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SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of perlite for all terrestrial animal species (IMERYS Talc Europe)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | Roberto Edoardo Villa | Giovanna Azimonti | Eleftherios Bonos | Henrik Christensen | Mojca Durjava | Birgit Dusemund | Ronette Gehring | Boet Glandorf | Maryline Kouba | Marta López-Alonso | Francesca Marcon | Carlo Nebbia | Alena Pechová | Miguel Prieto-Maradona | Ilen Röhe | Katerina Theodoridou | Noël Dierick | Giovanna Martelli | Secundino López-Puente | Jaume Galobart | Orsolya Holczknecht | Matteo L. Innocenti | Jordi Ortuño | Maria Vittoria Vettori | Maria Dulak

Correspondence: Ask a Question

The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

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 the safety and efficacy of perlite as a technological feed additive for all terrestrial animal species. The FEEDAP Panel concluded that perlite is considered safe at 20,000 mg/kg complete feed for the use in feed for poultry for fattening or reared for laying/reproduction, ornamental birds, piglets (suckling and weaned) and pigs for fattening. No conclusion could be drawn on the safety of the product for the rest of terrestrial species/categories. The Panel concluded that the use of perlite is safe for the consumers and the environment. The Panel also concluded that the additive is not irritant to skin or eyes, but it is considered a dermal and respiratory sensitiser. Exposure by dermal and inhalation routes is considered a risk and should be minimised. The FEEDAP Panel concluded that perlite is efficacious as an anticaking agent in feed for terrestrial animal species.

KEYWORDS

anticaking agents, efficacy, perlite, safety, technological feed additives

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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 feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Imerys Talc Europe[2] for the authorisation of the additive consisting of perlite when used as a feed additive for all terrestrial 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 4(1) (authorisation of a feed additive or new use of a feed additive). The dossier was received on 26th October 2023 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00704. The particulars and documents in support of the application were considered valid by EFSA as of 12th March 2024.

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 perlite, when used under the proposed conditions of use (see **Section**).

1.2 | Additional information

The additive perlite is currently not authorised as a feed additive in the European Union. In 2020, the FEEDAP Panel delivered a statement on perlite (EFSA FEEDAP Panel, 2020).

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 perlite as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 12 August 2024 to 2 September 2024 for which no comments were received.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 18 March 2024 to 18 June 2024; the comments received were considered for the assessment.

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, other scientific reports and experts' (elicitation) knowledge, 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 perlite in animal feed.

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2]Imerys Talc Europe, 2 place Edouard Bouillères - BP 33662, 31036 Toulouse, France.

[3]Dossier reference: FEED-2023-19452.

[4]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[5]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of perlite is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: 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 FEEDAP 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 safety of feed additives for the environment (EFSA FEEDAP Panel, 2019) and Guidance on assessment of the safety of feed additives the for users (EFSA FEEDAP Panel, 2023), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024).

3 | ASSESSMENT

The additive under assessment, consisting of perlite (a natural silicate of sodium and aluminium), is intended to be used as a technological feed additive (functional group: anticaking agents) in feed for all terrestrial animal species.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

Perlite is a natural silicate of sodium and aluminium from a mine in Corsico, Italy. After mining, the perlite [redacted]. The additive is specified to contain minimum of 95% of expanded perlite (expanded amorphous aluminosilicate volcanic glass), less than 1% sodium and potassium feldspars, less than 1% of respirable crystalline silica[7] and to be free of asbestos.[8] The Chemical Abstracts Service (CAS) number of perlite is 93763-70-3 and the EC number is 618-970-4.

The data provided by the applicant on the mineralogical[9] and elemental analysis,[10] impurities[11] and physical properties[12] of the additive are reported in Table 1.

TABLE 1 Data on the batch-to-batch variation, impurities and physical properties of the additive.

