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COMMISSION IMPLEMENTING DECISION

of 13.1.2021

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Ariane Group for a use of pitch, coal tar, high-temp. (CTPh_t)

(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/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Pitch, coal tar, high-temp. ('CTPht') 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)(a) of that Regulation.
- (2) On 14 February 2019, ArianeGroup ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of CTPht. The use for which authorisation was sought is industrial use of CTPht as a precursor of carbon matrix in the manufacturing of thermally and thermo-mechanically highly loaded carbon-carbon parts including nozzle throats and other critical carbon-carbon composite parts, resistant to very harsh erosion conditions, and very high temperature ranges, dedicated to high performance civilian and military aerospace launchers.
- (3) On 7 January 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 Agency² and sent to it pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) RAC concluded in its opinion that it is not possible to determine a derived no-effect level (DNEL) either for the carcinogenic properties of CTPht or for its environmental properties of concern in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore CTPht is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. As a

¹ OJ L 396, 30.12.2006, p. 1.

² <https://www.echa.europa.eu/documents/10162/604c43c0-b4a0-278e-b122-ac6d778aa893>

result, paragraph 2 of Article 60 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.

- (5) 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 human health and the environment posed by the use of CTPht described in the application. RAC considered that such measures and conditions constitute the best available techniques. However, in order to address the minor shortcomings in the assessment of dermal exposure and partial lack of air treatment of ventilation at one of the sites and to give an overview of the potential actions to further reduce the environmental emissions, RAC made recommendations regarding the information to be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006. Having evaluated the RAC assessment, the Commission agrees with that conclusion and recommendation.
- (6) In its opinion, SEAC raised no reservations on the quantitative and qualitative elements of the applicant's assessment of the socio-economic benefits and the monetised risk to human health and the environment associated with the use of CTPht described in the application. Having evaluated SEAC's assessment that the socio-economic benefits of continued use exceed the monetised risk by orders of magnitude, and RAC's conclusion that the exposure to CTPht and its releases into the environment are adequately minimised, the associated environmental impacts resulting from those releases, as well as the qualitatively assessed additional socio-economic benefits of continued use, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of continued use of CTPht outweigh the risk to human health and the environment arising from that use.
- (7) An authorisation may be granted under Article 60(4) of Regulation (EC) No 1907/2006 if there are no suitable alternative substances or technologies. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, the Commission should not consider a potential alternative to be technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers that it must be possible to depart from this approach where justified by particular circumstances, including the specific function of the substance for the use applied for, the public interest at stake, or a low net difference of the socio-economic benefits and the risk to human health or the environment. The Commission also considers that no particular factors justify less strict technical feasibility requirements in this case.
- (8) In its opinion, SEAC concluded that there are no available alternative substances or technologies with the same function and similar level of performance that are safer and technically and economically feasible for the applicant by the sunset date. SEAC also concluded that the identified alternatives are not suitable. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that, although an alternative has already been successfully implemented in components of some aerospace launchers, the applicant has demonstrated that neither this alternative

nor other potential alternatives provide the level of technical performance functionally necessary for the use applied for, which relates to high performance civil and military aerospace launchers. Consequently, the Commission concludes that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives.

- (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 CTPht described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.
- (10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessments on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional emission information.
- (11) SEAC recommended in its opinion that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should 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, that the exposure to the substance and its releases to the environment are adequately minimised, the conclusion that the benefits of continued use outweigh the monetised risk to human health by several orders of magnitude, the time needed for the development of the most promising alternative substances or technologies, as well as the fact that the research and development efforts by the applicant have not led to finding a suitable alternative that could be available within a shorter timeframe.
- (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) 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 Council³ 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 application of Union law in the area of health and safety at work, in particular Council

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).

Directives 89/391/EEC⁴, 92/85/EEC⁵, 94/33/EC⁶, 98/24/EC⁷ and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

- (14) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council⁸ or Directive 2010/75/EU of the European Parliament and of the Council⁹, 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 Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. 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.
- (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 hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of pitch, coal tar, high-temp. ('CTPht') (EC No 266-028-2; CAS No 65996-93-2):

Authorisation number	Authorised use
REACH/21/1/0	Industrial use of CTPht as precursor of carbon matrix in the manufacturing of thermally and thermo-mechanically highly loaded carbon/carbon parts including nozzle throats and other

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).

critical carbon-carbon composite parts, resistant to very harsh erosion conditions, and very high temperature ranges, dedicated to high performance civilian and military aerospace launchers

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹².

Article 2

1. The review period shall expire on 4 October 2032.
2. The authorisation shall cease to be valid on 4 October 2032 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 April 2031.

Article 3

1. The monitoring arrangements referred to in paragraphs 2 to 6 shall apply.
2. The authorisation holder shall ensure that the personal protective equipment (PPE) used to protect workers against dermal exposure to CTPht is suitable for that purpose and shall document the relevant actions. The authorisation holder shall test the gloves and the chemical protective clothing in accordance with the relevant standards.
3. The authorisation holder shall ensure that workers potentially exposed to CTPht are properly trained to use and maintain the PPE and shall keep record of such training activities.
4. The authorisation holder shall conduct measurements of CTPht emissions into air from local exhaust ventilation at least annually.
5. The authorisation holder shall carry out a feasibility study of additional means to reduce CTPht emissions to air from local exhaust ventilation and shall take actions on the basis of the results of that study.
6. If the authorisation holder submits a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information documented in accordance with paragraphs 2, 3, 4 and 5 of this Article in that report.

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.

¹² <https://ec.europa.eu/docsroom/documents/39484>

Article 5

This Decision is addressed to ArianeGroup, 11 quai André Citroën, 75015 Paris, France

Done at Brussels, 13.1.2021

For the Commission

Thierry BRETON

Member of the Commission

