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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of natrolite–phonolite obtained from volcanic rock from Kaiserstuhl for all animal species (Hans G. Hauri Mineralstoffwerk GmbH)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of natrolite–phonolite obtained from volcanic rock from Kaiserstuhl as a technological additive (functional group: anticaking) for all animal species. According to the conventional risk assessment, due to the lack of adequate data, the Panel is not in a position to conclude on the safety of the additive for the target species under the proposed conditions of use. However, from the tolerance studies in cattle for fattening and weaned piglets, effects observed in animal performance and blood clinical biochemistry suggest adverse effects on the animals supplemented with the additive. Based on current knowledge, there is no indication of substantial absorption of the components of the additive and, therefore, of concern for the consumer. The FEEDAP Panel is not in the position to conclude on the potential of the additive to be a skin and eye irritant. The additive is considered a respiratory and dermal sensitiser. In the absence of suitable data, the presence of small/nanoparticles cannot be excluded. As no suitable data in line with the requirements of the Guidance on risk assessment of nanomaterials were provided by the applicant, the potential risks associated with the presence of nanoparticles for the target species, the consumer and the user could not be assessed. Due to the lack of sufficient data, the Panel is not in a position to conclude on the efficacy of the additive.

KEYWORDS

anticaking, efficacy, natrolite–phonolite, safety, technological additives

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1 | INTRODUCTION

1.1 | Background and terms of reference

Regulation (EC) No 1831/20031 establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Hans G. Hauri Mineralstoffwerk[1] for the re-evaluation of the additive consisting of natrolite–phonolite when used as a feed additive for all animal species (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 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 4 June 2015.

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 feed additive consisting of natrolite–phonolite, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The feed additive natrolite–phonolite is authorised as a binder, anti-caking agent and coagulant for all animal species with a maximum content of 25,000 mg/kg feed, subject to re-evaluation.

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[2] in support of the authorisation request for the use of natrolite–phonolite as a feed additive.

The dossier was received on 02 December 2014, and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2014-00890.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers and other scientific reports 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.[3]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of active substance (trade name of the product) is in line with the principles laid down in Regulation (EC) No 429/2008[4] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021a), Guidance on risk

[1]Bergstrasse 114, 79,268 Bötzingen (Germany).

[2]FEED dossier reference: FAD-2010-0238.

[3]The full report is available on the EU Science Hub website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0238_en

[4]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.

assessment of nanomaterials to be applied in the food and feed chain: human and animal health (EFSA Scientific Committee, 2021b).

3 | ASSESSMENT

The additive under assessment, consisting of natrolite–phonolite obtained from volcanic rock from Kaiserstuhl, is intended to be used as a technological additive (functional group: anticaking agents) in feedingstuffs for all animal species.

3.1 | Characterisation

The product natrolite–phonolite is defined as a natural mixture of aluminosilicates and aluminohydrosilicates, with a content of natrolite (a common zeolite) ranging 43%–46.5%. Other specifications include loss on ignition (550°C; LOI) of 4%–9.5%, through fraction (< 0.063 mm) 99%–100% and Blaine fineness[5] of 14,000–21,000 cm^2/g.

The additive, after quarrying the volcanic rock from Fohberg in the Kaiserstuhl (Germany), is produced by crushing and milling the rocks up to a grain size of 0–35 mm, conditioning in a rotary furnace at 350–400°C and fine grinding and separation to obtain a grain size of < 0.063 mm.[6]

The mineral (analysis by X-ray powder diffraction) and chemical (analysed by X-ray fluorescence) composition of the additive was studied in five batches, and the results are presented in Tables 1 and 2.[7]

TABLE 1 Mineralogical composition (%) of the natrolite–phonolite.

Mineralogical components	Mean (%)	Range (%)
Natrolite	45.1	41.7–50.0
Alkali feldspar	30.6	24.6–34.3
Agirinaugite	11.3	10.3–12.0
Wollastonite	10.9	9.10–12.6
Calcite	2.20	1.20–3.00

The analysis of the same batches showed average values of LOI 6.44% (range 5.36%–7.70%);[8] < 0.063 mm through fraction 99.98% (range 99.9%–100%) and Blaine fineness of 19,088 cm^2/g (range 16,233–20,414 cm^2/g).[9]

TABLE 2 Average elemental composition of the additive natrolite–phonolite expressed as the respective oxides.

Element[a]	Mean (%)	Range (%)
SiO_2	48.3	47.3–48.9
Al_2O_3	18.3	18.1–18.5
Na_2O	7.91	7.07–8.93
CaO	7.58	7.32–7.74
Fe_2O_3	4.51	4.48–4.54
K_2O	3.77	3.04–4.14
BaO	0.47	0.44–0.48
MgO	0.47	0.40–0.61
SrO	0.40	0.36–0.43
TiO_2	0.37	0.37–0.38
MnO	0.32	0.32–0.34
SO_3	0.18	0.13–0.23
P_2O_5	0.12	0.12–0.12

[a]Expressed as oxide.

[5]The particle size or fineness in cm^2/g or m^2/kg, usually determined from air permeability tests using a device known as a Blaine permeameter.

[6]Technical dossier/Section II.

[7]Technical dossier/SIn_Jan18/Annexes_II_1_35 and_II_1_37.

[8]Technical dossier/Supplementary information (January 2018)/ Annexes_II_1_35 and_II_1_36.

[9]Technical dossier/Section II_Identity.

The content of cadmium (Cd), lead (Pb), mercury (Hg) and arsenic (As) was analysed in eight batches of the additive,[10] and that of fluorine (F) in three.[11] The average values (in mg/kg) were 0.34 (0.05–0.61) for Cd, 26.8 (20.2–40.0) for Pb, 0.19 (0.02–0.33) for Hg, 5.73 (4.82–6.19) for As and 1170 (1130 – 1230) for F. The content of other elements was also quantified (mg/kg) in six batches: antimony (< 0.2–0.5), chromium (0.5–4.3), copper (4.0–31.4), nickel (< 1–1.81), thallium (0.20–0.39), zinc (99.9–150) and tin (0.99–3.48).[12]

The analysis of three batches of the additive showed levels of dioxins and the sum of dioxins plus dioxin-like PCBs of 0.14 (ranging 0.09–0.17) ng WHO-PCDD/F-TEQ/kg and 0.20 (ranging 0.13–0.24) ng WHO-PCDD/F-PCB-TEQ per kg; non-dioxin-like PCBs (ranging 1.7–3.3 µg/kg additive).

Microbiological contamination was analysed in one batch of the additive by determination of *Escherichia coli* and coliforms (< 3 CFU in 1 g), *Salmonella* spp. (not detected in 25 g) and yeast and moulds (< 100 CFU/g).[13]

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns, except for the presence of nickel, which will be addressed in the user safety section. The FEEDAP Panel notes that the levels of F are high and adding the additive at the maximum level of 25,000 mg/kg feed may result in levels of F in complete feed above the maximum limit set in Directive 2002/32/EC for some animal species/categories.[14]

No data on the possible interference of the additive with the analytical determination of mycotoxins in feed was provided.

3.1.1 | Physical properties of the additive

Natrolite–phonolite appears as a grey to grey-brown powder with a density between 2500 and 2600 kg/m^3 and a melting point > 1343 K and is insoluble in water and organic solvents.

The dusting potential of three batches of the additive was determined using the Stauber-Heubach method and showed values on average of 7620 mg/m^3 (range 7175–7865 mg/m^3) (mg airborne dust per m^3 of air).[15]

The particle size of the additive was analysed by laser diffraction method in four batches of the additive.[16] The results showed that, on average, 10% of the particles of the additive have a diameter below 0.72 µm (range: 0.64–0.90), 50% below 4.98 µm (3.86–7.50) and 90% below 20.4 µm (18.7–25.0).

Laser diffraction analysis is not a suitable method to establish the presence of small/nanoparticles as foreseen in the *Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles* (EFSA Scientific Committee, 2021a). No suitable data were provided by the applicant to assess the presence of small particles, including nanoparticles, in the additive. Therefore, its presence in the additive cannot be excluded.

3.1.2 | Stability and homogeneity

Stability studies are not required for mineral-based products, which are assumed to be stable.

For technological additives, evidence of homogenous distribution is not considered necessary if the efficacy of the additive is demonstrated. The applicant provided evidence of homogenous distribution in feed in the efficacy studies done with several feedingstuffs/feed materials. The studies are described in the efficacy section (see Section 3.3).

3.1.3 | Conditions of use

The additive is intended for use in feed for all animal species and categories up to a maximum of 25,000 mg/kg complete feed. The applicant recommends use levels between 10,000 and 20,000 mg/kg complete feed.

3.2 | Safety

The Panel notes that the potential presence of small particles, including nanoparticles, could not be excluded and no suitable data in line with the requirements of the Guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021b) were provided by the applicant. Considerations of the implications of the potential presence of nanoparticles on the safety assessment are made at the end of the section.

[10]Technical dossier/Section II/Annexes II_1_11 to II_1_16; II_1_24 to II_1_31; II_1_33; SIn_Jan18/Annex_II_1_36 and II_1_37; SIn_Jun23/Annex II_1_1.

[11]Technical dossier/SIn_Jun23/Annexes_II_1_1 and II_1_2.

[12]Technical dossier/Annex_II_1_17 and SIn_Jan18/Annex_II_1_36; LOD (mg/kg): Sb = 0.2; Cr = 0.3; Cu = 0.2; Ni = 0.3; Tl = 0.2; Zn = 0.2; S = 10.

[13]Technical dossier/Section II/Annex II_1_32.

[14]Directive 2002/63/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed, establishes maximum levels of 30–350 mg F/kg feed, depending on the species/categories.

[15]Technical dossier/SIn_Jan18/Annex_II_5_5.

[16]Technical dossier/SIn_Jan18/Annex_II_5_6 and SIn_Jun23/Annex_II_7_1.

The studies submitted in the dossier considering a conventional risk assessment are described below.
The Panel notes that no studies assessing the genotoxic potential of the additive were submitted.

3.2.1 | Safety for the target species

The applicant provided three tolerance trials, one in chickens for fattening,[17] one in weaned piglets[18] and one in cattle for fattening[19] to support the safety for the target animals.

3.2.1.1 | *Chickens for fattening*

The Panel notes that the maximum intended overdose level applied in the tolerance trial with chickens for fattening was 2× the maximum use level; however, a gross pathology examination of the organs of the animals at the end of the study was not performed, and the set of blood parameters provided was very limited. Moreover, the zootechnical performance of the birds was monitored for a shorter time (32 days) than that recommended by the Guidance on the assessment of safety for the target species (EFSA FEEDAP Panel, 2018). Therefore, this study is not further considered as evidence for the assessment.

3.2.1.2 | *Cattle for fattening*

Twenty-four weaned Charolais bulls (initial body weight of 350–400 kg) were distributed in groups of 8 to three pens and randomly allocated into three groups. The animals were fed a partial mixed ration (PMR) composed of wheat bran, wheat and dried distiller grains with solubles (DDGS), which was either not supplemented (control) or supplemented with the additive to provide 25,000 or 50,000 mg per kg. The concentration was estimated based on the analysis of ash content in the diets. Straw was supplied ad libitum in collective troughs. The animals received the treatments for 42 days. Individual PMR feed intake was recorded (electronic feeders) every day. Straw dry matter intake was recorded weekly for each pen and individual body weight was measured at days 1, 21 and 42. On days 1, 21 and 42 of the experiment, blood samples were taken from all animals and analysed for some haematology and clinical biochemistry parameters.[20]

The Panel notes that individual straw consumption was not provided, as requested by the Guidance. In the absence of these data, it is not possible to calculate the overdose of the additive, which in any case would be < 2× the maximum use level. A gross pathology examination of the organs of the animals at the end of the study was not performed, and the set of blood parameters provided was very limited. Therefore, the Panel cannot perform a complete assessment of the safety of the additive for cattle for fattening.

The results showed a significantly reduced average daily feed intake of the animals in both supplemented groups (9.98 and 9.81 kg for the 25,000 or 50,000 mg per kg PMR) compared to the control (10.3 kg) for the overall period, and lower final body weight (479.3 vs. 496.7 kg) and average daily gain (1.34 vs. 1.65 kg/day) of the overdose group compared to the control. Regarding blood parameters, a significant dose-dependent decrease of the β-hydroxy butyrate concentration (0.59, 0.41 and 0.30 mmol/L for control, 25,000 or 50,000 mg per kg PMR, respectively) and an increase of AST activity were observed at the two supplemented levels (141.4 and 174.2 U/L) compared to the control (108.9 U/L). The activity of AST in both supplemented groups was above the normal physiological range for cattle (78–132 U/L; Kaneko et al., 2008) and the Panel considers it an adverse effect. The lack of gross pathology and histopathology evaluation of the liver prevents the assessment of the possible implications of the changes observed in blood biochemistry on this organ and the completion of an adequate assessment of the potential impact on the animal.

