



2025/757

22.4.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/757
of 16 April 2025
concerning the authorisation of sepiolite as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Sepiolite was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of sepiolite as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'technological additives' and in the functional groups 'binders' and 'anticaking agents'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 March 2022 ⁽³⁾ and 4 June 2024 ⁽⁴⁾ that the use of sepiolite at the level of 20 000 mg/kg of complete feed is safe for all animal species, for consumers and for the environment. It also concluded that for the user, sepiolite poses a risk by inhalation, in particular due to the presence in the additive of crystalline silica and of nickel, that it is not irritant to the skin or eyes but should be considered as skin and respiratory sensitiser. The Authority further concluded that the additive is efficacious as a binder and an anticaking agent. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) In view of the above, the Commission considers that sepiolite satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ EFSA Journal 2022;20(4):7250. <https://doi.org/10.2903/j.efsa.2022.7250>.

⁽⁴⁾ EFSA Journal 2024; 22(6): e8850. <https://doi.org/10.2903/j.efsa.2024.8850>.

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional groups 'binders' and 'anticaking agents', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additive sepiolite, as authorised pursuant to Directive 70/524/EEC, and premixtures containing this additive, which are produced and labelled before 12 November 2025 in accordance with the rules applicable before 12 May 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 12 May 2026 in accordance with the rules applicable before 12 May 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 12 May 2027 in accordance with the rules applicable before 12 May 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 3

Entry into force

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, 16 April 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: binders								
1g562	Sepiolite	<p><i>Additive composition</i></p> <p>Hydrated magnesium silicate of sedimentary origin, containing ≥ 60 % sepiolite, ≤ 30 % montmorillonite, free of asbestos ⁽¹⁾</p> <p>Solid form</p> <hr/> <p><i>Characterisation of the active substance</i></p> <p>Sepiolite (hydrous magnesium silicate): ≥ 60 % CAS number: 63800-37-3 Chemical formula: $Mg_4Si_6O_{15}(OH)_2 \cdot 6H_2O$ Montmorillonite: ≤ 30 %</p> <hr/> <p><i>Analytical method ⁽²⁾</i></p> <p>For the characterisation of the feed additive:</p> <ul style="list-style-type: none"> – X-ray diffraction (XRD) and – X-ray fluorescence (XRF) or atomic absorption spectrometry (AAS) 	All animal species	-	-	20 000	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment. 	12 May 2035

⁽¹⁾ Method employed: Transmission Electron Microscopy (TEM).

Identification number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			

Category: technological additives. Functional group: binders

(²) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identification number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			

Category: technological additives. Functional group: anticaking agents

1g562	Sepiolite	<p><i>Additive composition</i></p> <p>Hydrated magnesium silicate of sedimentary origin, containing ≥ 60 % sepiolite, ≤ 30 % montmorillonite, free of asbestos (¹)</p> <p>Solid form</p> <hr/> <p><i>Characterisation of the active substance</i></p> <p>Sepiolite (hydrous magnesium silicate): ≥ 60 %</p> <p>CAS number: 63800-37-3</p> <p>Chemical formula: Mg₄Si₆O₁₅(OH)₂·6H₂O</p> <p>Montmorillonite: ≤ 30 %</p> <hr/>	All animal species	-	-	20 000	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and</p>	12 May 2035
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