II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1950

of 14 October 2022

renewing the approval of creosote as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4), point (a), thereof,

Whereas:

(1) The active substance creosote was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) for use in biocidal products of product-type 8 and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the conditions set out in Annex I to that Directive.

(2) On 27 October 2016, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of creosote for use in biocidal products of product-type 8. That application was evaluated by the competent authority of the United Kingdom as the evaluating competent authority.

(3) On 16 September 2019, the evaluating competent authority submitted a recommendation on the renewal of the approval of creosote to the European Chemicals Agency ('the Agency'). Due to the withdrawal of the United Kingdom from the Union, the competent authority of Poland has taken over the role of evaluating competent authority regarding the application on 30 January 2020.

(4) In accordance with Article 14(3) of Regulation (EU) No 528/2012, on 4 December 2020 the Agency adopted an opinion ([3]) formulated by its Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([3]) Biocidal Products Committee (BPC) opinion on the application for renewal of the approval of the active substance: creosote, Product type: 8, ECHA/BPC/274/2020, adopted on 4 December 2020.

(5) According to that opinion, creosote is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]) and meets the criteria for being a persistent, bioaccumulative and toxic (PBT) substance and a very persistent and very bioaccumulative (vPvB) substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([5]). Creosote therefore meets the exclusion criteria set out in Article 5(1), points (a) and (e), of Regulation (EU) No 528/2012.

(6) Pursuant to Article 12(1) of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed if the active substance still meets at least one of the conditions set out in Article 5(2) of that Regulation.

(7) The Commission, with the support of the Agency, carried out a public consultation in order to gather information as to whether the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied.

(8) The opinion of the Agency and the contributions to the public consultation were discussed with Member States in the Standing Committee on Biocidal Products. Member States were also requested to indicate whether they consider that at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 would be met in their respective territory, and to provide justifications.

(9) From the information collected and the views expressed by Member States, it appears that creosote and wood treated with creosote are still needed in many Member States for railway sleepers and for utility poles for electricity and telecommunications.

(10) Wood treated with products containing creosote is used to make wooden railway sleepers for various technical reasons (light weight compared to concrete sleepers and corresponding ease of maintenance, good resilience, high service life expectancy sought for railway infrastructures which are built to last several decades, sustainable material). Wooden railway sleepers have great flexibility in terms of where they can be used (such as inaccessible areas, switching points, tunnels, bridges, small radius curves). Moreover, the railway sleeper use class is a safety-critical application which may be subject to rail infrastructure type approval or certification requirements for reasons related to the safety of people (passengers, train operators, etc.) and railway equipment, namely trains and infrastructures. Good operation of train infrastructures is essential for the proper functioning of society and economic activities. Alternative biocidal products to treat wooden railway sleepers are under development and one product containing a mixture of copper hydroxide, DDA Carbonate and penflufen has recently been authorised in several Member States. However, time is needed to test and have a sufficient return on experience of those alternative products, and to ensure that they can meet the long service life expected of railway sleepers.

(11) Alternative materials to wood for railway sleepers exist, including concrete, steel or composite materials such as fibre-reinforced foamed urethane, each presenting advantages (for example, similar mechanical properties and durability to creosote-treated wood railway sleepers) and disadvantages (for example, issues of maintenance of certain tracks in inaccessible areas, switching points, tunnels, secondary lines; cost; higher negative environmental footprint than wood; difficulty in track maintenance to mix wooden sleepers with sleepers made from other materials due to the different ballast requirements). A non-renewal of approval of creosote as an active substance for use in biocidal products for the treatment of wood to make railway sleepers would create serious technical and economic impacts on railway infrastructure operators in some Member States where substitution would be technically or economically difficult for the moment.

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([5]) 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 (OJ L 396, 30.12.2006, p. 1).

(12) Wood treated with products containing creosote is used to make utility poles for electricity and telecommunications for various technical reasons (for example, light weight compared to concrete poles and corresponding ease of maintenance, good resilience, high service life expectancy sought for electricity and telecommunication infrastructures which are built to last several decades, sustainable material). Alternative biocidal products to treat wooden poles are under development and a product containing a mixture of copper hydroxide, DDA Carbonate and penflufen has recently been authorised in several Member States. Some other biocidal products, based on copper compounds or quaternary ammonium compounds as active substances, have reached the final stage of authorisation procedure. However, time is needed to test and have a sufficient return on experience of those alternative products.

(13) Alternatives to wood as a material for utility poles exist, including steel, concrete, fibreglass, composite materials or composite barrier sleeves installed around treated wooden utility poles. Each of these alternatives presents advantages (for example, rigidity; invariant physical characteristics; fire retardancy) and disadvantages (for example, the need for further testing; possible shorter service life or other technical concerns; more expensive when compared to wooden poles). Another alternative is the laying of transmission cables underground, in particular in urban and city environments, although this option may become more technically challenging depending on the natural terrain across which the network must traverse (for example, remote areas or mountains), and an installation and maintenance may appear more complex, costly and not feasible in all circumstances. A non-renewal of approval of creosote for use in wooden poles might create an economic impact on electricity and telecommunication infrastructure operators, and problems for the maintenance of certain transmission cables (for example, areas not easily accessible, rapid response in case of serious storms) in some Member States where substitution with other materials or underground transmission cables would be technically or economically difficult for the moment.

(14) The Agency identified risks for human health arising from the use of biocidal products containing creosote for the treatment of railway sleepers and utility poles for the workers responsible for the treatment of wood, for the pole installers and the electricity pole installers, and for the exposure of the general public. Risk mitigation measures should be implemented to limit the exposure to creosote as far as possible, for example the recourse to mechanical or automated processes to avoid manual handling of treated wood, and the wearing of personal protective equipment by workers, and ensuring that treated wood is not accessible to the general public during storage. Risks for the environment have also been identified as creosote is PBT/vPvB, and risk mitigation measures should be implemented to limit the exposure of the environment to creosote as far as possible, for example providing that industrial application is to be conducted within a contained area or on impermeable hard standing with bunding; that freshly treated timber is to be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water; and that any losses from the application of the product are to be collected for reuse or disposal.

(15) On the basis of the information collected, it is concluded that the non-approval of creosote as an active substance for use in biocidal products would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance for the treatment of wood used to make railway sleepers and utility poles for electricity and telecommunications. The condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.

(16) It is therefore appropriate to renew the approval of creosote for use in biocidal products of product-type 8, subject to compliance with certain conditions.

(17) Creosote is a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012 and therefore the period of renewal should not exceed 7 years, pursuant to Article 10(4) of that Regulation.

(18) To keep exposure to humans and the environment to a minimum, biocidal products should only be authorised for the treatment by vacuum pressure impregnation of wood in industrial installations to make railway sleepers, or utility poles for electricity or telecommunications. Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment should include an evaluation as to whether the conditions of Article 5(2) of that Regulation are satisfied. It should be provided that products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied.

(19) To ensure that products are only supplied for use in industrial installations, it should be allowed to place products on the market only in packaging of a capacity equal to or greater than 200 litres, and it should not be allowed to make products available on the market to the general public.

(20) Furthermore, to ensure a high level of safety for human health, animal health and the environment, the placing on the market of wood treated with creosote should be subject to conditions. In particular, to ensure that wood treated with creosote is placed on the market only in Member States where the use of the biocidal products containing creosote could be authorised as the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied, lists of Member States where the placing on the market of railway sleepers or utility poles for electricity and telecommunication is allowed should be made publicly available. It should be possible for a Member State to ask to be removed from either of those lists so that wood treated for the concerned use(s) can no longer be placed on the market of that Member State. In addition, the person responsible for the placing on the market of wood treated with creosote should ensure that the label of that treated wood includes specific statements aiming to protect human health and the environment, avoid unauthorised use of the treated wood, and ensure that treated wood is placed on the market only in Member States included in such lists and in the Member States that have been removed from a list for a certain period of time.

(21) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ('Withdrawal Agreement'), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) No 528/2012 as well as the Commission acts based on it, applies to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement. For that reason the lists of states where treated wood may be placed on the market should also include the United Kingdom in respect of Northern Ireland, where necessary.

(22) In respect of uses of creosote other than for the treatment of wood to make railway sleepers and utility poles for electricity and telecommunications referred to in the application for renewal of approval, it has not been demonstrated that any of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is met. In particular, as regards the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012, it has not been demonstrated that the non-renewal of creosote as an active substance for use in biocidal products for such uses will have a disproportionate negative impact on society compared to the risks of using creosote and wood treated with creosote. Suitable and sufficient alternatives exist and are already implemented in almost all Member States, and can be implemented in the entire Union. In order to allow sufficient time for economic operators to adapt to the requirements set down in this Implementing Regulation, a period of transition should be set after which that wood treated with biocidal products containing creosote is no longer placed on the market other than as railway sleepers and utility poles for electricity and telecommunications. The same period should apply to the placing on the market of railway sleepers and utility poles for electricity and telecommunications treated with creosote in Member States not included in the lists for the concerned uses.

(23) By Commission Implementing Decision (EU) 2021/1839 ([6]), the expiry date of approval of creosote for use in biocidal products of product-type 8 was postponed to 31 October 2022. As the examination of the application for the renewal of that approval is now finalised, it is appropriate to repeal Implementing Decision (EU) 2021/1839.

(24) Creosote, its compounds, and wood treated with them, are subject to restrictions laid down in Annex XVII to Regulation (EC) No 1907/2006. This Regulation does not affect the obligation to comply with those restrictions.

(25) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([6]) Commission Implementing Decision (EU) 2021/1839 of 15 October 2021 postponing the expiry date of approval of creosote for use in biocidal products of product-type 8 (OJ L 372, 20.10.2021, p. 27).

HAS ADOPTED THIS REGULATION:

Article 1

The approval of creosote as an active substance for use in biocidal products of product-type 8 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

Implementing Decision (EU) 2021/1839 is repealed.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Expiry date of approval	Product type	Specific conditions
Creosote	IUPAC Name: Creosote EC No: 232-287-5 CAS No: 8001-58-9	100 % (w/w) Creosote shall contain less than: — 0,005 % (w/w) of benzo[a]pyrene — 3 % (w/w) of water extractable phenols	31 October 2029	8	Creosote is considered a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: (1) Products may only be authorised for the treatment by vacuum pressure impregnation of wood in industrial installations to make railway sleepers, or utility poles for electricity or telecommunications. (2) Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied. (3) Products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied. (4) Products may be placed on the market only in packaging of a capacity equal to or greater than 200 litres, and shall not be made available on the market to the general public. (5) The assessment of applications for product authorisation shall pay particular attention to: (a) professional users; (b) secondary exposure of the general public; (c) the soil and aquatic compartments; (d) the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

					(6) Labels and, where provided, safety data sheets of products authorised, shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding; that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water; and that any losses from the application of the product shall be collected for reuse or disposal. The placing on the market of treated articles is subject to the following conditions: (1) By 31 January 2023, the Agency shall make publicly available on its website, based on the requests made by Member States: (a) a list of Member States where railway sleepers treated with creosote may be placed on the market; (b) a list of Member States where utility poles for electricity and telecommunications treated with creosote may be placed on the market. (2) As from 30 April 2023, only railway sleepers, or utility poles for electricity or telecommunications treated with creosote may be placed on the market in Member States included in the respective list referred to in this paragraph, point (1). A Member State may ask the Agency to be removed from the respective list at any time. When the Agency removes a Member State from either of the lists, the date of removal shall be indicated, and treated articles for the concerned use shall no longer be placed on the market of that Member State 180 days after the date of removal. (3) The person responsible for the placing on the market of a treated article shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.

					(4) The person responsible for the placing on the market of a treated article shall ensure that the label of that treated article includes the statement: 'During storage, treated wood shall not be accessible to the general public. Measures shall be taken to prevent unauthorised access. Treated wood must be stored on impermeable hard standing or on absorptive material to prevent runoff to the environment, and under shelter or covered with a tarpaulin. Any spill or contaminated material must be collected on such sites and disposed as hazardous waste.'. (5) As from 30 April 2023, the person responsible for the placing on the market of a treated article shall ensure that the label of that treated article includes the statement: 'Only allowed for use as a railway sleeper' or 'Only allowed for use as utility pole for electricity lines or for telecommunication lines', as appropriate. (6) As from 30 April 2023, the person responsible for the placing on the market of a treated article shall ensure that the label of that treated article includes the statement: 'The placing on the market is restricted to certain Member States of the European Union: verify on the website of the European Chemicals Agency where the placing on the market is allowed.'.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1990

of 20 October 2022

cancelling the approval of tolylfluanid as an active substance for use in biocidal products of product-type 7 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 15(1) thereof,

Whereas:

(1) Tolylfluanid was approved as an active substance for use in biocidal products of product-type 7, film preservatives, as described in Annex V to Regulation (EU) No 528/2012, by Commission Implementing Regulation (EU) 2016/1087 ([2]), subject to compliance with certain conditions ('the approval').

(2) On 2 March 2020, Denmark requested that the Commission should initiate a review of the approval pursuant to Article 15(1) of Regulation (EU) No 528/2012, on the basis of significant indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. In more detail, a metabolite of tolylfluanid, dimethylsulfamid, has been found in a great number of Danish drinking water supplies, and these contaminations can be linked with use of paints treated with tolylfluanid. Where groundwater is ozonated in water treatment for the production of drinking water, dimethylsulfamid may turn into N-nitrosodimethylamine which is genotoxic, mutagenic and carcinogenic. Denmark therefore requested a revision of the evaluation of the groundwater risk assessment for tolylfluanid for product-type 7, with the view to restrict the use of tolylfluanid in outdoor paints treated with tolylfluanid.

(3) On 5 July 2021, the Commission announced to the initial applicant for approval of tolylfluanid its intention to start the procedure for the review of the approval of that active substance for product-type 7 in accordance with Article 15(1) of Regulation (EU) No 528/2012, and provided an opportunity for the initial applicant to submit comments. Moreover, the Commission made publicly available the information that it is carrying out this review on the website of the Directorate-General for Health and Food Safety in accordance with Article 15(1) of Regulation (EU) No 528/2012.

(4) On 7 October 2021, the initial applicant for the approval of tolylfluanid indicated that it stopped the production of the active substance and the placing on the market of biocidal products containing it, and will not seek the renewal of approval of the substance. The initial applicant for the approval of tolylfluanid is the only substance supplier within the meaning of Article 95(1), first subparagraph, of Regulation (EU) No 528/2012 included in the list referred to in that subparagraph, for that active substance and product-type, published on the European Chemicals Agency's website. Furthermore, no biocidal product containing tolylfluanid for product-type 7 is authorised in the Union.

(5) Given that there are no other suppliers of the substance, that no biocidal product containing tolylfluanid for product-type 7 is authorised in the Union and that the initial applicant will not seek the renewal of approval of the substance, the Commission did not consult the European Chemicals Agency pursuant to Article 15(2) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2016/1087 of 5 July 2016 approving tolylfluanid as an existing active substance for use in biocidal products of product-type 7 (OJ L 180, 6.7.2016, p. 18).

(6) After having reviewed the information provided, the Commission considers that the use of tolylfluanid in biocidal products and treated articles raises significant concerns about the safety of such biocidal products and treated articles. Given the fact that there are no other suppliers of the substance, that no biocidal product containing tolylfluanid for product-type 7 is authorised in the Union and that the initial applicant will not seek the renewal of approval of the substance, the Commission considers appropriate to cancel the approval of tolylfluanid as an active substance for use in biocidal products of product-type 7.

(7) Implementing Regulation (EU) 2016/1087 should therefore be repealed.

(8) As economic operators need time to adapt to the cancellation of the approval, it should be allowed to continue placing on the Union market treated articles treated with or incorporating tolylfluanid for product-type 7 for some time.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of tolylfluanid as an active substance for use in biocidal products of product-type 7 is cancelled.

Article 2

Implementing Regulation (EU) 2016/1087 is repealed with effect from 10 November 2022.

Article 3

Treated articles treated with or incorporating tolylfluanid for product-type 7 shall not be placed on the Union market from 10 May 2023.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1991

of 20 October 2022

approving didecyldimethylammonium chloride as an active substance for use in biocidal products of product-types 1 and 2 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes didecyldimethylammonium chloride.

