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Safety and efficacy of aluminosilicate of sodium, potassium, calcium and magnesium as a feed additive for pigs

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on aluminosilicate of sodium, potassium, calcium and magnesium as a feed additive for pigs. The additive, that contains at least 66% of aluminosilicate of sodium, potassium, calcium and magnesium as main component, is intended for use as a technological additive (functional groups: (i) anticaking agents) in premixtures and feedingstuffs for pigs at a maximum inclusion level of 30,000 mg/kg. In the absence of data, the FEEDAP Panel could not conclude on the safety of the additive for the target species and the users. The additive is considered safe for the consumer and the environment at the proposed conditions of use. The additive has the potential to act as an anticaking agent in complete feed of pigs at a concentration of 30,000 mg/kg feed.

Keywords: Aluminosilicate of sodium, potassium, calcium and magnesium safety, efficacy, technological additives, anticaking agent

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Verdi S.p.A.[2] for authorisation of the product aluminosilicate of sodium, potassium, calcium and magnesium for pigs (category: technological additives; functional group: anticaking agents).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 8 November 2017.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product aluminosilicate of sodium, potassium, calcium and magnesium, when used under the proposed conditions of use (see Section 3.1.5).

1.2. Additional information

The additive is an aluminosilicate of sodium, potassium, calcium and magnesium. The additive is not authorised for use as a feed additive in the European Union (EU), and it has not been previously assessed by EFSA as a feed additive.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[3] in support of the authorisation request for the use of aluminosilicate of sodium, potassium, calcium and magnesium as a feed additive.

The FEEDAP Panel used the data provided by the applicant to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.[4]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of aluminosilicate of sodium, potassium, calcium and magnesium is in line with the principles laid down in Regulation (EC) No 429/2008[5] and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012b) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012c), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008).

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Verdi SA. Via A. Volta 7/1, 42024, Castelnuovo di sotto, Italy.
[3] FEED dossier reference: FAD-2017-0022.
[4] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0096-steatite.pdf
[5] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

3. Assessment

The additive under assessment is an aluminosilicate of sodium, potassium, calcium and magnesium.

The applicant is seeking an authorisation for the use of the product as a technological additive (functional group: (i) anticaking agents) in feedingstuffs for pigs.

3.1. Characterisation

3.1.1. Characterisation of the additive

The product is obtained by mining from a quarry located in Italy, followed by crushing, grinding, drying and packaging. The production process is based on a mechanical process only, with no chemicals used during the manufacturing.

The product is specified to contain at least 66% of aluminosilicate of sodium, potassium, calcium and magnesium, called chabazite, as main component.

X-ray diffraction (XRD) is commonly used to provide a full mineralogical analysis of clays, which can also be characterised by their elemental composition, usually determined/expressed as the corresponding oxides. Both mineralogical and chemical approaches have been used to characterise the additive. The mineralogical and elemental composition (seven batches)[6] are summarised in Tables 1 and 2, respectively.

Table 1: Mineralogical composition of seven batches of the product (X-ray diffraction)

	Chabazite (%)	Phillipsite (%)	Feldspar (%)	Biotite (%)	Piroxene (%)	Volcanic glass (%)
Mean	68.4	3.6	6.3	12.6	3.7	12.6
Minimum	66	3	5	11	3	10
Maximum	71	5	8	15	5	15

Table 2: Elemental composition of seven batches of the product (expressed as oxide)

	SiO_2 (%)	Al_2O_3 (%)	K_2O (%)	CaO (%)	MgO (%)	Fe_2O_3 (%)
Mean	55.0	15.0	7.4	6.2	1.7	2.6
Minimum	53.0	13.8	6.0	5.0	1.5	2.3
Maximum	57.5	16.0	8.0	7.2	2.2	3.3

3.1.2. Purity

Several batches of the product were tested for heavy metals and arsenic content.[7,8] The analyses showed values of ≤ 10–28.6 mg/kg (15 batches) for lead, ≤ 2–0.96 mg/kg (15 batches) for cadmium and ≤ 4 mg/kg (seven batches) for arsenic. These results do not raise safety concerns.

One batch of the additive was analysed for residues of phytosanitary compounds.[9] More than 300 compounds were included in the analysis and all were below the respective limits of quantification.