		Analysis		
Parameter	**Specification**	**Average**	**Range**	**No. of batches**
Mineralogical analysis (XRPD) (%)				
Perlite	≥ 95	96.60	96.00–97.50	5
Feldspars	≤ 1	0.09	0.05–0.10	5
Quartz		0.24	0.17–0.30	5
Cristobalite		0.05	< 0.05–0.06	5
Elemental analysis (XRF) (expressed as oxides, %)				
SiO_2		75.58	75.57–75.59	5
Al_2O_3		13.10	13.07–13.12	5
K_2O		4.51	4.49–4.53	5
CaO		0.83	0.83–0.84	5
Fe_2O_3		0.84	0.83–0.87	5
Na_2O		3.49	3.47–3.51	5
MgO			0.25	5
Loss on ignition		1.26	1.25–1.29	5

[6]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.

[7]Respirable crystalline silica containing respirable fraction of quartz and cristobalite.

[8]Section II_Point 2–5 Conditions of use_PERLITE.pdf.

[9]Annex_II_1_2 XRD data YELLOW.pdf.

[10]Annex_II_1_3 XRF data YELLOW.pdf.

[11]Annex_II_1_4 Heavy metals YELLOW.pdf, Annex_II_1_8 Ni_Al_Fe elements YELLOW.pdf, Annex_II_1_5 Dioxins data YELLOW.pdf, Annex_II_1_6 Asbestos data YELLOW.pdf, Annex_II_1_7 Crystalline silica data YELLOW.pdf.

[12]Annex_II_1_9 Particle size distribution YELLOW.pdf, Annex_II_1_12 Dusting potential_Density YELLOW.pdf, Annex_II_1_13 Dust content YELLOW.pdf, Annex_II_4_2 Homogeneity feeds YELLOW.pdf.

TABLE 1 (Continued)

Parameter	Specification	Analysis		
		Average	Range	No. of batches
Impurities				
Lead (mg/kg)			1.04–1.06	3
Mercury (mg/kg)			< 0.01	3
Cadmium (mg/kg)			0.006–0.007	3
Arsenic (mg/kg)			1.85–1.94	3
Nickel (mg/kg)			2.32–2.48	3
Fluorine (mg/kg)			760–768	3
Dioxins and furans (upper bound)[1]				
PCDD/Fs (ng WHO_{2005}-TEQ/kg)			0.23–0.25	3
PCDD/Fs + PCBs (ng WHO_{2005}-TEQ/kg)			0.30–0.33	3
nDL-PCBs (μg/kg)			2.9	3
Asbestos (fibres > 0.2 μm)	Absent		Not detected	5
Crystalline silica (%)	≤ 1		0.036–0.139	5
Physical properties				
Physical form		Powder/granules		
Bulk density (kg/m^3)			[redacted]	3
Tap density (kg/m^3)			[redacted]	3
Solubility (mg/L)			1200–1400	
Dusting potential (Stauber Heubach) (mg/m^3)			7841–8150	3
Nickel in dust (mg/kg)			4.1–4.5	3
Particle size distribution (laser diffraction) (% of particles below, v/v)				
100 μm			[redacted]	
50 μm			[redacted]	
10 μm			[redacted]	3
Homogeneity (coefficient of variation, %)				
Chicken, pig and cattle feed			6.1–7.0	1

Abbreviations: <, means below the limit of quantification; nDL-PCBs, non-dioxin-like PCBs; PCBs, polychlorinated biphenyls; PCDDs, polychlorinated dibenzo-p-dioxins; PCDFs, polychlorinated dibenzofurans; TEQ, toxic equivalent factors for dioxins, furans and dioxin-like PCBs established by WHO in 2005 (Van den Berg et al., 2006); WHO, World Health Organization; XRF, X-ray fluorescence; XRPD, X-ray powder diffraction.

[1]Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. Values are expressed per kg of additive with 88% dry matter content.

The data provided showed that the batches analysed complied with the specifications set by the applicant. The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, with the exception of nickel and crystalline silica, which are addressed in the user safety section (see Section 3.2.5).

