COMMISSION IMPLEMENTING DECISION (EU) 2023/458

of 1 March 2023

on the non-approval of certain active substances for use in biocidal products 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 in its Annex II a list of active substance/product-type combinations included in the review programme of existing active substances in biocidal products.

(2) For a number of active substance/product-type combinations included in that list, all the participants have withdrawn or are considered to have withdrawn their support in a timely manner.

(3) In accordance with Article 14(1) of Delegated Regulation (EU) No 1062/2014, the European Chemicals Agency published an open invitation to take over the role of participant for those active substance/product-type combinations for which the role of participant had not previously been taken over. For those combinations no notification has been submitted to the European Chemicals Agency within the time limit provided for by Article 14(2) of Delegated Regulation (EU) No 1062/2014. Therefore, those active substance/product-type combinations, in accordance with Article 20, first paragraph, point (b), of Delegated Regulation (EU) No 1062/2014, should not be approved for use in biocidal products.

(4) 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

The active substances listed in the Annex are not approved for the product-types indicated therein.

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*.

([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).

Done at Brussels, 1 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Active substance/product-type combinations not approved:

Entry Number in Annex II to Regulation (EU) No 1062/2014	Substance name	Rapporteur Member State	EC number	CAS number	Product-type(s)
1022	Dialuminium chloride pentahydroxide	NL	234-933-1	12042-91-0	2
691	Sodium N-(hydroxymethyl) glycinate	AT	274-357-8	70161-44-3	6
459	Reaction mass of titanium dioxide and silver chloride	SE	Not available	Not available	1, 2, 6, 7, 9, 10, 11
531	(benzyloxy)methanol	AT	238-588-8	14548-60-8	13
1016	Silver chloride	SE	232-033-3	7783-90-6	1
444	7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)	PL	231-810-4	7747-35-5	6, 13
797	cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	PL	426-020-3	51229-78-8	6, 13
368	Methenamine 3-chloroallylochloride (CTAC)	PL	223-805-0	4080-31-3	6, 12, 13

COMMISSION IMPLEMENTING DECISION (EU) 2023/459

of 2 March 2023

not approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing active substance for use in biocidal products of product-type 4 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 2,2-Dibromo-2-cyanoacetamide (DBNPA) (EC No: 233-539-7; CAS No: 10222-01-2).

(2) DBNPA has been evaluated for use in biocidal products of product-type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.

(3) Denmark 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 27 December 2016. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(4) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is responsible for preparing the opinion of the Agency regarding 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 25 June 2019 ('the opinion of 25 June 2019') ([3]), having regard to the conclusions of the evaluating competent authority.

(5) According to the opinion of 25 June 2019, DBNPA has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Commission Delegated Regulation (EU) 2017/2100 ([4]). DBNPA therefore meets the exclusion criteria set out in Article 5(1), point (d), of Regulation (EU) No 528/2012. The opinion of 25 June 2019 also considered that the risks to human health and the environment of using the representative biocidal product presented in the application for approval of DBNPA for product-type 4 were acceptable subject to appropriate risk mitigation measures, but also concluded that, given the exposure of humans and the environment to DBNPA, a risk related to endocrine-disrupting properties cannot be excluded.

([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: 2,2-Dibromo-2-cyanoacetamide (DBNPA), Product type: 4, ECHA/BPC/225/2019, adopted on 25 June 2019.

([4]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

(6) Pursuant to Article 5(2) of Regulation (EU) No 528/2012, an active substance meeting the exclusion criteria may only be approved if it is shown that at least one of the conditions for derogation set out in that Article is met. When deciding whether an active substance may be approved on that basis, the availability of suitable and sufficient alternative substances or technologies is to be a key consideration.

(7) The Commission, with the support of the Agency, carried out a public consultation between 11 October 2019 and 10 December 2019 ('the 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 25 June 2019 and the contributions to the public consultation were discussed by the Commission with the Member States representatives in the meeting of the Standing Committee on Biocidal Products of February 2020. The Commission asked the Member States 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 justification. It was concluded that there was a need to further analyse the information provided by the applicant during the consultation to assess whether the condition in Article 5(2), point (a), could be considered met. On 8 July 2020, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([5]) to revise its opinion and clarify whether a safe threshold may be derived in relation to the endocrine-disrupting properties of DBNPA, to assess the contribution of the use of DBNPA as a biocidal active substance to the average daily bromide consumption and to the environmental background, and to conclude whether the risks for human health and for the environment could be considered acceptable or not.

(9) The Biocidal Products Committee adopted the revised opinion of the Agency on 30 November 2021 ('the opinion of 30 November 2021') ([6]), having regard to the conclusions of the evaluating competent authority.

(10) According to the opinion of 30 November 2021, the risks associated with the exposure to DBNPA-derived bromide arising from the use of biocidal products containing DBNPA of product-type 4, including the risks resulting from its endocrine-disrupting effects, are considered acceptable for humans and the environment for the representative biocidal product presented in the application for approval, subject to appropriate risk mitigation measures. Therefore, without prejudice to the provisions of Article 5(2) of Regulation (EU) No 528/2012, biocidal products of product-type 4 containing DBNPA may be expected to satisfy the requirements laid down in Article 19(1), point (b), of that Regulation.