Dioxins (polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F) in 12 batches[10] were ≤ 0.71 ng World Health Organization (WHO) PCDD/F-TEQ/kg. These concentrations comply with the limits set in the Commission Directive 2002/32/EC and are considered of no concern.[11]

3.1.3. Physical state of the product

The additive is a free-flowing powder, with a bulk density varying between 700 and 900 kg/m^3.[12]

[6] Technical dossier/Section II/ Annex II_1.
[7] Technical dossier/Section II/Annex II_ 1.
[8] Technical dossier/Section II/Annex II_ 2.
[9] Technical dossier/Section II/Annex II_ 4.
[10] Technical dossier/Section II/Annex II_3.
[11] Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls (OJ L 140, 30.5.2002, p. 10).
[12] Technical dossier/Section II.

Particle size distribution, analysed in three batches,[13] showed that 90% of particles (v/v) were < 515 μm, 50% < 136 μm and 10% < 13.6 μm; less than 0.6% of particles had a diameter < 1 μm.

Dusting potential was analysed in five batches of the additive[14] (Method UNI EN 15051). The results showed values for the breathable fraction of the dust (Wr) between of 633 and 800 mg/kg, and values for the inhalable fraction (Wi) between 1,876 and 7,123 mg/kg. These values indicate in the moderate tendency to dustiness, according to the UNI EN 15051 standard.

No information on interactions and/or incompatibilities of the additive with other feed components were made available.

3.1.4. Stability and homogeneity

Stability studies are not required for mineral-based products, which can be reasonably assumed to be stable. For an additive intended for use as an anticaking agent, no homogeneity studies are considered necessary, if efficacy is demonstrated (see Section 3.3).

3.1.5. Conditions of use

The additive is intended to be used in premixtures and feedingstuffs for pigs, with a maximum content of 30,000 mg/kg complete feed.

3.2. Safety

3.2.1. Safety for the target species

To support the safety for the target species, the applicant submitted one study in pigs for fattening.[15] The study was designed to include only two groups fed a basal diet supplemented with 0 or 30,000 mg additive/kg (the recommended maximum content). A group receiving the additive at a multifold the maximum recommended content was not included in the study. Therefore, the study cannot be used to assess the tolerance of the target species to the additive and is not further considered.

In the absence of any other information, including toxicological studies done with the additive under assessment, the FEEDAP Panel is not in the position to conclude on the safety of the additive for the target species.

3.2.2. Safety for the consumer

The FEEDAP Panel considers it unlikely that the additive, in common with other clays, will be degraded during their passage through the gastrointestinal tract of target animals or absorbed to any measurable extent and that harmful amounts of residues of any chemical component would occur in edible tissues/products from animals as a consequence of the use of the product as a feed additive.

Therefore, the use of the additive in animal nutrition is considered not to pose a risk for the consumer of tissues and products from animals fed the additive.

3.2.3. Safety for the user

No specific studies performed with the additive under assessment were provided. The additive is characterised by approximately 10% of particles with a diameter below 13.6 μm and approx. 0.6% with a diameter < 1 μm. The additive has a moderate tendency to produce respirable and inhalable dust. Therefore, an exposure via inhalation is considered likely. In the absence of data on the toxicological properties of the additive, the Panel is not in the position to conclude on the safety of aluminosilicate of sodium, potassium, calcium and magnesium for the user.

3.2.4. Safety for the environment

The components of the additive are ubiquitous in the environment, being natural components of soil. Therefore, it is not expected that its use as a feed additive would adversely affect the environment.

[13] Supplementary information October 2018/Annex_1 and Annex_2.
[14] Supplementary information October 2018/Annex_3.
[15] Technical dossier/Section III/Annex III_1.

3.3. Efficacy

Three studies were provided to support the efficacy of the additive as an anticaking substance in feedingstuffs.

In the first study, the efficacy of the additive as an anticaking agent was tested in 10 replicates of a complete mash feed for pigs.[16] The feed was supplemented with 30,000 mg additive/kg. Each subsample (2,000 g) was loaded in a standard cone with an orifice of 20 mm and left to fall. Below the cone, the sample formed a small pile, forming an angle of repose α, calculated as a quotient of the height (h) and the diameter (D) of the pile (tan α = h/0.5D). The angle (α) gives the tendency of the material to be cohesive or free-flowing, with lower values (25–30°) for very flowing materials and higher values (> 66°) for cohesive materials. The speed of flow through the cone (s) gives an indication of the flowability. The outcome is expressed in absolute values and as a percentage improvement by the additive. The results were not statistically analysed. The inclusion of the additive reduced the flow time of the feeds compared to the unsupplemented feedingstuffs from 85 s to 50 s. The angle of the unsupplemented feed was 48.7°, which was reduced by the additive to 43.8°.