(2) Didecyldimethylammonium chloride has been evaluated for use in biocidal products of product-type 1 (human hygiene biocidal products) and product-type 2 (private area and public health area disinfectants and other biocidal products), as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond respectively to product-types 1 and 2 as described in Annex V to Regulation (EU) No 528/2012.

(3) Italy was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 10 September 2012. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1) of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency ([4]) on 2 December 2021, having regard to the conclusions of the evaluating competent authority.

(6) According to those opinions biocidal products of product-types 1 and 2 containing didecyldimethylammonium chloride may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), read in conjunction with Article 10(1) of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([4]) Biocidal Products Committee Opinions on the applications for approval of the active substance didecyldimethylammonium chloride; Product-types: 1 and 2; ECHA/BPC/311/2021 and ECHA/BPC/312/2021, adopted on 2 December 2021.

(7) Taking into account the opinions of the Agency, it is appropriate to approve didecyldimethylammonium chloride as an active substance for use in biocidal products of product-types 1 and 2 subject to compliance with certain conditions.

(8) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Didecyldimethylammonium chloride is approved as an active substance for use in biocidal products of product-types 1 and 2 subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Didecyldimethy-lammonium chloride	IUPAC name: N,N-Didecyl-N,N-dimethylammonium chloride EC No: 230-525-2 CAS No: 7173-51-5	908 g/kg dry weight	1 February 2024	31 January 2034	1	The authorisation of biocidal products is subject to the following condition: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
					2	The authorisation of biocidal products is subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. 2. The product assessment shall pay particular attention to the exposure and potential risks for professional users.

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1992

of 20 October 2022

approving *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents.

(2) *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents has been evaluated for use in biocidal products of product-type 19, repellents and attractants, as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 19 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Spain was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 1 September 2010. After the submission of the assessment report, discussions took place in technical meetings organised by the Commission and, after 1 September 2013, by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1) of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency ([4]) on 3 December 2021, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion the biocidal products of product-type 19 containing *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), of Directive 98/8/EC, provided that requirements concerning their use are complied with.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents; Product-type: 19. ECHA/BPC/314/2021, adopted on 3 December 2021.

(7) Taking into account the opinion of the Agency, it is appropriate to approve *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents as an active substance for use in biocidal products of product-type 19 subject to compliance with certain conditions.

(8) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents is approved as an active substance for use in biocidal products of product-type 19 subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Chrysanthemum cinerariaefolium extract from hydrocarbon solvents	IUPAC name: *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents EC No: 289-699-3 CAS No: 89997-63-7	100 % w/w of *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents	1 February 2024	31 January 2034	19	The authorisation of biocidal products is subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (2) The product assessment shall pay particular attention to the exposure of and potential risks for non-professional users and the general public; (3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council [2] or Regulation (EC) No 396/2005 of the European Parliament and of the Council [3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1993

of 20 October 2022

approving *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide.

(2) *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide has been evaluated for use in biocidal products of product-type 19 (repellents and attractants), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-type 19 as described in Annex V to Regulation (EU) No 528/2012.

(3) Spain was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 1 September 2010. After the submission of the assessment report, discussions took place in technical meetings organised by the Commission and, after 1 September 2013, by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be assessed in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1) of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency ([4]) on 3 December 2021, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products of product-type 19 containing *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d) of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide; Product-type 19; ECHA/BPC/313/2021, adopted on 3 December 2021.

(7) Taking into account the opinion of the Agency, it is appropriate to approve *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide as an active substance for use in biocidal products of product-type 19 subject to compliance with certain conditions.

(8) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide is approved as an active substance for use in biocidal products of product-type 19 subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Chrysanthemum cinerariaefolium extract from supercritical carbon dioxide	*Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide EC No: 289-699-3 CAS No: 89997-63-7	100 % w/w of *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide	1 February 2024	31 January 2034	19	The authorisation of biocidal products is subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) The product assessment shall pay particular attention to the exposure of and potential risks for non-professional users and the general public; (3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council [2] or Regulation (EC) No 396/2005 of the European Parliament and of the Council [3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING DECISION (EU) 2022/2005

of 21 October 2022

not approving methylene dithiocyanate as an existing active substance for use in biocidal products of product-type 12 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes methylene dithiocyanate (EC No: 228-652-3; CAS No: 6317-18-6).

(2) Methylene dithiocyanate has been evaluated for use in biocidal products of product-type 12, slimicides, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-type 12 as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 7 August 2013. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 8 March 2022 ([4]), having regard to the conclusions of the evaluating competent authority.

(6) According to the opinion of the Agency, biocidal products of product-type 12 containing methylene dithiocyanate cannot be expected to meet the criteria laid down in Article 5(1), points (b) (iii) and (iv), and (c), read in conjunction with Article 10(1) of Directive 98/8/EC. The applicant did not submit data of sufficient quality to meet the data requirements set out in point 2.7 (specification of purity of the active substance in g/kg or g/l, as appropriate), point 2.8 (identity of impurities and additives together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate), and point 4.1 (analytical methods for the determination of pure active substance and, where

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance: methylene dithiocyanate, Product type: 12, ECHA/BPC/322/2022, adopted on 8 March 2022.

appropriate, for relevant degradation products, isomers and impurities of the active substance and additives) of Title II of Annex IIA to Directive 98/8/EC. As a result, it was impossible to confirm the minimum purity of the active substance and to set a reference specification for methylene dithiocyanate. Moreover, it was not possible to confirm that the material used to conduct (eco)toxicological studies cover the presented specifications and to conclude on the relevance of the impurities due to the lack of (eco)toxicological data. Lastly, the environmental risk assessment identified unacceptable risks, and no suitable risk mitigation measure could be identified.