3.2.1.3 | *Weaned piglets*

A total of 80 crossbred weaned piglets[21] were distributed in eight pens in groups of 10 animals. The feed intake of the animals in each pen was individually recorded by electronic feeders. The pens were randomly allocated to four groups (20 animals per treatment). Two basal diets (starter and grower) based on wheat, barley and soybean meal were either not supplemented (control) or supplemented with the additive to provide 8000 (0.75× maximum use level), 25,000 (1×) or 50,000 (2×) mg per kg feed. The content of the additive in the feeds was estimated based on the ash content. The experimental diets were offered in pelleted form for 42 days. Mortality and health status were checked every day. The growing performance of the animals was monitored during the experiment. Blood samples were taken from the animals and analysed for haematology and clinical chemistry parameters.[22] However, due to a lack of full reporting, it is not possible to establish from how many animals and when the samples were taken.

The Panel noted that the maximum intended overdose level applied in the trial was 2× the recommended level; a gross pathology examination of the organs of the animals at the end of the study was not performed; and the set of blood

[17]Technical dossier/SIn_Mar18/Tolerance study in chickens for fattening.

[18]Technical dossier/SIn_Mar18/Tolerance study in weaned piglets.

[19]Technical dossier/SIn_Mar18/Tolerance study in cattle for fattening.

[20]Red blood cells, total proteins, NEFSA, BHB, ALT (alanine aminotransferase), GGT (gamma-glutamyl transferase), cholesterol and total bilirubin.

[21]Pi × (DL × DE).

[22]Total count for red blood cells (RBC), haematocrit (HCT), haemoglobin (HGB), mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total and differential counts for leucocytes, platelet counts, procalcitonin, calcium, phosphate, magnesium, total protein, bilirubin, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyltransferase and glutamate dehydrogenase.

parameters provided was very limited. Therefore, the Panel cannot perform a complete assessment of the safety of the additive for weaned piglets.

The results showed a significantly lower performance of the animals receiving the 2× overdose compared to the control regarding the final body weight (23 vs. 29 kg), average daily gain (338 vs. 480 g), average daily feed intake (602 vs. 724 g) and feed-to-gain ratio (1.82 vs. 1.51). Regarding the clinical chemistry, despite that the number of blood samples analysed was limited due to haemolysis, the results showed that the supplementation with the additive at the use and overdose levels resulted in a significant dose-dependent increase in the activity of aspartate aminotransferase (AST; 48, 61 and 79 U/L for the control, 1× and 2× groups, respectively; physiological range: 32–84 U/L; Kaneko et al., 2008) and gamma-glutamyl transferase (GGT) activities (54, 68 and 81 U/L; physiological range: 10–60 U/L; Kaneko et al., 2008), and higher Ca (12.9, 13.5 and 15.0 mg/dL) and lower P (12.4, 11.0 and 9.5 mg/dL) serum concentrations. The lack of gross pathology and histopathology evaluation prevents the completion of an adequate assessment of the potential impact of the effects observed on the health of the animal.

3.2.1.4 | *In vivo interactions*

No information was provided on the possible interaction of the additive with feed materials, other approved additives or medicinal products.

3.2.1.5 | *Conclusions on safety for the target species*

The FEEDAP Panel notes that some adverse effects were seen in the studies in cattle for fattening and weaned piglets. In the absence of adequate studies, the relevance of these effects, and thus, their impact on the safety for the target animals, cannot be assessed. The FEEDAP Panel cannot conclude on the safety of the additive for the target species.

3.2.2 | Safety for the consumer

Based on the current knowledge and applying a conventional risk assessment, there is no indication of substantial absorption of the components of the additive. Therefore, the FEEDAP Panel concludes that the use of the additive in animal nutrition according to the conditions of use is of no concern for the consumer.

3.2.3 | Safety for the user

No studies performed with the additive under assessment were submitted to assess the safety for the user.

