation holder shall use the information gathered in the measurements referred to in paragraphs 2 and 4 to review regularly the appropriateness and effectiveness of the risk management measures and operational conditions and to take action, if appropriate, to further reduce workers' exposure to chromium (VI) and its emissions to the environment.

6. Following the implementation of the revised exposure scenarios referred to in Article 2.1 and 2.2(a), the authorisation holder and its downstream users may reduce the frequency of measurements to once every three years, provided that they can clearly demonstrate to the competent authority of the Member State where the use takes place that exposure to humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions correspond to the newly developed exposure scenarios and function appropriately.

7. The results of the measurements referred to in paragraphs 2 and 4, the outcome of the review referred to in paragraph 5, and the recommendations and guidelines referred to in paragraph 3, shall be documented and, upon request, submitted to the competent authority of the Member State where the authorised use takes place.

8. Where the frequency of the monitoring programme has been reduced in accordance with paragraph 6, any subsequent changes to the operational conditions or risk management measures that may affect the exposure at the site where the use takes place shall be documented. The authorisation holder and its downstream users shall assess the impact of such changes by monitoring, to demonstrate that exposure of workers and emissions to the environment continue to be reduced to as low a level as technically and practically possible.

9. For the first time 10 July 2020 the downstream users shall make available to the Agency the information collected in accordance with paragraph 2, including the contextual information related to each set of measurements, for transmission, to the authorisation holder for the purpose of validating the exposure scenarios in the format of the template referred in paragraph 3.

10. The authorisation holder and its downstream users shall periodically check the local exhaust ventilation and respiratory protective equipment as specified in manufacturers' recommendations, including fit testing of respiratory protective equipment. The authorisation holder and its downstream users shall keep the records of such periodical checks and tests and make them available to the competent authorities of the Member State where the use takes place.

Article 4

1. The review period shall expire on 22 January 2031.

2. The authorisation shall cease to be valid on 22 January 2031 unless a review report has been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 22 July 2029.

Article 5

The authorisation holder shall include the following information in the review report:

(a) an updated CSR, based on the results of the measurements referred to in Article 3(2) and 3(4) (for authorisation bearing number REACH/19/26/0) of this Decision. As regards the authorisation bearing number REACH/19/26/1, the exposure scenarios shall be for typical, representative downstream user sites, clearly describing the relationship between operational conditions, risk management measures and the resulting exposure levels, including a more detailed task descriptions and the description of how exposure occurs. A justification as to why the selected scenarios are representative and how the hierarchy of control principles is followed shall be included;

(b) a refinement of the assessment of indirect exposure and risk to humans via environment beyond the default assumptions outlined in Guidance on Information Requirements and Chemical Safety Assessment[13] and the European Union System for the Evaluation of Substances (EUSES) model[14] ;

(c) an assessment of all reasonably foreseeable routes of exposure to humans via the environment.

Article 6

Upon request, the authorisation holder shall submit a succinct 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.

[13] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

[14] https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances

Article 7

This Decision is addressed to Indestructible Paint Ltd, 16-25 Pentos Drive, B11 3TA, Birmingham, West Midlands, United Kingdom.

Done at Brussels, 10.7.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION