Official Journal
of the European Union

EN
L series

2026/1424

3.7.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/1424

of 30 June 2026

on the non-approval of poly(dimethyloctadecyl[3-(trihydroxysilyl)propyl]ammonium chloride) generated from dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride as an existing active substance for use in biocidal products of product-types 2, 7 and 9 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 existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride (EC No: 248-595-8; CAS No: 27668-52-6) for product-types 2, 7 and 9.

(2) Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride has been evaluated for use in biocidal products of product-types 2 (private area and public health area disinfectants and other biocidal products), 7 (film preservatives) and 9 (fibre, leather, rubber and polymerised materials preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-types 2 (disinfectants and algaecides not intended for direct application to humans or animals), 7 (film preservatives) and 9 (fibre, leather, rubber and polymerised materials preservatives), as described in Annex V to Regulation (EU) No 528/2012.

(3) Spain was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 14 September 2012. After the submission of that assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) During the examination of dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride, the name of that active substance has been renamed by the Agency to the *in situ* active substance poly(dimethyloctadecyl[3-(trihydroxysilyl)propyl]ammonium chloride) generated from dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride (hereinafter 'the active substance concerned').

(5) It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the substantive conditions for approval laid down in Directive 98/8/EC.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([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, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

([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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).

(6) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is to prepare 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 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency on 9 September 2025 ([4]), ([5]), ([6]), having regard to the conclusions of the evaluating competent authority.

(7) According to the opinions of the Agency, adequate analytical methods for the active substance concerned were not available in the application dossiers, and the applicant was therefore requested to provide them within a prescribed period. The applicant provided certain data, which the Agency considered not to be sufficient to quantify and characterise the active substance concerned. Therefore, reliable analytical methods could not be established.

(8) Furthermore, additional data were of poor quality or missing, as regards *in vitro* and *in vivo* genotoxicity/mutagenicity, reproductive toxicity (development, fertility), carcinogenicity, dermal absorption, acute oral, inhalation and dermal toxicity, skin sensitisation, toxicokinetics and repeated dose toxicity. Due to the lack of reliable analytical methods, necessary for the correct quantification of doses and concentrations of the active substance concerned used in the toxicological and ecotoxicological studies, and for the setting of reliable reference values, and because of the additional data gaps, the Agency could not conclude on the acceptability of the risks concerning human health and the environment related with any of the uses of the representative biocidal products containing the active substance concerned included in the application dossiers for the assessed product-types, and on any safe use. For the same reasons, the Agency could not conclude whether the active substance concerned is carcinogenic, mutagenic or toxic for reproduction.

(9) In addition, according to the opinions of the Agency, the data in the application dossiers were not sufficient to determine the physical and chemical properties of the active substance concerned. The applicant was requested to provide data sufficient to determine the physical and chemical properties of the active substance concerned within a prescribed period, but it failed to submit them.

(10) Sufficient efficacy has not been demonstrated either for any of the uses of the representative biocidal products for the assessed product-types, since, first, it was not possible to establish an effective dose due to the lack of a reliable analytical method, and, second, tier 2 studies submitted were on the one hand not representative for the uses of the respective representative biocidal product for product-type 2 and, on the other hand lacking for the uses of the representative biocidal products for product-types 7 and 9.

(11) Therefore, biocidal products of product-types 2, 7 and 9 containing the active substance concerned are not expected to satisfy the criteria set out in Article 5(1), point (b)(i), (iii) and (iv), and points (c) and (d), of Directive 98/8/EC read in conjunction with Article 10(1) of that Directive.

(12) It is therefore appropriate not to approve the active substance concerned for use in biocidal products of product-types 2, 7 and 9.

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

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance Poly(dimethyloctadecyl[3-(trihydroxysilyl)propyl]ammonium chloride) generated from dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride; Product-type: 2; ECHA/BPC/488/2025, adopted on 9 September 2025.

([5]) Biocidal Products Committee Opinion on the application for approval of the active substance Poly(dimethyloctadecyl[3-(trihydroxysilyl)propyl]ammonium chloride) generated from dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride; Product-type: 7; ECHA/BPC/489/2025, adopted on 9 September 2025.

([6]) Biocidal Products Committee Opinion on the application for approval of the active substance Poly(dimethyloctadecyl[3-(trihydroxysilyl)propyl]ammonium chloride) generated from dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride; Product-type: 9; ECHA/BPC/490/2025, adopted on 9 September 2025.

HAS ADOPTED THIS DECISION:

Article 1

Poly(dimethyloctadecyl[3-(trihydroxysilyl)propyl]ammonium chloride) generated from dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride is not approved as an active substance for use in biocidal products of product-types 2, 7 and 9.

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, 30 June 2026.

For the Commission
The President
Ursula VON DER LEYEN