The characterisation of particle size and the granulometric properties of the additive was also performed using dynamic light scattering (DLS) technique in five batches of the additive.[13] No numerical values were obtained from these measurements as it was not possible for the data processing software to establish the autocorrelation function required for the determination of the granulometric properties of particles. According to the applicant, this may indicate that the size of perlite particles, aggregates and agglomerates could be above the DLS detection limit [redacted].

Based on the scanning electron microscopy–energy dispersive X-ray spectroscopy (SEM–EDX) analysis, it was demonstrated that perlite grains are composed of aggregates and agglomerates of constituent particles. The grains have an ellipsoidal and angular shape with the size varying up to several hundred micrometres.[14] The majority of constituent particles have a plain-like structure, with a polygonal shape.

[13]Annex_II_1_10 DLS YELLOW.pdf.

[14]Annex_II_1_11 SEM-EDX YELLOW.pdf.

3.1.2 | Interference of the additive with the analysis of mycotoxins in feed

The capacity of the additive to interfere with the analytical determination of mycotoxins in feed was studied for aflatoxin B1 (AfB1), zearalenone, fumonisins B1/B2 and deoxynivalenol in three types of feeds (for dairy cows, chickens for fattening, piglets) supplemented with 20,000 mg perlite/kg complete feed. AfB1 was introduced at the final concentration of 0.03 mg/kg feed, zearalenone at 0.5 mg/kg feed, fumonisins B1/B2 at 50 mg/kg feed and deoxynivalenol at 5 mg/kg feed.[15] No effects on the analytical determination of mycotoxins in feed were observed with the addition of the additive in complete feed.[16]

3.1.3 | Conditions of use

The additive is intended for use in feed for all terrestrial animal species at a proposed maximum inclusion rate of 20,000 mg/kg of complete feed.

3.2 | Safety

3.2.1 | Genotoxicity studies

The FEEDAP Panel considers that perlite, as all the other clays, is mainly constituted of insoluble material, not suitable to be tested for in vitro genotoxicity; however, the potential genotoxicity of the additive can be evaluated considering the presence of potential genotoxic components in the soluble fraction of the additive. The applicant tested a water suspension of perlite.

3.2.1.1 | *Bacterial reverse mutation test*

To evaluate the potential of perlite to induce gene mutations, a bacterial reverse mutation test (Ames test) was performed in accordance with the OECD Testing Guidelines (TG) 471, in a study claimed to be compliant with Good Laboratory Practices (GLP).[17] Salmonella Typhimurium strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP2 uvrA were used in the absence and presence of metabolic activation. A homogeneous water suspension of perlite was tested at five concentrations ranging from 50 to 5000 μg/plate in two independent experiments, applying the plate incorporation and the pre-incubation methods. No precipitation of the test item was observed. No cytotoxicity was observed and no increase in the number of revertant colonies was induced by the test item in any of the experimental conditions tested. Therefore, the FEEDAP Panel concludes that the soluble part, if any, of a water suspension of the test item does not induce gene mutations in bacteria under experimental conditions applied in the study.

3.2.1.2 | *In vitro mammalian micronucleus test*

To evaluate the potential of perlite to induce chromosomal damage, an in vitro micronucleus test was performed in Chinese Hamster Ovary (CHO- K1) cell line in accordance with the OECD TG 487, in a study claimed to be compliant with GLP.[18] Based on the results of a preliminary range-finding experiment, perlite was tested at: (i) 128, 224 and 320 μg/mL applying a short treatment (3 + 1.5 to 2 times the cell cycle of recovery) with and without metabolic activation and (ii) 89.6, 128, 224 μg/mL in a continuous treatment of about 1.5–2 times the cell cycle without metabolic activation. To measure cytotoxicity, the reduction of the relative increase in cell counts was calculated. Values up to 47%, 43% and 41% were observed at the top concentrations tested after short treatment in the presence of metabolic activation, short and continuous treatments in the absence of metabolic activation, respectively. No increase in the frequency of micronucleated cells was induced by the test item at any concentration and treatment-time. Therefore, the FEEDAP Panel concludes that perlite did not induce structural and numerical chromosome aberrations in mammalian cells under the experimental conditions applied in this study.

3.2.1.3 | *Conclusions on genotoxicity*

Based on these results of the in vitro genotoxicity studies, the FEEDAP Panel concludes the additive under assessment does not raise concerns for genotoxicity.

[15]The levels of mycotoxin contamination are in alignment with Directive 2002/32/EC (for aflatoxin B1) and Commission Recommendation 2006/576/EC (for zearalenone, fumonisins and deoxynivalenol).

[16]Annex_II_4_3 Hiding_Mycotoxins YELLOW.pdf.

[17]Annex_III_2_2 AMES-PH-22-0721_OECD 471 rev Jan 2024 YELLOW.pdf.

[18]Annex_III_2_3 MNS-PH-22-0721_OECD 487 rev Jan 2024 YELLOW.pdf.

3.2.2 | Safety for the target species

The applicant provided tolerance trials in chickens for fattening, weaned piglets and dairy cows[19] to support the safety for the target animals. However, the trial conducted with dairy cows showed a great heterogeneity of the animals enrolled within each group: at the start of the trial, the variability between animals within each group was up to 20% in the milk yield and dry matter intake, and days in milk ranging from 32 to 181. The Panel considered that this high variability would preclude the possibility of detecting potential differences between groups. Therefore, the Panel concluded that the study was not fit for the assessment of the safety of the additive and was not further considered. The applicant provided a series of published studies to support the safety in ruminants. The Panel reviewed them and considered that none provided adequate evidence to support the safety for ruminants.[20]

Tolerance trial in chickens for fattening[21]

A total of 960 one-day-old male chickens for fattening (Ross 308) were distributed in 48 pens (20 chickens per pen), which were randomly allocated to four groups (representing 12 replicates per group). Three basal diets (starter from days 1 to 10; grower from days 11 to 21; finisher from days 22 to 38) based on maize and soybean were either not supplemented (control) or supplemented with the additive to provide 10,000, (0.5× maximum use level), 20,000 (1×) or 50,000 mg/kg complete feed (2.5×). The recovery rates in the feeds were confirmed indirectly via the analysis of the content of aluminium as a marker.[22] The experimental feeds were offered ad libitum for 38 days, either as crumbles (starter) or as pellets (grower/finisher). The diets were formulated to be isoenergetic and isonitrogenous.

Mortality and health status were checked daily, and all dead birds were subject to a necropsy. The birds were weighed at the start of the trial. Thereafter, the bodyweight and feed intake were recorded on days 10, 21 and 36 on a pen basis. The average daily gain, average daily feed intake and feed-to-gain ratio were calculated. The feed-to-gain ratio was corrected for mortality. On days 36 and 38, one bird per replicate and day was sampled and blood biochemistry[23,24] haematology[25] were analysed. The same 96 animals were necropsied, and organs sampled, weighed and evaluated for gross pathology.

The experimental data were analysed with a generalised linear model, using the pen as experimental unit and the diet as fixed affect. Group means were compared by Tukey's test. Mortality data was assessed using non-parametric analysis. The significance level was set at 0.05.

TABLE 2 Effects of the dietary supplementation of chickens for fattening with perlite on selected safety parameters.

