EUROPEAN
COMMISSION

Brussels, 17.3.2022
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COMMISSION IMPLEMENTING DECISION

of 17.3.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Sekisui S-lec BV Roermond for a use of 4-Nonylphenol, branched and linear, ethoxylated

(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) 4-Nonylphenol, branched and linear, ethoxylated ('4-NPnEO') 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 3 July 2019, Sekisui S-lec BV Roermond ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of 4-NPnEO[2]. The use for which authorisation was sought is industrial use of 4-NPnEO and other 4-Nonylphenol releasing entities as polymer additive in the manufacture of interlayer polymer films for laminated safety glass.

(3) On 29 September 2020, 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[3] and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine a predicted no-effect concentration (PNEC) for the endocrine disrupting properties for the environment of 4-NPnEO in accordance with Section 6.4, of Annex I to Regulation (EC) No 1907/2006 and that, therefore, 4-NPnEO 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 authorisations may therefore only be granted with respect to that substance under Article 60(4).

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1 OJ L 396, 30.12.2006, p. 1.

2 Different names and abbreviations are used to refer to the substance, including 'Nonylphenol releasing substances' or 'NPRs' in the chemical safety report.

3 https://echa.europa.eu/documents/10162/8f1dbf23-92ab-bc5d-b40c-0ed6ed3c6985

(5) RAC noted that the risk to the environment cannot be excluded for non-threshold substances, even at low exposure levels. Consequently, RAC takes the emissions of the substance as a proxy for the risk.

(6) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective to limit the risk to the environment posed by the use of 4-NPnEO described in the application. In particular, due to concerns related to effectiveness of the wastewater treatment with regard to the on-site oil-water separator, RAC recommended conditions and a monitoring programme, with a view to reducing to a minimum releases into the environment and ensuring the effectiveness of the risk management measures and operational conditions. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(7) 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 environment associated with the future use of 4-NPnEO. Taking into account SEAC's assessment, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with the use of 4-NPnEO, the estimated emissions of the substance in the order of a few kilograms per year, the estimated quantitatively assessed benefits due to avoided profit and employment losses at minimum in the order of tens of millions of euros over the entire review period, the estimated cost of avoiding the remaining releases of 4-NPnEO in the order of hundreds of thousands of euros per kilogram over the entire review period, the qualitatively assessed additional socio-economic benefits due to reduced CO_2 emissions, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the use of 4-NPnEO outweigh the risk to human health and the environment arising from that use.

(8) 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.

(9) In its opinion, SEAC concluded that there are no suitable alternative substances or technologies available by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that, for the time being, more research is still required to establish whether any of the shortlisted alternatives allows achieving the required solubility and dispersion of the inorganic particles in the organic matrix, the required overall stability of the mixture, or the required adhesion of the polymer film to the glass sheets. The Commission therefore considers that the identified alternatives do not allow the functionality needed for the use applied for. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

(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 4-NPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the conditions set out in this

Decision are fully applied. However, for the sake of legal clarity, the name of the substance in the description of the use authorised by this Decision should be 4-Nonylphenol, branched and linear, ethoxylated, as it is the name of the substance as listed in Annex XIV of Regulation (EC) No 1907/2006.

(11) 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 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) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at seven 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 emissions, the socio-economic benefits of the continued use of the substance, the lack of suitable alternatives within a shorter timeline, as well as the time necessary for testing and customers' approval.

(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]. 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] and 98/24/EC as well as any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

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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 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).

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).

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).

(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[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], 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[10] or the environmental quality standards 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 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 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO):

Authorisation number	Authorised use
REACH/22/7/0	Industrial use of 4-NPnEO as polymer additive in the manufacture of interlayer polymer films for laminated safety glass

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12] as well as to the conditions laid down in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 5.

2. The authorisation holder shall carry out a feasibility study by 17 March 2023 in order to assess the feasibility to implement additional risk management measures and operational conditions for reducing emission of 4-NPnEO with wastewater and shall subsequently act on the outcome of that study.

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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).

12 https://ec.europa.eu/docsroom/documents/43213

3. The authorisation holder shall develop and carry out a monitoring programme of 4-NPnEO and its principal degradation products in the wastewater prior to release to the off-site municipal sewage treatment plant. That monitoring programme shall:

   (a) ensure that the initial sampling frequency is sufficient to demonstrate daily fluctuation;

   (b) be carried out at least 4 times per year and during the time of operation in order to capture the variability in concentrations of the substance and its principal degradation products in the wastewater due to changes or operational fluctuations in the process;

   (c) be based on an analytical method capable of adequately characterising the substance and its principal degradation products in (waste)water at an appropriately low limit of quantification;

   (d) be recorded with details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

4. The authorisation holder shall use the information gathered in the measurements referred to in paragraph 3 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 emissions of 4-NPnEO to a level as low as technically and practically possible.

5. The authorisation holder shall document and retain the information obtained from the monitoring programme referred to in paragraph 3, the outcome and conclusions of the review and any action taken in accordance with paragraph 4, as well as from the feasibility study referred to in paragraph 2 and related actions. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 4 January 2028.

2. The authorisation shall cease to be valid on 4 January 2028 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2026.

Article 4

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 Article 2(5) of this Decision.

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 Sekisui S-lec BV Roermond, Metaalweg 5, 6045 JB Roermond, the Netherlands.

Done at Brussels, 17.3.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION