COMMISSION IMPLEMENTING REGULATION (EU) 2021/1045

of 24 June 2021

approving didecyldimethyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4

(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 didecyldimethyl ammonium chloride (DDAC) to be renamed for the purposes of this Regulation as didecyldimethyl ammonium chloride as a result of its evaluation.

(2) Didecyldimethyl ammonium chloride has been evaluated for use in biocidal products of product-type 3, veterinary hygiene biocidal products and product-type 4, food and feed area disinfectants, 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 3 and 4 as defined 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.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the European Chemicals Agency ([4]) ('the Agency') on 6 October 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 3 and 4 containing didecyldimethyl ammonium chloride may be expected to satisfy the requirements laid down in Article 5(1)(b), (c) and (d) of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve didecyldimethyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4 subject to compliance with certain specifications and conditions.

(7) 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.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal 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]) 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: 3 and 4; ECHA/BPC/265/2020 and ECHA/BPC/266/2020, adopted on 6 October 2020.

HAS ADOPTED THIS REGULATION:

Article 1

Didecyldimethyl ammonium chloride is approved as an active substance for use in biocidal products of product-types 3 and 4 subject to the specifications and 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 June 2021.

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
Didecyldimethyl ammonium chloride	IUPAC name: N,N-Didecyl-N,N-dimethylammonium chloride EC No: 230-525-2 CAS No: 7173-51-5	Minimum purity of the active substance evaluated: 908 g/kg dry weight	1 November 2022	31 October 2032	3	The authorisation of biocidal products is subject to the following conditions: (a) 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. (b) In the light of the outcome of the risk assessment for the uses assessed, the product assessment shall pay particular attention to: (1) professional users; (2) sediment and soil following disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment. (c) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residues 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 the applicable MRLs are not exceeded.
					4	The authorisation of biocidal products is subject to the following conditions: (a) 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. (b) In the light of the outcome of the risk assessment for the used assessed, the product assessment shall pay particular attention to: (1) professional users; (2) sediment and soil following disinfection in slaughterhouses and butcheries.

						(c) For products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. (d) Didecyldimethyl ammonium chloride shall not be incorporated in materials and articles intended to come into contact with food falling within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([4]), unless the Commission has established specific limits on the migration of didecyldimethyl ammonium chloride into food or it has been established pursuant to that Regulation that such limits are not necessary.

([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).

([4]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1063

of 28 June 2021

approving alkyl (C_{12-16}) dimethylbenzyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4

(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 alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12}-C_{16})) to be renamed for the purposes of this Regulation as alkyl (C_{12-16}) dimethylbenzyl ammonium chloride as a result of its evaluation.

(2) Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride has been evaluated for use in biocidal products of product-type 3, veterinary hygiene biocidal products and product-type 4, food and feed area disinfectants, 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 3 and 4 as defined 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.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the European Chemical Agency ([4]) ('the Agency') on 6 October 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 3 and 4 containing alkyl (C_{12-16}) dimethylbenzyl ammonium chloride may be expected to satisfy the requirements laid down in Article 5(1)(b), (c) and (d) of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve alkyl (C12-16) dimethylbenzyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4, subject to compliance with certain specifications and conditions.

(7) 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.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal 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]) 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 alkyl(C_{12-16}) dimethylbenzyl ammonium chloride; Product types: 3 and 4; ECHA/BPC/267/2020 and ECHA/BPC/268/2020, adopted on 6 October 2020.

HAS ADOPTED THIS REGULATION:

Article 1

Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride is approved as an active substance for use in biocidal products of product-types 3 and 4 subject to the specifications and 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, 28 June 2021.

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: not applicable EC No: 270-325-2 CAS No: 68424-85-1	Minimum purity of the active substance evaluated: 972 g/kg dry weight	1 November 2022	31 October 2032	3	The authorisation of biocidal products is subject to the following conditions: (a) 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. (b) In the light of the outcome of the risk assessment for the uses assessed, the product assessment shall pay particular attention to: (1) professional users; (2) sediment following disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment; (3) soil following disinfection of vehicles used for animal transport, footwear disinfection and disinfection in hatcheries after fogging treatment. (c) 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 the applicable MRLs are not exceeded.
					4	The authorisation of biocidal products is subject to the following conditions: (a) 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. (b) In the light of the outcome of the risk assessment for the uses assessed, the product assessment shall pay particular attention to: (1) professional users;

						(2) sediment and soil following disinfection in slaughterhouses and butcheries. (c) For products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. (d) Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride shall not be incorporated in materials and articles intended to come into contact with food falling within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([4]), unless the Commission has established specific limits on the migration of alkyl (C_{12-16}) dimethylbenzyl ammonium chloride into food or it has been established pursuant to that Regulation that such limits are not necessary.