	Control	0.5×	1×	2.5×
Additive content (mg/kg feed)				
Intended	0	10,000	20,000	50,000
Analysed content of Al (starter/grower/finisher)	62/62/55	77/73/69	93/95/91	139/141/135
Calculated level of perlite[1] (starter/grower/finisher)	0	7200/4900/6600	14,400/15,400/16,700	35,300/36,600/37,000
Mortality/culling (total) (%)	1.25/0.83 (2.08)	1.25/0.83 (2.08)	1.67/0.42 (2.09)	1.67/2.11 (3.78)
Performance parameters				
Final body weight (kg)	2855	2765	2849	2814
Average daily gain (g)	80.3	77.7	80.1	79.1
Average daily feed intake (g)	109	106	109	108
Feed-to-gain ratio	1.36	1.37	1.36	1.37
Blood parameters				
Cholesterol (mg/dL)	111.4[a]	109.1[ab]	105.3b[c]	102.8[c]

[a,b]Mean values within a line with a different superscript are significantly different $p < 0.05$.

[1]The FEEDAP Panel considers that the levels of perlite, calculated from the analysed Al concentration, are sufficient to confirm the intended concentrations.

[19]Annex_III_1_1 DC TOL trial_report.

[20]Annex_III_1_1D ELS_Perlite_Dairy Cows YELLOW.

[21]Annex_III_1_3 Broiler TOL B690_report.

[22]The content of perlite in the experimental diets (mg/kg complete feed) was calculated based on: ([Al] in feed 12% moisture – [Al] in control feed 12% moisture)/([Al] from perlite × 100).

[23]Sodium, potassium, chloride, calcium, phosphate, magnesium, total protein, albumin, globulin, glucose, uric acid, cholesterol, creatinine, bilirubin, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, gamma-glutamyltransferase, alkaline phosphatase and creatine kinase.

[24]Total count for red blood cells, haematocrit, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total leukocytes, eosinophils, basophils, lymphocytes, monocytes, heterophiles and prothrombin time.

[25]Liver, kidneys, spleen, heart, adrenal gland, lungs, gizzard, proventriculus, crop, pancreas, small intestine (duodenum), colon, caecum, thymus, thyroid gland, Bursa of Fabricius, testes. Out of these organs, only the relative weight of the heart, kidneys, spleen and liver was recorded. Based on the lack of effects observed in the gross pathology evaluation and the nature of the additive, the lack of the weight measurement of the rest of organs was not considered critical.

The health status of the animals was good during the whole trial. The overall mortality and culling were 2.5%, with no statistical differences between groups. The supplementation with perlite did not result in any statistical difference between groups on any of the zootechnical performance or the haematology and blood biochemistry parameters measured. The only exception was the serum cholesterol content, for which a dose-dependent decrease was observed with higher inclusion levels of the additive; however, this was not considered an adverse effect (Table 2). Regarding the organs' relative weights (heart, liver, kidneys and spleen), no significant differences were observed between the supplemented groups and the control.

Regarding the gross pathology observations, the main lesion found was a mild enlargement and redness of the caecal tonsils, found in 10 birds (4/24, 1/24, 2/24 and 3/24 for C, 0.5×, 1× and 2.5×, respectively). However, the values did not follow a clear trend and thus seem not to be related with the additive supplementation. No other relevant lesions were identified.

The results of the tolerance trial showed that perlite is well tolerated by chickens for fattening at 50,000 mg/kg feed. Therefore, the FEEDAP Panel concludes that perlite is safe at the proposed maximum level of 20,000 mg/kg complete feed. This conclusion is extended to chickens reared for laying/reproduction. Considering the margin of safety established, the Panel considers that the conclusion can also be extrapolated to other poultry for fattening, poultry reared for laying/reproduction and ornamental birds.

Tolerance trial in weaned piglets[26]

A total of 144 weaned piglets (28 day-old; BW 8.4 kg), male and female [Piétrain×(Large White×Landrace)] were distributed in 36 pens in groups of four animals (two males and two females) and allocated, on the basis of sex and BW, to four groups (representing nine replicates per group). Two basal diets (pre-starter, from day 1 to 14 and starter, from day 15 to 42) based on barley, maize and soybean meal were either not supplemented (control) or supplemented with the product to provide 10,000 (0.5×), 20,000 (1×) or 50,000 (2.5×) mg perlite per kg feed. The recovery rates in the feeds were confirmed via the indirect content of aluminium content as marker.[27] The experimental diets were offered on an ad libitum basis in pelleted form for 42 days.