The highest nickel content analysed in the additive was 1.81 mg/kg. The highest dusting potential of the product was 7865 mg/m^3, corresponding to about 0.014 mg Ni/m^3 which would not exceed the transitional limit value of 0.1 mg Ni/m^3 for the inhalable fraction and 8 h' time-weighted average exposure established in Directive (EU) 2022/431.[35]

In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the potential of the additive to be a skin and eye irritant. Due to the presence of nickel in the additive, it should be considered a respiratory and dermal sensitiser.

3.2.4 | Safety for the environment

The chemical constituents of natrolites–phonolites are widely distributed in the environment. Therefore, it is not expected that the use of the additive in animal nutrition would adversely affect the environment.

3.2.5 | Specific considerations on the potential presence of nanoparticles and the safety assessment of the additive

The additive under assessment is a silicate mineral and as such may be present in a nanostructured form and/or may contain a fraction of particles in the nano range. The applicant did not submit suitable data allowing to establish the presence of small/nanoparticles and did not address potential risks associated with the presence of small/nanoparticles as indicated by the guidance documents to establish the presence of small particles (EFSA Scientific Committee, 2021a) and the risk assessment of nanomaterials (EFSA Scientific Committee, 2021b).

In the absence of suitable data, the presence of small/nanoparticles cannot be excluded.

Therefore, an assessment on the potential risks associated with the presence of nanoparticles could not be undertaken with regard to the safety of target animals, consumers and users.

3.2.6 | Conclusions on the safety of the additive

According to the conventional risk assessment, due to the lack of adequate data, the Panel is not in a position to conclude on the safety of the additive for the target species under the proposed conditions of use. However, from the limited data reported from tolerance studies in cattle for fattening and weaned piglets, effects observed in animal performance and blood clinical biochemistry could be indicative of adverse effects on the animals. Based on the current knowledge, there is no indication of substantial absorption of the components of the additive and, therefore, of concern for the consumer. The FEEDAP Panel is not in the position to conclude on the potential of the additive to be a skin and eye irritant. The additive is considered a respiratory and dermal sensitiser.

In the absence of suitable data, the presence of small/nanoparticles cannot be excluded. As no suitable data in line with the requirements of the guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021b) were provided by the applicant, the potential risks associated with the presence of nanoparticles for the target species, the consumer and the user could not be assessed.

The additive is safe for the environment.

3.3 | Efficacy

The applicant submitted three in vitro trials in which different feeds were supplemented with natrolite–phonolite to support the efficacy of the additive as an anticaking agent.

In the first trial,[23] three samples of one complementary feed for cattle (containing 3% of molasses) were either not supplemented (control) or supplemented with 15,000 or 30,000 mg natrolite–phonolite/kg feed. In the second trial,[24] one high-fat (7.6%) complete feed for turkeys (based on wheat and soybean) was either not supplemented (control) or supplemented with 12,500 or 25,000 mg natrolite–phonolite/kg complete feed. In both cases, the flowability of three replicates of each subsample was measured following the Jenike method (Jenike, 1967), and the results were averaged and expressed as the ratio of consolidation stress (*ffc*).[25] The ratio of consolidation stress allows to establish the flowability of the product tested based on the Jenike classification: <1 = not flowing; $1<ffc<2$ = very cohesive; $2<ffc<4$ = cohesive; $4<ffc<10$ = easy-flowing; >10 = free-flowing. For the feed for turkeys, measurements were done before and after time consolidation (simulating storage conditions; time not specified). No statistical analysis of the data was performed (Table 3).

TABLE 3 Effects of the feed supplementation with natrolite–phonolite on flowability measured by the Jenike method.

Natrolite–phonolite (mg/kg)	Complementary feed for cattle (ratio *ffc*)[a]	Natrolite–phonolite (mg/kg)	Feed for turkeys (ratio *ffc*)	
			Pre-consolidation	Post-consolidation
0	3.0	0	4.3	3.6
15,000	2.8	12,500	9.5	4.9
30,000	4.4	25,000	4.9	4.0

[a]*ffc* = consolidation stress (σ_1)/compressive strength (σ_c).

The results are presented in Table 3 and showed that the complementary feed for cattle not supplemented or supplemented with the additive at 15,000 mg/kg showed an *ffc* ratio between 2 and 4, which is considered 'cohesive' according to the Jenike classification; while the complementary feed supplemented with 30,000 mg/kg showed a ratio between 4 and 10, which is considered 'easy-flowing'. Regarding the complete feed for turkeys, the results of the feed before the time consolidation showed that the supplementation with the additive at 15,000 mg/kg improved the flowability compared to the control, from a *ffc* ratio of 4.3–9.5; the supplementation of the feed with the additive at 25,000 mg/kg did not improve the flowability in the pre-consolidation phase. After time consolidation, the flowability of the unsupplemented control showed a 'cohesive' pattern (*ffc* = 2–4), while both supplemented feeds were classified as 'easy-flowing' (*ffc* = 4–10).

