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COMMISSION IMPLEMENTING DECISION

of 16.3.2022

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Industrial Quimica del Nalon, S.A. for a use of pitch, coal tar, high-temp. (CTPht)

(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) Pitch, coal tar, high-temp. (‘CTPht’) is listed in Annex XIV to Regulation (EC) No 1907/2006 and use of that substance is subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 20 February 2019, Industrial Quimica del Nalon, S.A. ('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 a use of CTPht for manufacture of formulations for various industrial uses.

(3) On 4 January 2021, the Commission received the opinion on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine either a derived no-effect level (DNEL) for the carcinogenic properties or a predicted no-effect concentration (PNEC) for the PBT and vPvB properties of CTPht 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), 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.

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

[2] https://echa.europa.eu/documents/10162/f7533053-187c-c990-0d12-c57703aefbbd

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective to limit the risk to workers, whereas they are not appropriate and effective to limit the risk to the environment and to members of the general population exposed via the environment. In particular, RAC noted that the exhaust air from the scrubbers is not further treated (e.g. by incineration or active carbon filters) as well as the absence of Worker Contributing Scenarios (WCSs) with operational conditions and risk management measures for maintenance workers. In addition, RAC noted that the potential risk associated with dermal exposure to CTPht as well as the effectiveness of dermal protection should be reconsidered. Therefore, RAC recommended imposing certain conditions and monitoring programmes. Having evaluated RAC's assessment, the Commission agrees with that conclusion and recommendations.

(6) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and the qualitative elements of the applicant's assessment of the socio-economic benefits and the risk to the human health and the environment associated with the continued use of the substance. Taking into account SEAC's assessment, the estimated monetised risk to human health in the order of hundreds of euros per year, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with the use of the substances, the estimated emissions of less than 300 grams of polycyclic-aromatic hydrocarbons (PAHs)[3] per year, the estimated quantitatively assessed benefits due to avoided profit losses at minimum in the order between tens of thousands to hundreds of thousands of euros over the entire review period, the estimated cost of avoiding the remaining releases of PAHs in the order between tens of thousands to hundreds of thousands of euros per kilogram, the qualitatively assessed additional socio-economic benefits of the continued use due to the maintained supply of formulations to customers, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits arising from the continued use of the substances outweigh the risk to human health and the environment arising from that use.

(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 applied for should be considered to be technically feasible.

(8) In its opinion, SEAC concluded that there are no suitable alternative substances or technologies available before the sunset date. SEAC noted that there is no function *per se* provided by the substance in the use applied for (formulation of mixtures). Therefore, SEAC concluded that alternatives do not have to be assessed by the applicant. The Commission, having evaluated SEAC's assessment, agrees with that conclusion.

(9) However, according to the applicant, the use applied for only covers those formulations that serve for industrial uses of CTPht that are outside the scope of the authorisation requirement set out in Regulation (EC) No 1907/2006. Therefore, the Commission considers it appropriate to adapt the description of the authorised use and limit the placing on the market of the mixtures resulting from the authorised use accordingly. Moreover, in order to align this use description with the terminology of

[3] Polycyclic aromatic hydrocarbons are substances released from CTPht.

Regulation (EC) No 1907/2006, the terms 'manufacture of formulations' should be replaced by the terms 'formulation of mixtures'. Consequently, the use description should be 'in formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation requirement set out in Regulation (EC) No 1907/2006'.

(10) 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, as limited in this Decision, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the condition set out in this Decision, are fully applied.

(11) 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 the existence of a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to request that additional exposure and emission information be submitted.

(12) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (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, the level of the estimated risk to human health and the estimated emissions to the environment, the magnitude of the estimated benefits of continued use, as well as the fact that CTPht have no specific function at the formulation stage and that substitution depends on the substitution of downstream uses not covered by this application.

(13) 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.

(14) 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 to eliminate or reduce to a minimum risks to the health and safety of workers at work involving hazardous chemical agents in accordance with Article 5(2) of Council Directive 98/24/EC[4] or the obligation of the employer under Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council[5] to reduce the

[4] 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).

[5] 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).

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 Directives 89/391/EEC[6], 92/85/EEC[7], 94/33/EC[8], 98/24/EC and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

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

(16) 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/22/10/0	In formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation requirement set out in Regulation (EC) No 1907/2006

6 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).

7 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).

8 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).

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).

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).

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).

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).

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 of this Decision.

Article 2

The authorisation shall be subject to the following conditions:

1. the mixtures resulting from the authorised use shall be placed on the market exclusively for industrial uses of CTPht that are outside the scope of the authorisation requirement set out in Regulation (EC) No 1907/2006;

2. the authorisation holder shall implement, at the latest by 16 March 2025, further treatment of the exhaust air from the scrubbers.

Article 3

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 4

1. The monitoring arrangements referred to in paragraphs 2 to 7 shall apply.

2. The authorisation holder shall implement the following monitoring programmes:

   (a) measurements of emissions of polycyclic aromatic hydrocarbons (PAHs) from CTPht. Those measurements shall:

   – be carried out at least quarterly;

   – provide estimates to quantify emission to air;

   – be based on relevant standard methodologies or protocols;

   – ensure a sufficiently low limit of quantification;

   – include as a minimum the 9 indicator PAHs: anthracene, phenanthrene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[a]pyrene, benzo[k]fluoranthene, and benzo[ghi]perylene;

   – be recorded as to include details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

   (b) occupational exposure measurements of CTPht. Those measurements shall:

   – contain as a minimum measurements of benzo[a]pyrene;

   – be carried out at least annually;

   – be based on relevant standard methodologies or protocols;

   – ensure a sufficiently low limit of quantification;

[13] https://ec.europa.eu/docsroom/documents/44411

– be carried out through personal air sampling in combination with post-shift urinary biomonitoring;

– be representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPht is possible, including maintenance;

– be recorded as to include contextual information about the tasks with possible exposure to CTPht.

(c) measurements of the concentrations of individual PAHs from CTPht in the combined wastewater stream at the release point. Those measurements shall:

– be carried out at least monthly and in accordance with certified methods and with the relevant national permit;

– ensure a sufficiently low limit of quantification;

– include as a minimum the 9 indicator PAHs: anthracene, phenanthrene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[a]pyrene, benzo[k]fluoranthene, and benzo[ghi]perylene;

– be recorded as to include details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

3. The authorisation holder shall use the information gathered in the measurements referred to in paragraph 2 and related contextual information to regularly review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce exposure to CTPht and emissions of PAHs to a level as low as technically and practically possible.

4. The authorisation holder shall review without delay the suitability of the personal protective equipment for protecting workers against dermal exposure to CTPht, revise the dermal exposure assessment accordingly and if needed implement additional risk management measures and operational conditions to control dermal exposure at a level as low as technically and practically possible. The authorisation holder shall act without delay upon the outcome of the review and document the relevant actions.

5. The authorisation holder shall review the exposure assessment as regards the maintenance operations, provide a quantitative assessment and if needed implement additional risk management measures and operational conditions to control exposure at a level as low as technically and practically possible. The authorisation holder shall act without delay upon the outcome of the review and document the relevant actions.

6. The authorisation holder shall document and keep the information obtained from the monitoring programmes referred to in paragraph 2, the outcome and conclusions of the review and any action taken in accordance with paragraphs 3 to 5. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

7. If the authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information referred to in paragraph 6.

Article 5

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.

Article 6

This Decision is addressed to Industrial Quimica del Nalon, S.A., Avda. Galicia 31, 33005, Oviedo, Asturias, Spain

Done at Brussels, 16.3.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION