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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of vermiculite for all poultry and ornamental birds, all porcine species, equines, leporids, camelids, pets and other non-food-producing animals (Regal B.V.)

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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 vermiculite as a technological feed additive for all poultry and ornamental birds, all porcine species, equines, leporids, camelids, pets and other non-food-producing animals. The FEEDAP Panel concluded that vermiculite is considered safe at 10,000 mg/kg complete feed for the use in feed for chickens for fattening and reared for laying/breeding and laying hens, and at 5000 mg/kg complete feed for piglets and pigs for fattening. No conclusion can be drawn on the safety of the product for ornamental birds, equines, leporids, camelids, pets and other non-food-producing animals. The Panel concluded that the use of vermiculite is safe for consumer and the environment. The additive is considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. Due to the lack of data, the Panel could not conclude on the potential of the additive to be an eye irritant. The FEEDAP Panel concluded that vermiculite is efficacious as anticaking agent in feed, when used at 10,000 mg/kg complete feed.

KEYWORDS

anticaking agent, efficacy, safety, technological additives, vermiculite

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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 Regal B.V.[2] for the authorisation of the additive consisting of vermiculite when used as a feed additive for all animal species (category: technological additive; functional group: anticaking agent and binder). During the assessment, the applicant requested a change in the target species from all animal species to all poultry and ornamental birds, all porcine species, equines, leporids, camelids, pets and other non-food-producing animals. Additionally, the applicant withdrew the application for the functional group "binders".

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 06 June 2023 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00391. The particulars and documents in support of the application were considered valid by EFSA as of 19 September 2023.

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 vermiculite when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The additive consists of vermiculite and was authorised for use in feed for all animal species under the functional groups binders and anticaking agents until 2023. However, it was withdrawn from the market and is currently not authorised.[3]

EFSA issued an opinion on the safety and efficacy of this product when used in feed for pigs, poultry, bovines, sheep, goats, rabbits and horses as a technological additive (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[4] in support of the authorisation request for the use of vermiculite as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 19 September 2023 to 19 December 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] 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,[6] 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 21 June to 12 July 2024 for which no comments were received.

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.

[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]Wilhelminalaan 86, 6042 EP Roermond. The Netherlands.
[3]COMMISSION IMPLEMENTING REGULATION (EU) 2023/1173 of 15 June 2023 withdrawing from the market certain feed additives, amending Regulation (EC) No 1810/2005 and repealing Regulations (EC) No 1453/2004, (EC) No 2148/2004 and (EC) No 943/2005.
[4]FEED-2023-16782.
[5]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, pp. 1–48.
[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the vermiculite in animal feeds.[7]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of vermiculite is in line with the principles laid down in Regulation (EC) No 429/2008[8] 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 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 safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024).

3 | ASSESSMENT

The additive vermiculite is intended to be used as a technological additive (functional group: anticaking agents) in feed for all poultry and ornamental birds, all porcine species, equines, leporids, camelids, pets and other non-food-producing animals.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

The additive under assessment is vermiculite, a magnesium aluminium iron silicate. Vermiculite is obtained by mining, followed by a thermal expansion process obtained with heat treatment at a temperature 600–1000°C called exfoliation. Depending on the size of the particles obtained, two commercial products are available: a larger 'micron' grade and a smaller 'superfine' grade.

The additive is specified to contain 100% vermiculite; specifications of the elemental components reported as oxides are 35%–45% of silicon dioxide (SiO_2), 20%–40% magnesium oxide (MgO), 7%–15% aluminium oxide (Al_2O_3), 4%–10% iron oxide (Fe_2O_3), < 6% potassium oxide (K_2O), < 1% sodium oxide (Na_2O) and 0.5%–5% calcium oxide (CaO) and a loss on ignition up to 20%.

The additive was characterised in a previous opinion of the FEEDAP Panel (EFSA FEEDAP Panel, 2020). The applicant provided additional data on the characterisation of the additive in the present submission which are described below.

The applicant provided results of the mineralogical analysis performed by X-ray diffraction (XRD)[9] and elemental analysis by X-ray fluorescence spectroscopy (XRF)[10] on five batches of vermiculite. Values are reported in Table 1 and Table 2, respectively.

TABLE 1 Mineralogical composition of vermiculite (%) (five batches).

	Average	Range
Vermiculite	89.7	87.0–96.6
Hydroxyapatite	3.7	1.0–4.9
Diopside (Fe^{+2}-bearing)	6.6	2.4–8.1

TABLE 2 Elemental composition of vermiculite expressed as oxides (%) (five batches).

	SiO_2	MgO	Al_2O_3	Fe_2O_3	CaO	K_2O	TiO_2	P_2O_5
Average	42.9	23.5	11.0	10.2	4.2	5.3	1.4	1.2
Range	42.7–43.3	22.9–23.9	10.6–11.2	9.4–10.8	3.0–6.0	5.0–5.5	1.3–1.4	0.5–1.6

[7]Evaluation report received on 19/12/2023 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/feed-2023-16782_en.

[8]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.

[9]Annex 2.1.3.

[10]Annex 2.1.3.a.

The Panel notes that four of the batches ranged between 87.0 and 88.7% vermiculite mineral, while only one had a content of 96.6%.

Three batches of the additive were analysed for impurities[11] and showed the following values: 948.3 mg fluorine/kg (864.0–997.0 mg/kg), 4.9 mg lead/kg (4.1–5.8 mg/kg), 1.1 mg arsenic/kg (< limit of detection (LOD) -1.2 mg/kg), 362.3 mg copper/kg (258.0–468.0 mg/kg), 195.6 mg chromium (193.0–199.0 mg/kg) and 142.3 mg nickel/kg (135.0–148.0 mg/kg). Cadmium and mercury were also determined but were below the LOD in all batches.[12]

The applicant also submitted data on the content of asbestos using polarised light microscopy (PLM) and dispersion staining microscopy in six batches of micron vermiculite and 11 batches of superfine vermiculite.[13] The data confirmed the absence of asbestos.

Two of the above batches of each product were analysed for the content of quartz and cristobalite using X-ray diffraction. The results showed that cristobalite was not present in any batch (LOD < 0.01%) while crystalline silica was present ranging 0.02%–0.06%.[14]

Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were analysed in the same three batches. All values were below the corresponding limit of quantification (LOQ).[15] The calculated upper bound (UB) concentration was 0.156 ng WHO-TEQ/kg for the sum of PCDD/Fs, and 0.222 ng WHO-TEQ/kg the sum of PCDD/Fs and DL-PCBs. The UB for the sum of non-DL-PCBs was 0.003 mg/kg.

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, except for the presence of nickel and crystalline silica, which will be addressed in the user safety section (see Section 3.2.9).

Data on the physical properties of the additive including dusting potential, particle size distribution were assessed in the previous opinion on the same product (EFSA FEEDAP Panel, 2020). New data were provided on the qualitative scanning electron microscope (SEM) analysis, which showed that the material contains a fraction of small particles including nanoparticles.[16]

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

The applicant investigated the potential of the additive to interfere with the analytical determination of mycotoxins in feed.[17] Three batches of corn meal were analysed for the content of aflatoxins, ochratoxins, deoxynivalenol and fumonisins B1 + B2. Zearalenone was analysed in one batch of barley, rice and corn meal. All batches were either not supplemented or supplemented with 10,000 mg vermiculite/kg feed 2 h prior the analysis of mycotoxins. The results showed that there were no differences in the analysed values of the different mycotoxins between the feeds with and without vermiculite at the maximum recommended level used in feed.

3.1.3 | Conditions of use

The additive is intended for use in feed for all poultry species and ornamental birds, equines, leporids, camelids, pets and other non-food-producing animals at a maximum use level of 10,000 mg/kg complete feed, and in feed for all porcine species with a maximum use level of 5000 mg/kg complete feed.

3.2 | Safety

3.2.1 | Genotoxicity studies

Clays are essentially not absorbed and therefore a systemic exposure is not expected. However, the potential genotoxicity at the level of site of contact needs to be excluded.

The FEEDAP Panel considers that vermiculite, 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.

No genotoxicity studies conducted with the soluble fraction of the additive under assessment were submitted. However, the applicant provided a justification supported by analytical data demonstrating the absence of impurities in the soluble fraction of the additive.

[11] Annex 2.1.4.a.

[12] LOD for cadmium 0.1 mg/kg, mercury 0.1 µg/kg, arsenic 1 mg/kg.

[13] Annex 2.4.3b, Annex 2.4.3c and Annex 2.4.3d.

[14] Annex 2.4.3b, Annex 2.4.3c and Annex 2.4.3d.

[15] 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. TEQ = toxic equivalency factors for dioxins, furans and dioxin-like PCBs established by the WHO in 2005 (Van den Berg et al., 2006).

[16] Annex 2.4.3.a.

[17] Annex 2.1.3.b and Annex 2.1.3.c.

The product under assessment undergoes an expansion process at high temperatures after which it is expected that all the organic impurities and any volatile substances are evaporated. To confirm this, the applicant provided an high-performance liquid chromatography (HPLC) analysis of the soluble fraction of the additive obtained after its treatment with HCl for 12 h.[18] The results showed that no organic impurities were detected in the additive. The applicant provided also analytical data on possible presence of inorganic impurities in the additive. The results are described in Section 3.1.1 and they did not raise any safety concern.

The FEEDAP Panel considers that the explanation and the supporting data provided by the applicant are acceptable and that no further testing for genotoxicity is necessary.

3.2.2 | Safety for the target species

In support of the safety of the additive for the target species, the applicant submitted three tolerance trials, one in chickens for fattening, one in laying hens and one in weaned piglets.

3.2.3 | Chickens for fattening

A total of 300 one-day-old male chicks (Ross 308) were distributed in 30 pens of 10 birds each, which were randomly allocated to three experimental groups (10 replicates per group).[19] Three basal diets (starter, from day 1 to 11; grower, from day 11 to 24; finisher, from days 24 to 35) based on maize, soybean meal and wheat, were either not supplemented (control) or supplemented with vermiculite to provide 10,000 (1× maximum use level) or 25,000 (2.5×) mg/kg feed (confirmed based on the analysis of crude ash content; see Table 3).[20] The Panel notes that the additive was added on top of the basal diets without any correction to compensate for the energy imbalance due to the additive inclusion. The diets were offered ad libitum in pelleted form for 35 days. The finisher feed included an external marker for the evaluation of the potential interactions with nutrients (see Section 3.2.6).

The mortality and health status were checked every day and the most likely cause of death or reason for culling recorded. Animals were weighed at the start of the trial. Thereafter, the body weight and the feed intake were measured on days 11, 24 and 35 (on pen basis). The average body weight gain, average pen feed intake and feed-to-gain ratio were calculated and corrected for mortality for the overall period. Blood samples were collected on day 35 from two animals per pen. The blood samples were analysed for haematology[21] and clinical biochemistry parameters.[22] On the same day, another two birds per pen were killed and organs sampled, weighed and evaluated for gross pathology and, if relevant, for histopathological lesions.[23]

The data were analysed with a generalised linear model, including the diet as fixed effect and the pen as experimental unit. When differences between groups were detected, means were compared with Duncan's multiple range test. The significance level was set at 0.05. The parameters showing significant differences are reported in Table 3.

The health status of the animals was good throughout the study. The overall mortality was 1.7%, with an additional 1.3% of animals culled, with no differences between groups. The inclusion of vermiculite in the diet of chickens for fattening showed no differences in the average body weight gain at any level at the end of the study. The feed intake and the feed-to-gain ratio showed a dose-dependent increase with higher levels of vermiculite, which resulted in a significant difference between the 2.5× overdose in comparison with the control group. No differences were observed in the feed intake and feed-to-gain ratio between 1× and the other groups.

[18]Annex 2.1.4.b.

[19]Annex 3.1.1.1.

[20]Analysed crude ash content in feed for the control/1×/2.5× (mg/kg complete feed): 59,800/68,700/82,100; 54,700/63,400/75,700; and 54,000/62,500/75,600 for the starter; grower; and finisher diets, respectively.

[21]Total count for red blood cells, packed cell volume, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total counts for leukocytes (lymphocytes, granulocytes, others), fibrinogen.

[22]Sodium, potassium, chloride, calcium, phosphate, magnesium, total protein, albumin, glucose, uric acid, cholesterol, bilirubin, creatinine, amylase, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, gamma-glutamyltransferase, alkaline phosphatase, creatine kinase, serum amyloid A.

[23]Liver, kidneys, spleen, adrenal gland, lungs, stomach, pancreas, ileum, colon, caecum, thymus, thyroid gland, heart and testes.

TABLE 3 Effects of the dietary supplementation of chickens for fattening with vermiculite on selected parameters.

	Control	1×	2.5×
Vermiculite (mg/kg complete feed)[1]			
Intended	0	10,000	25,000
Calculated	–	8700	21,400
Mortality/culling (%)	1.0/1.0	2/2	2.0/1.0
Performance parameters			
Total weight gain (g)	2737	2734	2741
Total feed intake (g/bird)	3712^{b}	3777^{ab}	3860^{a}
Feed-to-gain ratio	1.36^{b}	1.38^{ab}	1.41^{a}
Blood parameters			
White blood cells (10^9/L)	26.6^{b}	30.8^{a}	30.0^{ab}
Lymphocytes (10^9/L)	19.9^{b}	20.9^{ab}	22.9^{a}
Granulocytes (10^9/L)	6.52^{b}	9.60^{a}	6.77^{b}
LDH (U/L)	4096^{a}	4377^{a}	3608^{b}
ALT (U/L)	15.2^{a}	10.3^{b}	9.30^{b}
Bilirubin (mg/dL)	0.26^{a}	0.09^{b}	0.11^{b}
K (mmol/L)	4.64^{b}	4.84^{b}	5.90^{a}
Mg (mg/dL)	1.83^{c}	2.22^{b}	2.45^{a}
P (mg/dL)	10.8^{b}	10.6^{b}	14.5^{a}
Ca (mg/dL)	9.76^{b}	9.87^{b}	10.4^{a}
Organ weight (% body weight)			
Lungs	0.55^{a}	0.47^{b}	0.45^{b}
Jejunum	1.52^{a}	1.32^{ab}	1.15^{b}
Ileum	0.90^{b}	1.30^{a}	1.14^{ab}
Caeca	0.36^{ab}	0.37^{a}	0.32^{b}

Abbreviations: ALT, alanine aminotransferase; LDH, lactate dehydrogenase.

[1]Calculated based on the analytical content of crude ash in the supplemented diets with respect to the control one.

[a,b,c]Different superscripts in a row mean significant differences ($p < 0.05$).

Significant differences were observed in some haematological parameters, electrolytes, ALT, LDH and bilirubin, as shown in Table 3. The Panel considers that the changes in the white blood cells and electrolytes, despite showing a clear link with the additive supplementation, were minor and within physiological ranges, while the reduction of the enzymatic activities and the bilirubin concentration were not considered an adverse effect.

No differences were observed in the gross pathology evaluation of the organs between groups. The relative weight of jejunum and lungs showed a dose-dependent reduction with higher levels of vermiculite, which resulted in significant differences at 1× (only for lungs) and 2.5× compared to the control. No histopathological examination was done. However, the Panel notes that the differences in the relative weights between treatments were relatively small and no macroscopic lesions were reported. Therefore, the absence of histopathological examination was not considered critical.

Based on the effects observed in the feed-to-gain ratio, the Panel considers that the inclusion of vermiculite in the feed for chickens for fattening is safe at 10,000 mg/kg complete feed. No margin of safety can be established. This conclusion is extended to chickens reared for laying or breeding.

3.2.4 | Laying hens

A total of 120 21-weeks-old Lohmann-brown hens were distributed in 24 pens of five animals each and randomly allocated to three experimental groups (eight replicates per group).[24] One basal diet based on maize, wheat and soybean meal, was either not supplemented (control) or supplemented with vermiculite to provide 0, 10,000 (1×) or 25,000 (2.5×) mg/kg feed. The inclusion rate was calculated indirectly, based on the analytical content of crude ash in the supplemented diets in comparison with the control; according to the results of the analyses provided, the inclusion levels reached about 60% of the intended ones (see Table 4).[25] The diets were offered ad libitum in mash form for 56 days.

[24]Annex 3.1.1.2.a.

[25]Analysed crude ash content in feed (mg/kg feed 88%DM): 92,900/99,000/108,700 for the control/1×/2.5× groups, respectively.

The mortality and health status were checked every day. Animals were weighed at the start of the trial. Thereafter, the body weight, feed intake, laying rate and egg mass output were measured on days 1, 29 and 56. The feed-to-egg mass ratio egg weight were calculated and corrected for mortality for the overall period. The egg quality data (egg yolk colour, eggshell breaking strength) was measured on days 1, 29 and 55. The consistency of the excreta was checked in two hens per replicate (16 per group) at the end of the trial.[26] Blood samples were collected on day 56 from two animals per pen. The blood samples were analysed for haematology[27] and clinical biochemistry[28] parameters. The same birds were killed, and organs[29] were sampled, weighed and evaluated for gross pathology.

The data were analysed with a generalised linear model, including the diet as fixed effect and the pen as experimental unit. When differences between groups were detected, means were compared with Tukey test. The significance level was set at 0.05. Relevant parameters, including those showing significant differences, are reported in Table 4.

The health status of the animals was good throughout the trial and no hen died. The inclusion of the vermiculite up to 2.5× the maximum intended use level showed no adverse effects on the laying performance of the hens or the egg quality compared to the control group. The excreta consistency was not affected by the vermiculite supplementation, and it was close to the optimal score in all groups. Regarding the blood parameters evaluated, some differences between the supplemented groups and the control were observed in the values of thrombocytes, monocytes (relative content), electrolytes (Na, K, Cl), AST serum activity and albumin concentration; however, the differences observed between groups were either not considered adverse or minor in absolute terms. In all cases, the values were within physiological ranges.

TABLE 4 Effects of the dietary supplementation of laying hens with vermiculite on selected parameters.

	Control	1×	2.5×
Vermiculite (mg/kg complete feed)[1]			
Intended	0	10,000	25,000
Calculated	–	6100	15,800
Mortality and culling (%)	0	0	0
Initial body weight (g)	1414	1411	1410
Final body weight (g)	1829	1844	1850
Laying rate (%)	87.0	90.4	88.8
Total egg mass (g)	2619^{b}	2796^{a}	2731^{ab}
Feed-to-egg mass ratio	2.42^{a}	2.22^{b}	2.35^{b}
Blood parameters			
Thrombocytes (G/L)	2.4^{b}	4.8^{a}	2.8^{b}
Monocytes (% WBC)	7.8^{a}	4.6^{b}	5.4^{b}
Na (mmol/L)	155^{a}	154^{a}	151^{b}
K (mmol/L)	5.2^{b}	5.2^{b}	5.6^{a}
Cl (mmol/L)	118^{a}	118^{a}	116^{b}
AST (U/L)	187^{a}	171^{b}	181^{ab}
Organ weight (% body weight)			
Small intestine (jejunum and ileum)	2.46^{b}	2.51^{ab}	2.70^{a}

Abbreviations: AST, aspartate aminotransferase; WBC, white blood cells.

[1]Calculated based on the analytical content of crude ash in the supplemented diets with respect to the control one.

[a,b]Different superscripts in a row mean significant differences ($p < 0.05$).

No differences were observed on the gross pathology evaluation of the organs between groups. Regarding the relative organ weight, a significantly higher weight of the jejunum and ileum in the 2.5× group compared to the control was observed, which combined with the results observed in the laying performance, was not considered an adverse effect.

The results of the tolerance trial showed that the additive was tolerated by laying hens when included in the feed at 15,800 mg/kg (approximately 1.6x the maximum recommended level). Therefore, the Panel concludes that the inclusion of vermiculite in the feed of laying hens is safe at 10,000 mg/kg complete feed.

[26]Scale used: 1 = normal excreta; 2 = loose excreta; abnormal colour or volume; 3 = watery or blood strained excreta.

[27]Total count for red blood cells, packed cell volume, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total counts for leukocytes, thrombocytes, fibrinogen, prothrombin time.

[28]Sodium, potassium, chloride, calcium, phosphate, magnesium, total protein, albumin, globulins, glucose, urea, cholesterol, bilirubin, triglycerides, creatinine, amylase, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyltransferase, alkaline phosphatase, glutamate-dehydrogenase, creatine kinase, haptoglobin.

[29]Liver, gall bladder, kidneys, spleen, heart, thyroid gland, thymus.

3.2.5 | Weaned piglets

A total of 384 26-day-old Goland piglets (50:50 male: female) were distributed in 24 pens by gender, body weight and sow origin in groups of 16 animals, which were randomly allocated to three groups (8 replicates per group).[30] Two basal diets (pre-starter from day 1 to 14; starter from day 15 to 42) based on barley, bakery by-products, maize and sweet whey, were either not supplemented (control) or supplemented with vermiculite to provide 5000 (1×) and 12,500 (2.5×) mg/kg feed. The inclusion rate was calculated indirectly, based on the analytical content of crude ash in the supplemented diets in comparison with the control one; according to the results of the analyses provided, the inclusion levels reached about 60% of the intended ones (see Table 4).[31] The diets were offered in mash form ad libitum for 42 days.

The mortality and health status were checked every day and the most likely cause of death or reason for culling recorded. Animals were weighed at the start of the trial. Thereafter, the body weight and the feed intake were measured on days 1, 14 and 42. The average daily gain, average daily feed intake and feed-to-gain ratio were calculated and corrected for mortality. Blood samples were collected on day 1 and 42 from two animals per pen and were analysed for haematology[32] and clinical biochemistry[33] parameters. At the end of the trial, eight piglets from each group were killed and organs[34] sampled, weighed and evaluated for macroscopic lesions.

The data were analysed with a generalised linear model, including the diet as fixed effect and the pen as experimental unit. When differences between groups were detected, means were compared with Tukey test. The significance level was set at 0.05. The parameters showing significant differences are reported in Table 5.

TABLE 5 Effects of the dietary supplementation of weaned piglets with vermiculite on selected parameters.

	Control	1×	2.5×
Vermiculite (mg/kg complete feed)[1]			
Intended	0	5000	12,500
Calculated	–	3650	7200
Mortality (%)	2.3	1.6	0.8
Final pen body weight (kg)[2]	390	424	413
Average pen daily gain (kg)[2]	6.63[b]	7.33[a]	6.96[ab]
Average daily feed intake (kg)[2]	10.6	10.2	10.3
Feed-to-gain ratio	1.61[a]	1.38[b]	1.45[ab]

[1]Calculated based on the analytical content of crude ash in the supplemented diets with respect to the control one.

[2]The body weight, weight gain and feed intake parameters are provided on a pen basis. Individual data on final body weight (kg): 24.9, 26.9 and 26.0 for control, 1× and 2×, respectively. Individual data on average daily gain (g): 379, 423 and 416 for control, 1x and 2x, respectively.

[a,b]Different superscripts in a row mean significant differences ($p < 0.05$).

The health status of the animals was good during the trial. The inclusion of the vermiculite up to 2.5× the maximum intended use level did not result in adverse effects on the health status of the animals, zootechnical performance parameters, blood haematology and biochemistry parameters evaluated in comparison with the control. The Panel notes that the dossier did not include a detailed report of the gross pathology and that some organs were not weighted, without a proper justification. No macroscopic lesions were identified. The relative weight of the stomach, intestines, heart, kidneys, liver and lungs showed no differences between groups.

The results of the tolerance trial showed that the inclusion of vermiculite at 7200 mg/kg feed (approximately 1.4x the maximum recommended level) was tolerated by weaned piglets. Therefore, the Panel concludes that the additive is safe for weaned piglets when supplemented at 5000 mg/kg complete feed.

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

An in vivo interaction/digestibility study was conducted in parallel to the tolerance trial in chickens for fattening (Section 3.2.3) to evaluate the interactions of vermiculite with other components of the diet.[35] For this purpose, retention

[30]Annex 3.1.1.3.a.

[31]Analysed crude ash content in feed for the control/1×/2.5× (mg/kg feed 88%DM): 65,300/67,400/69,500 and 55,400/60,600/64,600 for the pre-starter and starter diets, respectively.

[32]Total count for red blood cells, haematocrit, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total counts for leukocytes, thrombocytes.

[33]Sodium, potassium, chloride, calcium, phosphate, magnesium, total protein, albumin, globulins, glucose, urea, uric acid, cholesterol, bilirubin, triglycerides, creatinine, amylase, lactate dehydrogenase, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyltransferase, alkaline phosphatase, creatine kinase.

[34]Stomach, intestines, heart, kidneys, liver and lungs.

[35]Annex 3.1.1.1.

collection trays were installed in 10 floor pens per group on day 34 to allow excreta collection. After approximately 3 h, samples from all pens were collected. The feed and excreta samples were analysed for the content of the external marker, nitrogen, zinc, salinomycin, retinyl and tocopherol esters, pyridoxin and thiamine, and the retention of the different nutrients was calculated. The retention data were statistically analysed with a generalised linear model, including the diet as fixed effect and the pen as experimental unit. When differences between groups were detected, means were compared with Duncan's test. The significance level was set at 0.05.

Results showed that the inclusion of vermiculite at 2.5× resulted in a significantly higher retention of nitrogen compared to the control and 1× (50.2, 50.3, 58.8% for the control, 1× and 2.5× groups), while the thiamine retention was lower in the 1× (99.7%) and 2.5× (99.8%) compared to the control (99.9%); however, the differences are considered minor and of no relevance. No differences were observed in any of the other substances analysed between the supplemented groups and the control. The results of the study suggest that vermiculite does not adversely interfere with the availability of nutrients to the animals.

3.2.7 | Discussion of the safety studies for the target species

The applicant provided one tolerance trial in chickens for fattening, one in laying hens and one in weaned piglets to support the safety for the target species at the respective maximum proposed use levels (10,000 mg/kg feed for poultry, ornamental birds, equines, leporids, camelids, pets and other non-food-producing animals; and 5000 mg/kg feed for porcine species). Analytical results showed that only 60%–70% of intended vermiculite supplementation was reached in the trials with laying hens and piglets. The maximum use level was effectively not tested, and only one diet exceeded the maximum proposed level, leading to 1.6× and 1.4× overdoses for hens and piglets, respectively, which limits the identification of a margin of safety from these studies.

The Panel also notes that the limitations in the study in piglets (lack of detailed report of gross pathology and of some organ weights) introduce additional uncertainties that would prevent the extrapolation of the conclusions to other porcine species.

In the trial of chickens for fattening, the additive was added on top of the basal diets without any correction to compensate for the energy imbalance due to the additive inclusion. Therefore, the Panel considers that it is not possible to adequately assess if the dose-dependent differences observed in the feed intake and feed-to-gain ratio are due to the diet formulation or to the effects of the additive. This does not allow the Panel to disregard the effects observed at the highest level tested, and therefore, prevents establishing a margin of safety.

3.2.7.1 | Conclusions on the safety for the target species

The Panel concludes that the use of vermiculite at 10,000 mg/kg feed is safe for chickens for fattening, chickens reared for laying/breeding and laying hens, and at 5000 mg/kg feed for suckling and weaned piglets and pigs for fattening.

However, considering the limitations of the studies assessed and the lack of a margin of safety, no conclusion can be reached on the safety of vermiculite for other poultry species, ornamental birds, sows, other porcine species, equines, leporids, camelids, pets and other non-food-producing animals.

3.2.8 | 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.

3.2.9 | Safety for the user

Based on the highest dusting potential measured (900 mg/m^3) (EFSA FEEDAP Panel, 2020), the FEEDAP Panel considers that the exposure of users through inhalation is likely.

No studies conducted with the additive under assessment were submitted by the applicant.

The FEEDAP Panel notes that the additive contains nickel (135–148 mg/kg). The European Directive 2022/431[36] set an occupational exposure limit (OEL) of 0.01 and 0.05 mg/m^3 for both respirable and inhalable fraction, respectively as nickel

[36]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.

meets the criteria for classification as carcinogenic (category 1A). Therefore, to reduce the risk, the FEEDAP Panel considers that the exposure of the users should be minimised.

The FEEDAP Panel notes that the additive contains crystalline silica (0.02%–0.06%). Inhalation of silica is known to be hazardous and is associated with increased risk of lung cancer and the industrial disease, silicosis. The European Directive 2017/2398[37] set an OEL of 0.1 mg/m^3 of air for respirable crystalline silica dust. Therefore, to reduce the risk, the FEEDAP Panel considers that the exposure of the users should be minimised.

Due to the presence of nickel, the additive is considered a skin and respiratory sensitiser.

3.2.9.1 | Conclusions on safety for the user

The additive is considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. Due to the lack of data, the Panel could not conclude on the potential of the additive to be an eye irritant.

3.2.10 | Safety for the environment

The minerals of the additive are ubiquitous in the environment, being natural components of soil. Therefore, the use of the additive in animal nutrition under the proposed condition of use is considered safe for the environment.

3.3 | Efficacy

To support the efficacy of the additive as an anticaking agent, the applicant provided two in vitro studies studying the flowability of the additive.

The first study was not further considered due to poor reporting of the results which did not allow a proper assessment.

In the second study,[38] the effect of the additive in feed flowability was studied in feeds for pigs for fattening, weaned piglets and chickens for fattening (six replicates each) either non-supplemented or supplemented with 10,000 mg of vermiculite/kg feed by using a powder rheometer, the powder flow analyser (PFA). The PFA compacts a column filled with the feeds until reaching a force of 5 N. Once this force is reached, it measures the height of the cake. The amount of compression (cohesiveness) gives an indication of the flowability of the additive. A rotor then breaks the cake and measures the force required to destroy the cake. Force needed gives an indication of the caking properties of the additive.

The results showed a significant decrease of the flow index in the supplemented feeds for pigs and piglets and a significant reduction of the cake strength in the supplemented feeds for piglets and chickens, as reported in Table 6.

The FEEDAP Panel notes that for weaned piglets and pigs for fattening the tested levels are twice the maximum use level.

TABLE 6 Cake strength (g) measured in feeds supplemented with 10,000 mg vermiculite/kg.

Feed	Supplementation level (mg/kg)	Flow index	Bridging (g)	Cake strength (g)
Pigs for fattening	0	15.26^b	12.76	90.38
	10,000	14.59^a	9.88	85.98
Weaned piglets	0	14.94^b	10.53	158.23^a
	10,000	13.27^a	11.50	127.18^b
Chickens	0	15.79	9.52	111.51^a
	10,000	14.91	9.47	93.54^b

^{a,b}Different superscripts in a row mean significant differences ($p < 0.05$).

3.3.1 | Conclusions on efficacy

Based on the data available covering different types of feed for poultry and pigs, the FEEDAP Panel concludes that vermiculite is efficacious as an anticaking agent. The Panel notes that for weaned piglets and pigs for fattening the tested levels are twice the maximum use level.

[37]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.

[38]Annex 4.1.1.1.a.

4 | CONCLUSIONS

Vermiculite is considered safe at 10,000 mg/kg complete feed for chickens for fattening, chickens reared for laying/breeding and laying hens, and at 5000 mg/kg complete feed for suckling and weaned piglets and pigs for fattening. However, considering the limitations of the studies assessed and the lack of a consistent margin of safety, no conclusion can be reached on the safety of vermiculite for other poultry species, ornamental birds, sows, other porcine species, equines, leporids, camelids, pets and other non-food-producing animals.

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

The additive should be considered a skin and respiratory sensitiser and inhalation and dermal exposure considered a risk. Due to the lack of data, the Panel could not conclude on the potential of the additive to be an eye irritant.

The FEEDAP Panel concludes that the additive vermiculite is efficacious as an anticaking agent in feeds. The FEEDAP Panel notes that the concentration shown to be efficacious is higher than the maximum and safe use level for weaned piglets and pigs for fattening.

5 | RECOMMENDATIONS

The FEEDAP Panel recommends that the additive composition in the authorisation reflects the analysed content of vermiculite mineral (e.g. minimum of 87.0% vermiculite).

Considering the hazards identified for the users, the FEEDAP Panel recommends that inhalation exposure of users is minimised.

ABBREVIATIONS

ALT	alanine aminotransferase
AST	aspartate aminotransferase
DL-PCBs	dioxin-like polychlorinated biphenyls
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
HPLC	High-performance liquid chromatography
LDH	lactate dehydrogenase
LOD	limit of detection
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
OEL	occupational exposure limit
PCDDs	polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzofurans
PFA	powder flow analyser
PLM	polarised light microscopy
SEM	scanning electron microscopy
TEQ	toxic equivalent factor
UB	upper bound
WBC	white blood cells
WHO	World Health Organization
XRD	X-ray diffraction
XRF	X-ray fluorescence spectroscopy

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