



Brussels, **XXX**
SANTE/2020/12424
(POOL/E4/2020/12424/12424-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 products¹, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² 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- (2) For a number of active substance/product-type combinations included in that list, all the participants have withdrawn or are considered to have withdrawn their support in a timely manner.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- $\alpha,\alpha,4$ -trimethylcyclohexanemethanol (product-type 19); chlorine dioxide generated from sodium chlorite and sodium persulfate (product-types 2, 3, 4, 5, 11).

- (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



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ANNEX

ANNEX

to the

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

**on the non-approval of certain active substances in biocidal products pursuant to
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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	<i>Eucalyptus citriodora</i> oil and citronellal, hydrated, cyclized	CZ	n/a	n/a	19
609	2-Hydroxy- $\alpha,\alpha,4$ -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 <i>Hordeum</i> , <i>Gramineae</i>	AT	232-310-9	8002-48-0	19