([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).

([4]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/2020/12424 Rev1
(POOL/E4/2020/12424/12424R1-EN.docx)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on the non-approval of certain active substances in biocidal products pursuant to 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 in its Annex II a list of active substance/product-type combinations included in the review programme of existing active substances in biocidal products on 30 March 2019.

(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 ('the 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 some of those combinations no notification has been submitted or the notification has been rejected pursuant to Article 17(4) or (5) of that Regulation. Those active substance/product-type combinations which, 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 are the following: metam-sodium (product-types 9 and 11); thiram (product-type 9); bronopol (product-type 9); peroxyoctanoic acid (product-type 2, 3, 4); Malt, ext. - Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Hordeum, Gramineae* (product-type 19); 2,2-Dibromo-2-cyanoacetamide (product-type 13).

(4) In addition, in accordance with Article 12(3) of Delegated Regulation (EU) No 1062/2014, the Agency informed the Commission of those active substance/product-type combinations for which all participants have withdrawn or are considered to have withdrawn their support in a timely manner, and for which the role of participant had

[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).

previously been taken over. Those active substance/product-type combinations which, in accordance with Article 20, first paragraph, point (a), of that Regulation, should not be approved for use in biocidal products are the following: silver, as a nanomaterial (product-types 2, 4, 9); *eucalyptus citriodora* oil and citronellal, hydrated, cyclized (product-type 19); 2-Hydroxy-α,α,4-trimethylcyclohexanemethanol (product-type 19); chlorine dioxide generated from sodium chlorite and sodium persulfate (product-types 2, 3, 4, 5, 11); amines, C10-16-alkyldimethyl, N-oxides (product-type 4); *capsicum oleoresin* (product-type 19); *capsicum annuum*, ext. (product-type 19); reaction mass of (6E)-N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnon-6-enamide and N-(4-hydroxy-3-methoxy-2-methylphenyl)-8- methylnonanamide (product-type 19).

(5) 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*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12424/2020 ANNEX Rev1
(POOL/E4/2020/12424/12424R1-EN
ANNEX.docx)
[…](2021) XXX draft

ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING DECISION (EU) .../...

on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council

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)
9	Bronopol	ES	200-143-0	52-51-7	9
206	Thiram	BE	205-286-2	137-26-8	9
210	Metam-sodium	BE	137-26-8	137-42-8	9, 11
1023	Silver, as a nanomaterial	SE	231-131-3	7440-22-4	2, 4, 9
494	2,2-Dibromo-2-cyanoacetamide (DBNPA)	DK	233-539-7	10222-01-2	13
1047	*Eucalyptus citriodora* oil and citronellal, hydrated, cyclized	CZ	n/a	n/a	19
609	2-Hydroxy-α,α,4-trimethylcyclohexanemethanol	CZ	255-953-7	42822-86-6	19
813	Peroxyoctanoic acid	FR	n/a	33734-57-5	2, 3, 4
1044	Chlorine dioxide generated from sodium chlorite and sodium persulfate	DE	n/a	n/a	2, 3, 4, 5, 11
1064	Malt, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Hordeum, Gramineae*	AT	232-310-9	8002-48-0	19
692	Amines, C10-16-alkyldimethyl, N-oxides	PT	274-687-2	70592-80-2	4

1059	*Capsicum oleoresin* Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes, and oxidation or polymerization products of these terpenes. (*Capsicum frutescens, Solanaceae*)	BE	Not available	8023-77-6	19
1060	*Capsicum annuum*, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Capsicum annuum, Solanaceae*.	BE	283-403-6	84625-29-6	19
1061	Reaction mass of (6E)-N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnon-6-enamide and N-(4-hydroxy-3- methoxy-2-methylphenyl)-8-methylnonanamide	BE	Not available	Not available	19

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12420/2020 Rev1
(POOL/E4/2020/12420/12420R1-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of boric acid for use in biocidal products of product-type 8

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of boric acid for use in biocidal products of product-type 8

(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) The active substance boric acid 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 specifications and conditions set out in Annex I to that Directive.

