



Brussels, **XXX**
SANTE/10632/2020
(POOL/E4/2020/10632/10632-EN.docx)
[...] (2020) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of **XXX**

not approving chlorophene as an existing active substance for use in biocidal products of product-type 2

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of **XXX**

not approving chlorophene as an existing active substance for use in biocidal products of product-type 2

(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 a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That lists includes chlorophene (EC No: 204-385-8; CAS No 120-32-1).
- (2) Chlorophene has been evaluated for use in biocidal products of product-type 2, disinfectants and algacides not intended for direct application to humans or animals, as described in Annex V to Regulation (EU) No 528/2012.
- (3) Norway was designated as a rapporteur State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('Agency') on 22 December 2016.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 4 March 2020³, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products of product-type 2 containing chlorophene may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012 as the human health risk assessment identified unacceptable risks.
- (6) Taking into account the opinion of the Agency, it is not appropriate to approve chlorophene for use in biocidal products of product-type 2.
- (7) The measures provided for in this Decision 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 Biocidal Products Committee Opinion on the application for approval of the active substance: Chlorophene, Product type: 2, ECHA/BPC/238/2020, adopted on 4 March 2020.

HAS ADOPTED THIS DECISION:

Article 1

Chlorophene (EC No: 204-385-8, CAS No: 120-32-1) is not approved as an active substance for use in biocidal products of product-type 2.

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