In the second study, a mash pig feed was supplemented with 30,000 mg additive/kg.[17] The feed (10 replicates) was loaded in a plastic cylinder (diameter: 100 mm; height: 140 mm), turned upside down on the end of a smooth surface, which was then raised on one side, forming an angle with the floor, up to the height at which the cylinder started moving. This height was then measured, and the angle calculated. The results were not statistically analysed. The inclusion of the additive reduced the angle compared to the control from 23.1° to 20.4°.

In the third study, a mash pig feed was supplemented with 30,000 mg additive/kg feed.[18] Replicates (12) of 75 g of unsupplemented and supplemented feeds were poured into a test tube (diameter 40 mm), and laid on an horizontal wood plank, which was raised slowly until the feed started to flow out of the tube. At a certain angle, the run-off occurs quite abruptly; this measured angle is called 'angle of flowability'. The results were not statistically analysed. The results showed that the inclusion of the additive improved the flowability of the feed, reducing the angle from 74.4° to 67.5°.

3.3.1. Conclusions on efficacy

Based on the results of three *in vitro* studies, the additive appears to act as an anticaking agent in complete feed of pigs at a concentration of 30,000 mg/kg feed.

4. Conclusions

The FEEDAP Panel could not conclude on the safety of the additive for the target species and the users.

The additive is considered safe for the consumer and the environment at the proposed conditions of use.

The additive has the potential to act as an anticaking agent in complete feed of pigs at a concentration of 30,000 mg/kg feed.

Documentation provided to EFSA/Chronology

Date	Event
12/04/2017	Dossier received by EFSA
19/06/2017	Reception mandate from the European Commission
08/11/2017	Application validated by EFSA – Start of the scientific assessment
07/02/2018	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
08/02/2018	Comments received from Member States
09/07/2018	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety for target species and efficacy*

[16] Supplementary information October 2018/Annex_4.
[17] Supplementary information October 2018/Annex_5.
[18] Supplementary information October 2018/Annex_6.

Date	Event
16/10/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
14/05/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EFSA (European Food Safety Authority), 2008. Technical Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for assessing the safety of feed additives for the environment. EFSA Journal 2008;6(10):842, 28 pp. https://doi.org/10.2903/j.efsa.2008.842

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. https://doi.org/10.2903/j.efsa.2011.2175

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for technological additives. EFSA Journal 2012;10(1):2528, 23 pp. https://doi.org/10.2903/j.efsa.2012.2528

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance for establishing the safety of additives for the consumer. EFSA Journal 2012;10(1):2537, 12 pp. https://doi.org/10.2903/j.efsa.2012.2537

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

Abbreviations

EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
OECD	Organisation for Economic Co-operation and Development
PCDD/F	polychlorinated dibenzo-*p*-dioxins and dibenzofurans
TEQ	toxic equivalent
WHO	World Health Organization
XRD	X-ray diffraction
XRF	X-ray fluorescence spectrometry

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for aluminosilicate of sodium, potassium, calcium and magnesium

In the current application authorisation is sought under Article 4(1) for *aluminosilicate of sodium, potassium, calcium and magnesium* under the category/functional group (1i) "technological additives"/ "anticaking agents", according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the *feed additive* for pigs. The *feed additive* is a powder derived from crushed and milled natural aluminosilicate rocks, containing a minimum of 65.6 % (w/w) *chabazite* and other minerals such as phillipsite, K-feldspar, biotite, piroxene and volcanic glass. The *feed additive* is intended to be used directly in *feedingstuffs* or through *premixtures* to ensure flowability within storage silos. The Applicant proposed a minimum inclusion level of the *feed additive* of 30 g/kg complete *feedingstuffs*. For the determination of the mineralogical and chemical composition of the *feed additive* the Applicant applied (i) X-ray diffraction (XRD) and (ii) X-ray fluorescence spectrometry (XRF) based on the EN 13925 and ISO 29581-2 standard methods, respectively. Based on the experimental evidence available, the EURL recommends these two standard methods for official control for the characterisation of the *feed additive*. As the accurate determination of the *aluminosilicate of sodium, potassium, calcium and magnesium* content added to *premixtures* and *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control. Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.