Mortality and health status were checked every day, and the most likely cause of death or reason for culling was recorded. Piglets were weighed at the start of the trial. Thereafter, the body weight and the feed intake were measured on days 7, 14, 28 and at the end of the trial. The average daily gain, average daily feed intake and feed-to-gain ratio were calculated. The feed-to-gain ratio was corrected for mortality. Blood samples were collected on day 0 and 43 from the same two animals (one male and one female) per pen and treatment. The blood samples were analysed for haematology and clinical biochemistry parameters. After finishing the trial, 36 piglets (one piglet per pen) were killed, organs[28] sampled, weighed and evaluated for gross pathology.

The experimental data were analysed with a generalised linear model, including the pen as experimental unit and the diet and block as fixed effects. When differences were observed, group means were compared with Tukey test. Mortality was analysed using the Kruskall–Wallis method. Significance level was set at 0.05.

TABLE 3 Effects of the dietary supplementation of weaned piglets with perlite on selected safety parameters.

	Control	0.5×	1×	2.5×
Additive content (mg/kg feed)				
Intended	0	10,000	20,000	50,000
Analysed content of Al (pre−/starter)	46/46	60/65	79/82	140/132
Calculated level of perlite[1]	0	6600/8500	15,000/16,500	42,900/38,800
Mortality / culling (%)	0	0	0	0
Performance parameters				
Final body weight (kg)	28.8	27.7	27.5	26.6
Average daily gain (g)	485	461	456	435
Average daily feed intake (g)	710	674	658	641
Feed-to-gain ratio	1.47	1.46	1.44	1.48
Organ's relative weight				
Spleen (%)	0.21b	0.25ab	0.27ab	0.30a
Liver (%)	2.83b	2.98ab	2.81b	3.17a

[a,b]Mean values within a line with a different superscript are significantly different $p < 0.05$.

[1]The FEEDAP Panel considers that the levels of perlite, calculated from the analysed Al concentration, are sufficient to confirm the intended concentrations.

[26]Annex_III_1_2 P-758 Perlite final report.

[27]The content of perlite in the experimental diets (mg/kg complete feed) was calculated based on: ([Al] in feed 12% moisture – [Al] in control feed 12% moisture)/([Al] from perlite × 100).

[28]Liver, kidneys, spleen, heart, adrenal gland, lungs, stomach, small intestine, intestinal lymph nodes, pancreas, colon, caecum, thymus, thyroid gland, ovaries/testes. Out of these organs, only the relative weight of the heart, kidneys, spleen and liver was recorded. Based on the lack of effects observed in the gross pathology evaluation and the nature of the additive, the lack of the weight measurement of the rest of organs was not considered critical.

No piglets died or were culled during the trial. The inclusion of the additive in the diet of weaned piglets up to 50,000 mg/kg complete feed showed a numerical dose-dependent worsening of the final body weight (reduction of 2.2 kg between control and 2.5× groups), average daily gain (50 g lower in 2.5× than control) and average daily feed intake (69 g lower in 2.5× than control). These differences showed no statistical differences (Table 3). However, the Panel noted that the fact that the power of the study was below the minimum requested (< 0.80) may prevent to adequately assess the potential effect of the additive at this level.

Regarding the blood data, all values were within physiological range, and no differences between the supplemented groups and the control were observed at the end of the trial.

The relative weight of the spleen and liver showed a dose-dependent increase with higher inclusion levels of the additive, resulting in significant differences between the 2.5× group and the control. No effects on blood-related parameters and no macroscopical lesions were observed in the spleen, liver and kidneys of any group. However, an adverse effect could not be excluded as no histopathology evaluation was performed in any of the tissues.

The results observed in the relative organ weights and the zootechnical performance data suggested that the inclusion of perlite in the diet of weaned piglets at 50,000 mg/kg is not well tolerated. Therefore, the Panel concluded that perlite is safe for weaned piglets at 20,000 mg/kg complete feed with no margin of safety. This conclusion is extended to pigs for fattening. Considering the nature of the additive and the results of the toxicological studies, this conclusion could be extended to suckling piglets.

3.2.3 | In vivo interaction with nutrients and other components of the diet

An in vivo interaction/digestibility study in chickens for fattening was conducted in parallel to the corresponding tolerance trial to evaluate the interactions of Perlite with with other relevant components of the diet over 18 days. Sixteen birds from the control and sixteen from the 1× group (20,000 mg perlite/kg feed) were distributed in pairs in 16 cages (eight replicates per group). Excreta samples were quantitatively collected between days 16 and 18. Feed and excreta samples were analysed to calculate the nitrogen retention, the utilisation of total tocopherol, riboflavin, pyridoxine and manganese, and the disappearance of monensin from the gut lumen. The utilisation of total tocopherol (71.2% vs. 80.3%) and Mn (16.6% vs. 21.8%) was significantly decreased and that of pyridoxine significantly increased (57.1% vs. 50.6%) by the inclusion of perlite at 20,000 mg/kg complete feed compared to control. No effects were observed on the nitrogen retention, riboflavin utilisation and monensin disappearance.

3.2.3.1 | *Conclusions on safety for the target species*

Based on the results of the tolerance trials submitted, the Panel concludes that perlite is safe when supplemented in the feed of chickens for fattening and weaned piglets at the maximum use level of 20,000 mg/kg. This conclusion is extended to chickens reared for laying/reproduction, suckling piglets and pigs for fattening and can be extrapolated to other poultry for fattening and reared for laying/reproduction and ornamental birds. No conclusion can be drawn for other terrestrial species/categories.

3.2.4 | Safety for the consumer

The FEEDAP Panel considers it unlikely that the additive, in common with other clays, will be degraded during its 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.

3.2.5 | Safety for the user

Based on the highest dusting potential (see **Section 3.1.1**), the FEEDAP Panel considers that the exposure through inhalation is likely.

An acute inhalation study was performed following the OECD Testing Guideline 403.[29] The lethal concentration 50 (LC_{50}) is greater than 1.99 mg/L.

The FEEDAP Panel notes that the additive contains crystalline silica (see **Section 3.1.1**). Inhalation of crystalline silica is known to be hazardous and is associated with increased risk of lung cancer and the industrial disease, silicosis. The Directive (EU) 2017/2398[30] set an occupational exposure limit (OEL) of 0.1 mg/m^3 of air for respirable crystalline silica dust.

[29]Annex_III_3_1 Acute inhalation_OECD 403 rev Feb 2024 YELLOW.pdf.

[30]Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 345, 27.12.2017, 8 pp.

The FEEDAP Panel notes that the additive contains nickel (see Section **3.1.1**). The Directive (EU) 2022/431[31] set an OEL of 0.01 and 0.05 mg/m^3 for both respirable and inhalable fraction, respectively as nickel meets the criteria for classification as carcinogenic (category 1A).

Due to the presence of nickel the additive should be considered as a skin and respiratory sensitiser.

The skin irritation potential of perlite was tested in a study performed according to OECD TG 439 which showed that perlite is not a skin irritant.[32]

The eye irritation potential of perlite was tested in a study performed according to OECD TG 438 which showed that perlite is not an eye irritant.[33]

The skin sensitisation potential of perlite was tested in a study performed according to OECD TG 442-B, which showed that perlite is not a skin sensitiser.[34]

3.2.5.1 | *Conclusions on safety for the user*

The additive is not irritant to skin or eyes but is considered to be dermal and respiratory sensitiser. Exposure by dermal and inhalation routes is considered a risk and should be minimised.

3.2.6 | Safety for the environment

Perlite is a naturally occurring mineral widely distributed in the environment. Therefore, it is not expected that the use of the additive in animal nutrition would adversely affect the environment.