(2) The approval of boric acid for use in biocidal products of product-type 8 will expire on 31 August 2021. On 28 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of boric acid.

(3) As boric acid is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3], it meets the exclusion criteria set out in Article 5(1), point (c), of Regulation (EU) No 528/2012.

(4) On 2 July 2020, the evaluating competent authority of the Netherlands 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 Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a

[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] 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).

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.

(6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('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) Consequently, for reasons beyond the control of the applicant, the approval of boric acid 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 approval of boric acid for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of boric acid may therefore be renewed, it is appropriate to postpone the expiry date of approval to 28 February 2024.

(8) Except for the expiry date of approval, boric acid remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of boric acid for use in biocidal products of product-type 8 is postponed to 28 February 2024.

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
SANTE/12422/2020 Rev1
(POOL/E4/2020/12422/12422R1-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8

(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) The active substance disodium tetraborate 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 specifications and conditions set out in Annex I to that Directive.

(2) The approval of disodium tetraborate for use in biocidal products of product-type 8 will expire on 31 August 2021. On 28 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of disodium tetraborate.

(3) As disodium tetraborate is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3], it meets the exclusion criteria set out in Article 5(1), point (c), of Regulation (EU) No 528/2012.

(4) On 2 July 2020, the evaluating competent authority of the Netherlands 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 Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a

[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] 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).

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.

(6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('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) Consequently, for reasons beyond the control of the applicant, the approval of disodium tetraborate 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 approval of disodium tetraborate for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of disodium tetraborate may therefore be renewed, it is appropriate to postpone the expiry date of approval to 28 February 2024.

(8) Except for the expiry date of approval, disodium tetraborate remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8 is postponed to 28 February 2024.

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
SANTE/10500/2021 Rev1
(POOL/E4/2021/10500/10500R1-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of hexaflumuron for use in biocidal products of product-type 18

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of hexaflumuron for use in biocidal products of product-type 18

(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) The active substance hexaflumuron was approved as an active substance for use in biocidal products of product-type 18[2].

(2) The approval of hexaflumuron for use in biocidal products of product-type 18 will expire on 31 March 2022. On 23 September 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of hexaflumuron.

(3) As hexaflumuron meets the criteria for being a persistent, bioaccumulative and toxic substance (PBT substance), and a very persistent and very bioaccumulative substance (vPvB substance) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3], it meets the exclusion criteria set out in Article 5(1), point (e), of Regulation (EU) No 528/2012.

(4) On 18 February 2021, the evaluating competent authority of Greece 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 Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of

---

1 OJ L 167, 27.6.2012, p. 1.

2 Commission Implementing Regulation (EU) 2015/1982 of 4 November 2015 approving hexaflumuron as an existing active substance for use in biocidal products for product-type 18 (OJ L 289, 5.11.2015, p. 13).

3 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).

Regulation (EU) No 528/2012. In such case, 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.

(6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('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) Consequently, for reasons beyond the control of the applicant, the approval of hexaflumuron for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of hexaflumuron for use in biocidal products of product-type 18 for a period of time sufficient to enable the examination of the application.

(8) Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of hexaflumuron may therefore be renewed, it is appropriate to postpone the expiry date of approval to 30 September 2024.

(9) Except for the expiry date of approval, hexaflumuron remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Implementing Regulation (EU) 2015/1982,

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of hexaflumuron for use in biocidal products of product-type 18 is postponed to 30 September 2024.

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
SANTE/10504/2021
(POOL/E4/2021/10504/10504-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18

(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) The active substance aluminium phosphide 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-types 14 and 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) The approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 will expire on 31 August 2021 and 31 January 2022, respectively. On 26 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of aluminium phosphide for use in biocidal products of product-types 14 and 18.

(3) On 25 May 2020, 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 application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, 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, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, 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 (‘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.

---

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).

(6) Consequently, for reasons beyond the control of the applicant, the approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 to 31 July 2024.

(7) Except for the expiry date of approval, aluminium phosphide remains approved for use in biocidal products of product-types 14 and 18 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 is postponed to 31 July 2024.