(7) Taking into account the opinion of the Agency, it is not appropriate to approve methylene dithiocyanate for use in biocidal products of product-type 12.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal products,

HAS ADOPTED THIS DECISION:

Article 1

Methylene dithiocyanate (EC No: 228-652-3; CAS No: 6317-18-6) is not approved as an active substance for use in biocidal products of product-type 12.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 21 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2048

of 24 October 2022

approving L-(+)-lactic acid as an existing active substance for use in biocidal products of product-type 6 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes L-(+)-lactic acid.

(2) L-(+)-lactic acid has been evaluated for use in biocidal products of product-type 6, preservatives for products during storage, as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 3 September 2020.

(4) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency ([3]) on 15 June 2021, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, the biocidal products of product-type 6 containing L-(+)-lactic acid may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that conditions concerning their use are complied with.

(6) Taking into account the opinion of the Agency, it is appropriate to approve L-(+)-lactic acid for use in biocidal products of product-type 6 subject to compliance with certain conditions.

(7) In particular, since L-(+)-lactic acid is classified for skin corrosion/irritation, sub-category 1C, and eye damage and irritation, Category 1, as specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]), the person responsible for placing on the market of substances or mixtures treated with or incorporating the active substance at concentrations leading to classification for skin corrosion/irritation or eye damage/eye irritation should ensure that exposure to the general public is minimised by appropriate risk mitigation measures.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Biocidal Products Committee Opinion on the application for approval of the active substance: L-(+)-lactic acid, Product type: 6; ECHA/BPC/280/2021, adopted on 15 June 2021.

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(8) Since L-(+)-lactic acid meets the criteria for classification as corrosive to the respiratory tract as specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, the person responsible for placing on the market of substances or mixtures treated with or incorporating the active substance at a concentration leading to classification for corrosion of the respiratory tract should ensure that exposure to the general public is minimised by appropriate risk mitigation measures.

(9) In order to guarantee a safe use of biocidal products containing L-(+)-lactic acid in treated articles and enable users of treated articles to make informed choices, the person responsible for the placing on the market of a treated article treated with or incorporating L-(+)-lactic acid should ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. Furthermore, Member States competent authorities or, in the case of a Union authorisation, the Commission should specify in the summary of the biocidal product characteristics of a biocidal product containing L-(+)-lactic acid the relevant instructions for use and precautions to be included on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

(10) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

L-(+)-lactic acid is approved as an active substance for use in biocidal products of product-type 6, subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
L-(+)-lactic acid	IUPAC Name: (2S)-2-Hydroxypropanoic acid EC No: 201-196-2 CAS No: 79-33-4	≥ 955 g/kg (dry weight)	1 November 2023	31 October 2033	6	The authorisation of biocidal products is subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment ([2]) of the active substance. 2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) industrial and professional users; (b) non-professional users. The placing on the market of treated articles is subject to the following conditions: 1) The person responsible for the placing on the market of a substance or mixture treated with or incorporating L-(+)-lactic acid at concentrations in the substance or mixture leading to classification for: (a) local effects concerning skin corrosion/irritation or eye damage/eye irritation, in accordance with Regulation (EC) No 1272/2008, shall ensure that exposure to the general public is minimised by appropriate risk mitigation measures. Those measures may include using a gel-like formulation, a packaging with dosing aid or a packaging with a self-dissolving shell; (b) acute toxicity regarding corrosivity to the respiratory tract, in accordance with Regulation (EC) No 1272/2008, shall ensure that airborne exposure to the general public is minimised by appropriate risk mitigation measures. Those measures may include a label to indicate: no entry in the treated area until dry, or no application in the presence of the/in proximity to general public.

						2) The person responsible for the placing on the market of a treated article treated with or incorporating L-(+)-lactic acid shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. 3) Member States competent authorities or, in the case of a Union authorisation, the Commission shall specify in the summary of the biocidal product characteristics of a biocidal product containing L-(+)-lactic acid the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

(2) Biocidal Products Committee Opinion on the application for approval of the active substance: L-(+)-lactic acid, Product type: 6; ECHA/BPC/280/2021, adopted on 15 June 2021.

COMMISSION IMPLEMENTING DECISION (EU) 2022/2054

of 21 October 2022

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Preventol A 12 TK 50 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2022) 7408)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 36(3) thereof,

Whereas:

(1) On 29 November 2016, the company Lanxess Deutschland GmbH ('the applicant') submitted an application for the mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Preventol A 12 TK 50 ('the biocidal product') to the competent authorities of a number of Member States, including France, Sweden and Germany. The biocidal product, containing propiconazole as an active substance, is a film preservative of product-type 7, to be used by industrial users to preserve water-based and solvent-based paints and coatings. The Netherlands is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) On 16 September 2020, Germany referred objections to the coordination group indicating that the conditions of the authorisation set by the Netherlands do not ensure that the biocidal product meets the requirements laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

(3) On 17 September 2020, the secretariat of the coordination group invited the other concerned Member States and the applicant to submit written comments on the referral. The applicant submitted written comments on 29 September 2020. The referral was discussed in the coordination group on 21 October 2020 with the participation of the applicant.

(4) Germany considers that risk mitigation measures for placing on the market of treated articles treated with or incorporating the product can only be included in an authorisation of a biocidal product if they were referred to in the conditions of approval of the active substance. As Commission Implementing Regulation (EU) 2015/1609 ([2]) does not include the necessary risk mitigation measures for placing on the market of treated articles treated with or incorporating the product, Germany considers that the risk mitigation measures for placing on the market of treated articles proposed by the Netherlands cannot be included in the authorisation of the biocidal product. Consequently, according to Germany, as unacceptable effects on human health and the environment from the use of the biocidal product cannot be properly addressed in the authorisation of the product, the product therefore should not be authorised.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/1609 of 24 September 2015 approving propiconazole as an existing active substance for use in biocidal products for product-type 7 (OJ L 249, 25.9.2015, p. 17).

(5) As no agreement was reached by the coordination group on the objection raised by Germany, on 16 December 2021 the Netherlands referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the applicant.

(6) Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 provides that one of the conditions for granting an authorisation is that it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI to that Regulation, that the biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans and animals, and on the environment.

(7) Article 19(2), point (b), of Regulation (EU) No 528/2012 provides that the evaluation of whether a biocidal product fulfils the criteria set out in paragraph 1, point (b), of that Article is to take into account the way in which treated articles treated with the biocidal product or containing the biocidal product may be used.

(8) Article 58(2) of Regulation (EU) No 528/2012 provides that a treated article is not to be placed on the market unless all active substances contained in the biocidal product that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2) of that Regulation, for the relevant product-type and use, or in Annex I to that Regulation, and any conditions or restrictions specified therein are met. The Netherlands concluded that there would be unacceptable effects on human health and the environment arising from the use of the biocidal product which necessitate risk mitigation measures on the placing on the market and use of treated articles treated with or incorporating the biocidal product to be included in the authorisation of the biocidal product. The conditions set in Implementing Regulation (EU) 2015/1609 do not include specific risk mitigation measures related to placing on the market of treated articles treated with or incorporating propiconazole, and that Implementing Regulation does not provide the possibility for the competent authorities of Member States to set those risk mitigation measures in the authorisation of biocidal products containing propiconazole for product-type 7, which would be needed to address the unacceptable risks identified for human health and the environment from the use of treated articles treated with or incorporating the biocidal product.

(9) After having carefully examined all the information the Commission understands that the fulfilment of the conditions in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 for the biocidal product cannot be ensured by imposing conditions on the use of the biocidal products in the treated articles without simultaneously imposing obligations on the persons placing on the market treated articles incorporating those biocidal products. However, as the necessary conditions or restrictions for ensuring a safe use of the biocidal product taking into account the way in which treated articles treated with or containing the biocidal product may be used were not set in Implementing Regulation (EU) 2015/1609 and cannot be laid down in the authorisation of the biocidal product, the use of the biocidal product in the treated articles would have unacceptable effects on human health and the environment.

(10) Consequently, the Commission considers that given that the safe use of the biocidal product in treated articles cannot be ensured only by imposing conditions on the use of the biocidal products in the treated articles without simultaneously imposing obligations on the persons placing on the market of treated articles, the product does not meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012.

(11) On 21 June 2022, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. On 18 July 2022 the applicant provided written comments that the Commission has taken into account.

(12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Given that the safe use of the biocidal product in treated articles cannot be ensured only by imposing conditions on the use of the biocidal products in the treated articles, the biocidal product identified by the case number BC-HH028132-58 in the Register for Biocidal Products does not meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 21 October 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/1195/2022
(POOL/E4/2022/1195/1195-EN.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving 1,2-benzisothiazol-3(2H)-one (BIT) as an active substance for use in biocidal products of product-type 10 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving 1,2-benzisothiazol-3(2H)-one (BIT) as an active substance for use in biocidal products of product-type 10 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[1], and in particular Article 9(1), point (b), thereof,

Whereas:

(1) Pursuant to Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], an application for approval of 1,2-benzisothiazol-3(2H)-one (BIT) for use in biocidal products of product-type 10, masonry preservatives, as described in Annex V of that Directive, corresponding to product-type 10, construction material preservatives, as described in Annex V to Regulation (EU) No 528/2012, was submitted to the competent authority of Spain on 22 December 2009.

(2) Pursuant to Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 are to be evaluated by the competent authorities in accordance with the provisions of that Regulation.

(3) On 1 October 2019, during the evaluation of the active substance by the evaluating competent authority, the applicant withdrew its application and no longer requests the approval of BIT as an active substance for use in biocidal products of product-type 10.

(4) BIT is not included for product-type 10 in Annex II to Commission Delegated Regulation (EU) No 1062/2014[3], which lists the active substance/product-type combinations included in the work programme for the examination of existing biocidal active substances contained in biocidal products. Biocidal products of product-type 10 containing BIT are therefore not covered by the transitional provisions laid down in Article 89(2) of Regulation (EU) No 528/2012 and may therefore not be made available or used on the Union market.

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1 OJ L 167, 27.6.2012, p. 1.

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

3 Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

(5) However, in accordance with the transitional provision set out in Article 94(1), point (a), of Regulation (EU) No 528/2012, a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) of that Regulation on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) of that Regulation for the relevant product-type and use or included in Annex I, may be placed on the market until the date falling 180 days after a decision not to approve one of the active substances for the relevant use, when such decision is adopted after 1 September 2016.

