Commission Implementing Regulation (EU) 2019/10 of 3 January 2019 concerning the authorisation of a preparation of a natural mixture of illite- montmorillonite-kaolinite as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/10

of 3 January 2019

concerning the authorisation of a preparation of a natural mixture of illite- montmorillonite-kaolinite 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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of a natural mixture of illite-montmorillonite-kaolinite. 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 a natural mixture of illite-montmorillonite-kaolinite as a feed additive for all animal species, to be classified in the additive category ‘technological additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 1 December 2015[(2)], 5 July 2017[(3)] and 5 July 2018[(4)] that, under the proposed conditions of use, the preparation of a natural mixture of illite-montmorillonite-kaolinite does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that it is effective as a binder and anticaking 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) The assessment of the preparation of a natural mixture of illite-montmorillonite-kaolinite 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/10. (See end of Document for details)*

(6) 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 ‘binders’ and ‘anticaking agents’, is authorised as an additive in animal nutrition, subject to the conditions laid down in the Annex.

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, 3 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/10. (See end of Document for details)*

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: binders								
1g599	Illite-montmorillonite-kaolinite	*Additive composition* Preparation of a natural mixture of illite-montmorillonite-kaolinite, having a minimum content of: — 40 % of illite — 10 % of montmorillonite — 8 % of kaolinite *Characterisation of the active substance* Illite: CAS number 106958-53-6 $K(Al,Fe)_2AlSi_3O_{10}(OH)_2 . H_2O$ Montmorillonite: CAS number 1318-93-0	Chickens for fattening and minor poultry species for fattening. Cattle for fattening and minor ruminants for fattening. Pigs for fattening and weaned piglets	—	5 000	50 000	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	24 January 2029
			All other animal species and categories	—	5 000	20 000		

a 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

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			Nax[(Al2-xMgx)Si4O10)(OH)2] Kaolinite: CAS number 1318-74-7 Al2(OH)4(SiO5) Iron (structural) 10 % average Free of asbestos *Analytical method*[a] Characterisation of the feed additive: — X-ray diffraction (XRD) together with — X-ray fluorescence (XRF).				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. 3. In the labelling of the additive and premixtures containing it, the following shall be indicated: ‘The additive illite-montmorillonite-kaolinite is rich in (inert) iron’.

a 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

							4. The total amount of different uses of illite-montmorillonite-kaolinite in complete feedingstuff shall not exceed the permitted maximum level for the relevant species or category of animals.	The
							5. The instructions for use shall indicate the following: —	‘The simultaneous oral use with macrolides shall be avoided’.
Technological additives: anticaking agents								
1g599	Illite-montmorillonite-kaolinite	*Additive composition* Preparation of a natural mixture of illite-	Chickens for fattening and minor poultry species	—	5 000	50 000	1. In the directions for use of the additive	24 January 2029

a 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