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
SANTE/10506/2021
(POOL/E4/2021/10506/10506-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18

(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) The active substance magnesium phosphide 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 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) The approval of magnesium phosphide for use in biocidal products of product-type 18 will expire on 31 January 2022. On 28 July 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of magnesium phosphide.

(3) On 1 October 2020, 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 application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, 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, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, 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 (‘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.

---

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).

(6) Consequently, for reasons beyond the control of the applicant, the approval of magnesium phosphide for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 31 July 2024.

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

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18 is postponed to 31 July 2024.

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
SANTE/10496/2021
(POOL/E4/2021/10496/10496-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of dinotefuran for use in biocidal products of product-type 18

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of dinotefuran for use in biocidal products of product-type 18

(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) The active substance dinotefuran was approved as an active substance for use in biocidal products of product-type 18[2].

(2) The approval of dinotefuran for use in biocidal products of product-type 18 will expire on 31 May 2022. On 11 November 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of dinotefuran.

(3) On 25 March 2021, the evaluating competent authority of Belgium 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 Regulation (EU) No 528/2012, 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, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, 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 ('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.

(6) Consequently, for reasons beyond the control of the applicant, the approval of dinotefuran for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of dinotefuran for use in biocidal products of product-type 18

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

[2] Commission Implementing Regulation (EU) 2015/416 of 12 March 2015 approving dinotefuran as an active substance for use in biocidal products for product-type 18 (OJ L 68, 13.3.2015, p. 30).

for a period sufficient to enable the examination of the application. Considering the time limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 30 November 2024.

(7) Except for the expiry date of approval, dinotefuran remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Implementing Regulation (EU) 2015/416,

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of dinotefuran for use in biocidal products of product-type 18 is postponed to 30 November 2024.

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
SANTE/10498/2021
(POOL/E4/2021/10498/10498-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of indoxacarb for use in biocidal products of product-type 18

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of indoxacarb for use in biocidal products of product-type 18

(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) The active substance indoxacarb 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 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) On 26 June 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of indoxacarb for use in biocidal products of product-type 18.

(3) On 12 November 2018, the evaluating competent authority of France 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) As the competent authority is carrying out a full evaluation of the application, in accordance with Article 14(3) of Regulation (EU) No 528/2012, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance within 270 days of receipt of the recommendation from the evaluating competent authority.

(5) Pursuant to Implementing Decision (EU) 2019/1030[3], the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 has been postponed to 30 June 2022 in order to allow sufficient time for the examination of the application. However, the evaluating competent authority has not yet finalised the examination and

---

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) 2019/1030 of 21 June 2019 postponing the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 (OJ L 167, 24.6.2019, p. 32).

has not yet submitted its assessment report and the conclusions of its evaluation to the Agency.

(6) On 29 October 2020, the evaluating competent authority has requested the applicant to submit additional information to carry out the evaluation in accordance with Article 8(2) of Regulation (EU) No 528/2012 and has set the deadline of 30 September 2022 for submitting this information.

(7) Consequently, for reasons beyond the control of the applicant, the approval of indoxacarb for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 for a period of time sufficient to enable the completion of the examination of the application.

(8) Considering the time necessary for the completion of the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 30 June 2024.

(9) Except for the expiry date of approval, indoxacarb remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of indoxacarb for use in biocidal products of product-type 18 is postponed to 30 June 2024.

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
SANTE/10494/2021
(POOL/E4/2021/10494/10494-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of dazomet for use in biocidal products of product-type 8

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of dazomet for use in biocidal products of product-type 8

(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) The active substance dazomet 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 specifications and conditions set out in Annex I to that Directive.

(2) The approval of dazomet for use in biocidal products of product-type 8 will expire on 31 July 2022. On 26 January 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of dazomet.

(3) On 24 March 2021, the evaluating competent authority of Belgium 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 Regulation (EU) No 528/2012, 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, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, 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 ('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.

---

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).

(6) Consequently, for reasons beyond the control of the applicant, the approval of dazomet 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 approval of dazomet for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 31 January 2025.

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

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of dazomet for use in biocidal products of product-type 8 is postponed to 31 January 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,

For the Commission
The President
Ursula VON DER LEYEN