(11) The opinion of 30 November 2021 and the contributions to the public consultation were discussed by the Commission with the Member States representatives in the meetings of the Standing Committee on Biocidal Products of March 2022 and June 2022. The Commission again asked the Member States 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 justification. No Member State indicated that those conditions would be met in its territory, in the light of the availability of alternatives, which is a key consideration in the context of Article 5(2) of Regulation (EU) No 528/2012.

(12) In fact, based on the information collected and the views expressed by Member States, suitable and sufficient alternative substances or technologies are available. The representative biocidal product presented by the applicant in the application for approval is a product used for the disinfection of food processing vessels by professional/industrial users (such as industrial mayonnaise or yogurt producing facilities, fermenters for beer or other fermented

([5]) Mandate requesting ECHA an opinion under Article 75(1)(g) of the BPR, 'Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4'.

([6]) Biocidal Products Committee Opinion on the application for approval of the active substance: 2,2-Dibromo-2-cyanoacetamide (DBNPA), Product type: 4, ECHA/BPC/300/2021, adopted on 30 November 2021.

products). The opinion of 30 November 2021 lists several active substances as potential alternatives ([7]). 26 active substances are already approved for use in biocidal products of product-type 4, while another 37 active substances are still under examination within the work programme for the systematic examination of existing active substances pursuant to Article 89 of Regulation (EU) No 528/2012. Moreover, other active substances have been approved under Regulation (EU) No 528/2012 following the assessment of representative biocidal products similar to the representative biocidal product presented in the application for the approval of DBNPA ([8]). No evidence has been submitted by the applicant showing that any of those active substances could not be used for the same purpose as DBNPA. Lastly, several Member States representatives indicated during the discussions in the Standing Committee on Biocidal Products that no biocidal products containing DBNPA for product-type 4 were registered under their national rules or placed on their market despite the presence of food processing industries on their territory, and that alternative active substances and biocidal products were available on their territory for the same or similar use, like biocidal products containing peracetic acid or hydrogen peroxide.

(13) Furthermore, the representative biocidal product presented by the applicant cannot be considered as a product used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment, as, according to the opinion of 30 November 2021, its use may lead to the presence of residues in disinfected bottles even after rinsing and may lead to releases into the environment via waste water. Although the opinion of 30 November 2021 concludes that the risks to humans and to the environment could be considered acceptable, in view of the positions expressed by Member States representatives in the Standing Committee on Biocidal Products, it is not concluded that the risks could be considered negligible. Considering in addition that suitable and sufficient alternative substances or technologies are available, the condition in Article 5(2), point (a), of Regulation (EU) No 528/2012 is therefore not met.

(14) No specific information or justification has been submitted by the applicant to demonstrate that DBNPA would be essential to prevent or control a serious danger to human health, animal health or the environment. Considering in addition that suitable and sufficient alternative substances or technologies are available, the condition in Article 5(2), point (b), of Regulation (EU) No 528/2012 is therefore not met.

(15) No information has been submitted by the applicant that demonstrates that the non-approval of DBNPA would have disproportionate negative impacts on society when compared to the risks to human health, animal health or the environment arising from the use of the substance. Considering in addition that suitable and sufficient alternative substances or technologies are available, the condition in Article 5(2), point (c), of Regulation (EU) No 528/2012 is therefore not met.

(16) Consequently, the applicant has not shown that any of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is met. It is therefore appropriate not to approve DBNPA for use in biocidal products of product-type 4.

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

([7]) Biocidal Products Committee Opinion on the application for approval of the active substance: 2,2-Dibromo-2-cyanoacetamide (DBNPA), Product type: 4, ECHA/BPC/300/2021, adopted on 30 November 2021, on page 16: 2-phenoxy ethanol, Active chlorine (generated from sodium chloride by electrolysis or released from hypochlorous acid), Active chlorine (released from calcium hypochlorite), Active chlorine (released from sodium hypochlorite), Bromoacetic acid, C(M)IT/MIT, Decanoic acid, Glutaraldehyde, Hydrogen peroxide, Iodine, L(+) lactic acid, Octanoic acid, Peracetic acid, Peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium percarbonate, PHMB (1415;4.7), PHMB (1600;1.8), Polyvinyl-pyrrolidone iodine, Propan-1-ol, Propan-2-ol, Salicylic acid.

([8]) For instance: lactic acid, octanoic acid, decanoic acid, peracetic acid or glutaraldehyde.

HAS ADOPTED THIS DECISION:

Article 1

2,2-Dibromo-2-cyanoacetamide (DBNPA) (EC No: 233-539-7; CAS No: 10222-01-2) is not approved as an active substance for use in biocidal products of product-type 4.

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, 2 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2023/460

of 2 March 2023

postponing the expiry date of the approval of imidacloprid for use in biocidal products of product-type 18 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) Imidacloprid 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 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) The approval of imidacloprid for use in biocidal products of product-type 18 ('the approval') is to expire on 30 June 2023. On 23 and 24 December 2021, two applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the applications').

(3) On 27 April 2022, the evaluating competent authority of Germany informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications 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) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals 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.

(6) Consequently, for reasons beyond the control of the applicants, the approval 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 enable the examination of the applications. Taking into account the time-limits for evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of imidacloprid for use in biocidal products for product-type 18 may be renewed, the expiry date should be postponed to 31 December 2025.

(7) After the postponement of the expiry date of the approval, imidacloprid remains approved for use in biocidal products of product-type 18 subject to the conditions set out in Annex I to Directive 98/8/EC,

([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).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of imidacloprid for use in biocidal products of product-type 18 set out in Annex I to Directive 98/8/EC is postponed to 31 December 2025.

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, 2 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2023/470

of 2 March 2023

not approving d-Allethrin as an existing active substance for use in biocidal products of product-type 18 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 (RS)-3-Allyl-2-methyl-4-oxocyclopent-2- enyl-(1R,3R;1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 4 isomers 1R trans, 1R: 1R trans, 1S: 1R cis, 1R: 1R cis, 1S 4:4:1:1) ('d-Allethrin') (CAS No: 231937-89-6).

(2) D-Allethrin has been evaluated for use in biocidal products of product-type 18, (insecticides, acaricides and products to control other arthropods), 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 11 January 2017. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(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 on 12 October 2021 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) According to the opinion of the Agency, biocidal products of product-type 18 containing d-Allethrin cannot be expected to meet the criteria laid down in Article 19(1), points (b)(iii), and (iv), of Regulation (EU) No 528/2012.

(6) In its opinion, the Agency noted that the proposed reference specifications, established on the basis of data provided by one of the applicants, are not in line with the composition of the material that was used for testing to generate the toxicological data provided by the applicants. As a result, on the basis of the data provided in the applications, it could not be established whether the representative biocidal products could fulfil the criteria referred to in Article 19(1), point (b) of Regulation (EU) No 528/2012.

(7) According to the opinion of the Agency, based on the available toxicological data, an unacceptable risk has been identified for the general public due to secondary exposure to genotoxic photometabolites formed after the application of the representative products.

([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: d-Allethrin, Product type: 18, ECHA/BPC/293/2021, adopted on 12 October 2021.

(8) In addition, according to the opinion of the Agency, an unacceptable risk to the environment has been identified for the aquatic compartment (surface water and sediment) and for soil.

(9) In conclusion, no safe use could be identified when considering the risks to human health and the environment for each of the representative biocidal products submitted in the applications.

(10) The conditions for approval of d-Allethrin laid down in Article 4(1) of Regulation (EU) No 528/2012 are therefore not met.

(11) Taking into account the opinion of the Agency, it is not appropriate to approve d-Allethrin for use in biocidal products of product-type 18.

(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

D-Allethrin (CAS No: 231937-89-6) is not approved as an active substance for use in biocidal products of product-type 18.

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, 2 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2023/471

of 2 March 2023

postponing the expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one 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) 4,5-Dichloro-2-octyl-2H-isothiazol-3-one ('DCOIT') 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 is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) The approval of DCOIT for use in biocidal products of product-type 8 ('the approval') is to expire on 30 June 2023. On 23 December 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 24 October 2022, the evaluating competent authority of Norway 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) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals 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.

(6) Consequently, for reasons beyond the control of the applicant, the approval 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 enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of DCOIT for use in biocidal products for product-type 8 may be renewed, the expiry date should be postponed to 31 December 2025.

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

([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).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one for use in biocidal products of product-type 8 set out in Annex I to Directive 98/8/EC is postponed to 31 December 2025.

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, 2 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/680

of 23 March 2023

approving Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-C16})) as an active substance for use in biocidal products of product-type 1 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 Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-C16})).

(2) Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-C16})) has been evaluated for use in biocidal products of product-type 1, human hygiene biocidal products, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 1, disinfectants: human hygiene, 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 assessed in accordance with 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 2 December 2021, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products of product-type 1 containing Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-C16})) 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 Alkyl(C12-16) dimethylbenzyl ammonium chloride; Product-type: 1; ECHA/BPC/309/2021, adopted on 2 December 2021.

(7) Taking into account the opinion of the Agency, it is appropriate to approve Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-C16})) as an active substance for use in biocidal products of product-type 1 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

Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-C16})) is approved as an active substance for use in biocidal products of product-type 1 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, 23 March 2023.

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
Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride	IUPAC name: Quaternary ammonium compounds, benzyl-C_{12-16}-alkyldimethyl, chlorides EC No: 270-325-2 CAS No: 68424-85-1	Minimum purity of the active substance evaluated: 972 g/kg dry weight	1 July 2024	30 June 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.

[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.