(6) As the applicant has withdrawn the application for approval of BIT for use in biocidal products of product-type 10, there is no biocidal product to be evaluated. Consequently, the competent authority did not finalise the assessment report and the European Chemicals Agency did not prepare an opinion. Finally, as there is no biocidal product of product-type 10 containing BIT that may be expected to meet the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, the conditions laid down in Article 4(1) of that Regulation are not met. Considering also the need to ensure that treated articles treated with or intentionally incorporating BIT for product-type 10 are no longer placed on the Union market, it is appropriate not to approve BIT for use in biocidal products of product-type 10.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

1,2-benzisothiazol-3(2H)-one (BIT) (EC No: 220-120-9; CAS No: 2634-33-5) is not approved as an active substance for use in biocidal products of product-type 10.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/1198/2022
(POOL/E4/2022/1198/1198-EN.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving epsilon-metofluthrin as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving epsilon-metofluthrin as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[1], and in particular Article 9(1), point (b), thereof,

Whereas:

(1) Pursuant to Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], an application for approval of epsilon-metofluthrin for use in biocidal products of product-type 19, repellents and attractants, as described in Annex V of that Directive, corresponding to product-type 19, repellents and attractants, as described in Annex V to Regulation (EU) No 528/2012, was in January 2011 submitted to the competent authority of the United Kingdom, replaced by the competent authority of Spain as of 1 February 2020.

(2) Pursuant to Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 are to be evaluated by the competent authorities in accordance with the provisions of that Regulation.

(3) On 24 October 2019, during the preparation of the opinion on the approval by the European Chemicals Agency, the applicant withdrew its application and no longer requests the approval of epsilon-metofluthrin as an active substance for use in biocidal products of product-type 19.

(4) Epsilon-metofluthrin is not included for product-type 19 in Annex II to Commission Delegated Regulation (EU) No 1062/2014[3], which lists the active substance/product-type combinations included in the work programme for the examination of existing biocidal active substances contained in biocidal products. Biocidal products of product-type 19 containing epsilon-metofluthrin are therefore not covered by the

[1] OJ L 167, 27.6.2012, p. 1.

[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

[3] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

transitional provisions laid down in Article 89(2) of Regulation (EU) No 528/2012 and may therefore not be made available or used on the Union market.

(5) However, in accordance with the transitional provision set out in Article 94(1), point (a), of Regulation (EU) No 528/2012, a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) of that Regulation on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) of that Regulation for the relevant product-type and use or included in Annex I, may be placed on the market until the date falling 180 days after a decision not to approve one of the active substances for the relevant use, when such decision is adopted after 1 September 2016.

(6) As the applicant has withdrawn the application for approval of epsilon-metofluthrin for use in biocidal products of product-type 19, there is no biocidal product to be evaluated. Consequently, the European Chemicals Agency did not prepare an opinion. Finally, as there is no biocidal product of product-type 19 containing epsilon-metofluthrin that may be expected to meet the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, the conditions laid down in Article 4(1) of that Regulation are not met. Considering also the need to ensure that treated articles treated with or intentionally incorporating epsilon-metofluthrin for product-type 19 are no longer placed on the Union market, it is appropriate not to approve epsilon-metofluthrin for use in biocidal products of product-type 19.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Epsilon-metofluthrin (CAS No: 240494-71-7) is not approved as an active substance for use in biocidal products of product-type 19.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/1197/2022
(POOL/E4/2022/1197/1197-EN.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving chloramin B as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving chloramin B as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[1], and in particular Article 9(1), point (b), thereof,

Whereas:

(1) Pursuant to Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], applications for approval of chloramin B for use in biocidal products of product-types 2, 3, 4 and 5 (private area and public health area disinfectants and other biocidal products, veterinary hygiene biocidal products, food and feed area disinfectants, drinking water disinfectants) as described in Annex V of that Directive, corresponding to product-types 2, 3, 4 and 5 (disinfectants and algaecides not intended for direct application to humans or animals, veterinary hygiene, food and feed area, drinking water) as described in Annex V to Regulation (EU) No 528/2012, were submitted to the competent authority of the Czech Republic on 25 October 2008.

(2) Pursuant to Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 are to be evaluated by the competent authorities in accordance with the provisions of that Regulation.

(3) On 25 October 2021, during the evaluation of the active substance by the evaluating competent authority, the applicant withdrew its applications and no longer requests the approval of chloramin B as an active substance for use in biocidal products of product-types 2, 3, 4 and 5.

(4) Chloramin B is not included for product-types 2, 3, 4 and 5 in Annex II to Commission Delegated Regulation (EU) No 1062/2014[3], which lists the active substance/product-type combinations included in the work programme for the examination of existing biocidal active substances contained in biocidal products.

[1] OJ L 167, 27.6.2012, p. 1.

[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

[3] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

Biocidal products of product-types 2, 3, 4 and 5 containing chloramin B are therefore not covered by the transitional provisions laid down in Article 89(2) of Regulation (EU) No 528/2012 and may therefore not be made available or used on the Union market.

(5) However, in accordance with the transitional provision set out in Article 94(1), point (a), of Regulation (EU) No 528/2012, a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) of that Regulation on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) of that Regulation for the relevant product-type and use or included in Annex I, may be placed on the market until the date falling 180 days after a decision not to approve one of the active substances for the relevant use, when such decision is adopted after 1 September 2016.