3.3 | Efficacy

To support the efficacy of the additive as an anticaking agent, the applicant submitted data from an in vitro trial in which three different types of mash feeds (for chickens, pigs and cattle) were supplemented with perlite at 0, 1000, 3000 or 5000 mg/kg complete feed.[35] These feeds were then pelleted at 65°C. The efficacy of the additive as an anticaking agent was evaluated by measuring the flowability of feeds. The results, analysed with Kruskal–Wallis and followed by Dunn's post-test, are presented in Table 4.

TABLE 4 Flowability of chicken, pig and cattle feeds supplemented with different doses of perlite.

Perlite inclusion level (mg/kg feed)	Mean flowability (kg/min)		
	Chicken feed	Pig feed	Cattle feed
0	14.2^{a}	12.6^{a}	12.3^{a}
1000	14.6^{b}	13.4^{b}	13.1^{b}
3000	14.5^{bc}	13.3^{b}	13.1^{b}
5000	14.5^{c}	13.3^{b}	13.1^{b}

^{a,b,c} mean values within a group with a different superscript are significantly different ($p < 0.05$).

The inclusion of perlite, starting from 1000 mg/kg, significantly improved the flowability in all three tested feeds when compared to the control ($p < 0.05$).

3.3.1 | Conclusions on efficacy

The FEEDAP Panel concludes that the additive perlite is efficacious as an anticaking agent in feed for terrestrial animal species.

[31]DIRECTIVE (EU) 2022/431 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 88/2, 16.3.2022, 14 pp.

[32]Annex_III_3_3 HSMI-PH-22-0721_OECD 439 rev Jan 2024 YELLOW.pdf.

[33]Annex_III_3_2 ICE-PH-22-0721_OECD 438 rev Jan 2024 YELLOW.pdf.

[34]Annex_III_3_4 LLNA-BrdU-22-0721_OECD 442-B rev Jan 2024 YELLOW.pdf.

[35]Annex_IV_1_1 Perlite_anticaking efficacy

4 | CONCLUSIONS

The FEEDAP Panel concludes that perlite at the maximum proposed inclusion level of 20,000 mg/kg complete feed is safe for all poultry for fattening or reared for laying/reproduction, ornamental birds, suckling and weaned piglets and pigs for fattening. No conclusion can be drawn for the rest of terrestrial animal species/categories.

The use of the feed perlite in animal nutrition under the proposed conditions of use is of no concern for the consumer and environment.

The additive is not irritant to the skin or eyes but should be considered a dermal and skin sensitiser. Exposure by dermal and inhalation routes is considered a risk and should be minimised.

The additive is considered to be efficacious as an anticaking agent in feedingstuffs for terrestrial animal species.

5 | REMARKS

Considering the effects observed on the utilisation of specific nutrients in the in vivo interaction study, feed formulators should take into account the inclusion of these nutrients in the formulated diets.

ABBREVIATIONS

ADFI	average daily feed intake
ADG	average daily gain
AfB1	aflatoxin B1
BW	body weight
CAS	Chemical Abstracts Service
CHO	Chinese Hamster Ovary
DLS	dynamic light scattering
DM	dry matter
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GLP	Good Laboratory Practice
IUPAC	International Union of Pure and Applied Chemistry
LC_{50}	lethal concentration 50
nDL-PCBs	non-dioxin-like PCBs
OECD	Organisation for Economic Co-operation and Development
OEL	occupational exposure limit
PCBs	polychlorinated biphenyls
PCDDs	polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzofurans
SEM–EDX	scanning electron microscopy–energy dispersive X-ray spectroscopy
TEQ	toxic equivalent factors for dioxins, furans and dioxin-like PCBs
WHO	World Health Organization
XRF	X-ray fluorescence
XRPD	X-ray powder diffraction

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PANEL MEMBERS

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Ilen Röhe, and Katerina Theodoridou.

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