Considering the inconsistency of the results observed in these studies, together with the reduced number of samples and the lack of statistical analysis, the Panel considers that the results do not support the efficacy of the additive.

In a third trial,[26] the anticaking effect of natrolite–phonolite was studied in a commercial vitamin–mineral premix for cattle including molasses. The premix was either not supplemented (control) or supplemented with the additive with 15,000 or 30,000 mg natrolite–phonolite/kg. The flowability was evaluated in five replicates of 200 g each in an outflow test. The flow time, cone height and cone radius were recorded. The results of each supplemented level were compared with the control with a *t*-test (Table 4).

[23]Technical dossier/Section II/Annex II_2_3.

[24]Technical dossier/Section II/Annex II_2_4.

[25]The ratio *ffc* is calculated by dividing the consolidation stress strength (σ_1) by the compressive strength (σ_c) obtained by the Jenike Shear Tester.

[26]Technical dossier/Section II/Annex II_2_1.

TABLE 4 Results of flow time, cone height and cone radius in cattle premix supplemented with natrolite–phonolite.

Natrolite–phonolite (mg/kg)	Flow time (s)	Cone height (mm)	Cone radius (mm)
0	24.34	41.00	5.97
15,000	18.15[a]	41.25	5.93
30,000	16.73[a]	41.40	5.92

[a]Significant differences between the supplemented feed and the control ($p < 0.001$).

The commercial vitamin–mineral premix for cattle supplemented with the additive at 15,000 and 30,000 mg/kg showed a significant reduction of the flow time compared to the control. No effect was observed on the cone height or the cone radius at any supplementation level of additive.

3.3.1 | Conclusions on efficacy

Due to the lack of sufficient data, the FEEDAP Panel is not in a position to conclude on the efficacy of the additive as an anticaking agent at the proposed conditions of use.

4 | CONCLUSIONS

According to the conventional risk assessment, due to the lack of adequate data, the Panel is not in a position to conclude on the safety of the additive for the target species under the proposed conditions of use. However, from the limited data reported from tolerance studies in cattle for fattening and weaned piglets, effects observed in animal performance and blood clinical biochemistry could be indicative of adverse effects on the animals. Based on the current knowledge, there is no indication of substantial absorption of the components of the additive and, therefore, of concern for the consumer. The FEEDAP Panel is not in the position to conclude on the potential of the additive to be a skin and eye irritant. The additive is considered a respiratory and dermal sensitiser.

In the absence of suitable data, the presence of small/nanoparticles cannot be excluded. As no suitable data in line with the requirements of the guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021b) were provided by the applicant, the potential risks associated with the presence of nanoparticles for the target species, the consumer and the user could not be assessed.

The additive is safe for the environment.

Due to the lack of sufficient data, the FEEDAP Panel is not in a position to conclude on the efficacy of the additive as an anticaking agent at the proposed conditions of use.

5 | RECOMMENDATION AND REMARK

The additive should be specified as a natrolite–phonolite obtained from volcanic rock from Kaiserstuhl, Germany.

The FEEDAP Panel notes that the iron content of the product (average 3.16%) would limit the use of this additive in compound feedingstuffs, for which a maximum content of iron is set by EU legislation. This may raise issues for control authorities and feed compounders.

ABBREVIATIONS

AST	aspartate aminotransferase
BW	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming unit
CV	coefficient of variation
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GC–MS	gas chromatography–mass spectrometry
GGT	gamma-glutamyl transferase
GLP	Good Laboratory Practice
LOD	limit of detection
LOI	Loss on ignition
LOQ	limit of quantification
MCHC	mean corpuscular haemoglobin concentration

MCV	mean corpuscular volume
OECD	Organisation for Economic Co-operation and Development
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofuran
PMR	partial mixed ration
SC	EFSA Scientific Committee
TEQ	toxic equivalent
TG	Test Guideline
XRF	X-ray fluorescence
WHO	World Health Organisation

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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