

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1564**of 17 October 2018****concerning the authorisation of a preparation of dolomite-magnesite as a feed additive for all animal species with the exception of dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening****(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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of dolomite-magnesite. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of dolomite-magnesite as a feed additive for all animal species to be classified in the additive category 'technological additives'.
- (4) The preparation of dolomite-magnesite belonging to the additive category of 'technological additives', was previously authorised for 10 years as a feed additive for dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) 2016/1964 ⁽²⁾.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 April 2018 ⁽³⁾ and 25 January 2017 ⁽⁴⁾ that, under the proposed conditions of use, the preparation of dolomite-magnesite does not have an adverse effect on animal health, human health or the environment. The Authority has also concluded that it is effective as an anti-caking agent. The Authority does not consider that there is a need for specific requirements of post-market monitoring. 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.
- (6) The assessment of the preparation of dolomite-magnesite shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (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

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2016/1964 of 9 November 2016 concerning the authorisations of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening and a preparation of montmorillonite-illite for all animal species as feed additives (OJ L 303, 10.11.2016, p. 7).

⁽³⁾ EFSA Journal 2018;16(5):5272.

⁽⁴⁾ EFSA Journal 2017;15(2):4711.

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, 17 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the 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 %			
Technological additives: anticaking agents								
1g598	Dolomite-Magnesite	<p><i>Additive composition</i></p> <p>Preparation of a natural mixture of: Dolomite and magnesite ≥ 40 % (having a minimum content of: carbonates 24 %).</p> <p><i>Characterisation of the active substance</i></p> <p>Dolomite CAS number 16389-88-1 (CaMg)(CO₃)₂</p> <p>Magnesite CAS number 546-93-0 MgCO₃</p> <p>Talc (hydrated silicates of magnesium) CAS number 14807-96-6 Mg₃Si₄O₁₀(OH)₂</p> <p>Talc ≥ 35 %</p> <p>Chlorite (aluminium–magnesium) CAS number 1318-59-8 (Mg,Fe,Al)₆(Si, Al)₄O₁₀(OH)₈</p> <p>Iron (structural) 6 % (average)</p> <p>Chlorite ≥ 16 %</p> <p>Free of quartz and asbestos</p>	All species and categories with the exception of dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening	—	5 000	20 000	<ol style="list-style-type: none"> In the labelling of the additive and premixtures containing it, the following shall be indicated: 'The additive dolomite-magnesite is rich in (inert) iron'. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 	8 November 2028

Identification number of the 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 %			
		<i>Analytical method</i> ⁽¹⁾ Characterisation of the feed additive: — X-ray diffraction (XRD) together with — atomic absorption spectrophotometry (AAS)						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>