(6) As the applicant has withdrawn the applications for approval of chloramin B for use in biocidal products of product-types 2, 3, 4 and 5, there are no biocidal products to be evaluated. Consequently, the competent authority did not finalise the assessment reports and the European Chemicals Agency did not prepare any opinion. Finally, as there are no biocidal products of product-types 2, 3, 4 and 5 containing chloramin B that may be expected to meet the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, the conditions laid down in Article 4(1) of that Regulation are not met. Considering also the need to ensure that treated articles treated with or intentionally incorporating chloramin B for product-types 2, 3, 4 and 5 are no longer placed on the Union market, it is appropriate not to approve chloramin B for use in biocidal products of product-types 2, 3, 4 and 5.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Chloramin B (EC No: 204-847-9; CAS No: 127-52-6) is not approved as an active substance for use in biocidal products of product-types 2, 3, 4 and 5.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/1196/2022
(POOL/E4/2022/1196/1196-EN.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving silver nitrate as an active substance for use in biocidal products of product-type 7 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving silver nitrate as an active substance for use in biocidal products of product-type 7 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[1], and in particular Article 9(1), point (b), thereof,

Whereas:

(1) Pursuant to Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], an application for approval of silver nitrate for use in biocidal products of product-type 7, film preservatives, as described in Annex V of that Directive, corresponding to product-type 7, film preservatives, as described in Annex V to Regulation (EU) No 528/2012, was submitted to the competent authority of Sweden on 23 December 2010.

(2) Pursuant to Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 are to be evaluated by the competent authorities in accordance with the provisions of that Regulation.

(3) On 10 February 2022, during the evaluation of the active substance by the evaluating competent authority, the applicant withdrew its application and no longer requests the approval of silver nitrate as an active substance for use in biocidal products of product-type 7.

(4) Silver nitrate is not included for product-type 7 in Annex II to Commission Delegated Regulation (EU) No 1062/2014[3], which lists the active substance/product-type combinations included in the work programme for the examination of existing biocidal active substances contained in biocidal products. Biocidal products of product-type 7 containing silver nitrate are therefore not covered by the transitional provisions laid down in Article 89(2) of Regulation (EU) No 528/2012 and may therefore not be made available or used on the Union market.

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1 OJ L 167, 27.6.2012, p. 1.

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

3 Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

(5) However, in accordance with the transitional provision set out in Article 94(1), point (a), of Regulation (EU) No 528/2012, a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) of that Regulation on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) of that Regulation for the relevant product-type and use or included in Annex I, may be placed on the market until the date falling 180 days after a decision not to approve one of the active substances for the relevant use, when such decision is adopted after 1 September 2016.

(6) As the applicant has withdrawn the application for approval of silver nitrate for use in biocidal products of product-type 7, there is no biocidal product to be evaluated. Consequently, the competent authority did not finalise the assessment report and the European Chemicals Agency did not prepare an opinion. Finally, as there is no biocidal product of product-type 7 containing silver nitrate that may be expected to meet the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, the conditions laid down in Article 4(1) of that Regulation are not met. Considering also the need to ensure that treated articles treated with or intentionally incorporating silver nitrate for product-type 7 are no longer placed on the Union market, it is appropriate not to approve silver nitrate for use in biocidal products of product-type 7.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Silver nitrate (EC No: 231-853-9; CAS No: 7761-88-8) is not approved as an active substance for use in biocidal products of product-type 7.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/1890/2022
(POOL/E4/2022/1890/1890-EN.doc)
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[1], and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Propiconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 31 March 2020 under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) On 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of propiconazole for use in biocidal products of product-type 8 ('the application').

(3) On 8 February 2019, the evaluating competent authority of Finland informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) Commission Implementing Decision (EU) 2020/27[3] postponed the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 to 31 March 2021 in order to allow sufficient time for the examination of the application.

(5) Commission Implementing Decision (EU) 2021/354[4] postponed again the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 to 31 December 2022.

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1 OJ L 167, 27.6.2012, p. 1.

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

3 Commission Implementing Decision (EU) 2020/27 of 13 January 2020 postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8 (OJ L 8, 14.1.2020, p. 39).

4 Commission Implementing Decision (EU) 2021/354 of 25 February 2021 postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8 (OJ L 68, 26.2.2021, p. 219).

(6) On 2 June 2021, the evaluating competent authority submitted the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency'). Within 270 days of receipt of a recommendation from the evaluating competent authority, the Agency is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(7) On 9 March 2022, the Agency adopted its opinion[5] on renewal of the approval of propiconazole in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(8) Propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6], and therefore meets the exclusion criterion set out in point (c) of Article 5(1) of Regulation (EU) No 528/2012. Furthermore, propiconazole is considered as having endocrine disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in point (d) of Article 5(1) of Regulation (EU) No 528/2012. While the examination to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled, and whether the approval of propiconazole may therefore be renewed, is ongoing, it will not be possible to complete this examination before the current expiry of approval.

(9) Consequently, for reasons beyond the control of the applicant, the approval of propiconazole for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to complete the full procedure of the examination of the application. Taking into account the time needed to assess if at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled, and the time to decide whether to renew the approval of propiconazole for use in biocidal products of product-type 8, the expiry date should be postponed to 31 December 2023.

(10) After the postponement of the expiry date of the approval, propiconazole remains approved for use in biocidal products of product-type 8 subject to the requirements set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of propiconazole for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2021/354 is postponed to 31 December 2023.

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5 Biocidal Products Committee (BPC) opinion on the application for approval of the active substance: propiconazole, Product type: 8, ECHA/BPC/324/2022, adopted on 9 March 2022.

6 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula Von der Leyen