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 (Text with EEA relevance)

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

(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 applications were submitted for the authorisations of a preparation of dolomite-magnesite and a preparation of montmorillonite-illite. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) Those applications concern the authorisations of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned piglets and pig for fattening and a preparation of montmorillonite-illite as feed additives for all animal species to be classified in the additive category ‘technological additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 December 2015[(2)] that the preparation of dolomite-magnesite does not have an adverse effect on animal health, on the environment or on human health. The Authority has also concluded that it is efficacious 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.

(5) Due to the physiological similarity of the dairy cows with all ruminants for dairy production, it is appropriate to extend the use of this additive to other ruminants for dairy production.

(6) The Authority concluded in its opinions of 30 October 2014 and 10 September 2015[(3)] that the preparation of montmorillonite-illite does not have an adverse effect on animal health, on the environment or on human health. The Authority has also concluded that it is efficacious as an anti-caking agent and as binder. 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.

(7) The assessment of the preparation of dolomite-magnesite and of the preparation of montmorillonite-illite shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annexes to this Regulation.

(8) 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 I, belonging to the additive category ‘technological additives’ and to the functional group ‘anti-caking agents’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

The preparation specified in the Annex II, belonging to the additive category ‘technological additives’ and to the functional groups ‘anti-caking agents’ and ‘binders’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 3

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, 9 November 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1964. (See end of Document for details)*

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1964. (See end of Document for details)*

ANNEX I

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	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: anti-caking agents								
1g598	Dolomite-Magnesite	*Additive composition* Preparation of natural mixture of: dolomite and magnesite ≥ 40 % (having a minimum content of: carbonates 24 %). *Characterisation of the active substance* Dolomite: CAS number 16389-88-1 $(CaMg)(CO_3)_2$ Magnesite: CAS number 546-93-0 $MgCO_3$ Talc (hydrated silicates of magnesium):	Dairy cows and other ruminants for dairy production Weaned piglets Pigs for fattening	—	5 000	20 000	1. For use in weaned piglets until 35 kg. 2. In the labelling of the additive and premixtures containing it, the following shall be indicated: ‘The additive dolomite-magnesite is rich in (inert) iron’. 3. For users of the additive and premixtures, feed business	30 November 2026

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

			CAS number 14807-96-6 $Mg_3Si_4O_{10}(OH)_2$ Talc ≥ 35 % Chlorite (aluminium–magnesium): CAS number 1318-59-8 $(Mg,Fe,Al)_6(Si,Al)4O_{10}(OH)_8$ Iron (structural) 6 % (average) Chlorite ≥ 16 % Free of quartz and asbestos *Analytical method*[a] Characterisation of the feed additive: — X-ray diffraction (XRD), together with — atomic absorption spectrophotometry (AAS).				operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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.

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports