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SCIENTIFIC OPINION

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

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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 clinoptilolite of volcanic origin as a technological feed additive for all terrestrial animal species. The FEEDAP Panel concluded that clinoptilolite of volcanic origin is considered safe at 20,000 mg/kg complete feed for the use in feed for poultry for fattening and 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 clinoptilolite of volcanic origin is safe for 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 clinoptilolite of volcanic origin is efficacious as a pellet binder and anticaking agent in feed for terrestrial animal species.

KEYWORDS

anticaking agents, binders, clays, clinoptilolite of volcanic origin, efficacy, 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 clinoptilolite of volcanic origin, when used as a feed additive for all terrestrial animal species (category: technological additives; functional groups: binders and 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 16 October 2023 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00674. The particulars and documents in support of the application were considered valid by EFSA as of 12 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 clinoptilolite of volcanic origin, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The additive clinoptilolite of volcanic origin is currently not authorised as a feed additive in the European Union and has not been previously assessed by EFSA as a feed additive.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[3] in support of the authorisation request for the use of clinoptilolite of volcanic origin 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 30 July 2024 to 20 August 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 clinoptilolite of volcanic origin in animal feed.[6]

[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, 31,036 (31100) Toulouse, France.

[3]Dossier reference: FEED-2023-19273.

[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.

[6]Evaluation report received on 18/6/2024 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

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2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and efficacy of clinoptilolite of volcanic origin is in line with the principles laid down in Regulation (EC) No 429/2008[7] 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), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023) and on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024).

3 | ASSESSMENT

The additive under assessment consists of clinoptilolite of volcanic origin and is intended to be used as a technological feed additive (functional groups: binders and anticaking agents) in feed for all terrestrial animal species.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

Clinoptilolite of volcanic origin is a natural calcium hydrated aluminosilicate from a zeolite mine in [redacted] The additive is specified to contain a minimum of 85% clinoptilolite, a maximum of 15% feldspar, micas and clays, less than 0.1% respirable crystalline silica and to be free of asbestos. The Chemical Abstracts Service (CAS) number of clinoptilolite is 1318-02-1, the European Community (EC) number is 215-283-8 and the chemical formula is $(Na,K,Ca)_2{-}3Al_3(Al,Si)_2Si_{13}O_{36}{\bullet}12H_2O$.

The data provided by the applicant on the mineralogical[8] analysis, elemental[9] analysis and impurities[10] of the additive are reported in Table 1, and the physical properties[11] in Table 2.

TABLE 1 Data on the mineralogical and elemental analysis, and impurities of the additive.

		Analysis		
Parameter	**Specification**	**Average**	**Range**	**No. of batches**
Mineralogical analysis (XRPD) (%)				
Clinoptilolite	≥ 85	91.6	88.0–94.0	5
Feldspar (sodium and potassium)	≤ 15	1.7	1.0–4.0	5
Micas (illite)		1.8	1.0–3.0	5
Clays (smectite/montmorillonite)		3.0	2.0–4.0	5
Elemental analysis (XRF) (expressed as oxides, %)				
SiO_2		70.70	70.61–70.86	5
Al_2O_3		11.91	11.87–11.92	5
K_2O		3.56	3.41–3.61	5
CaO		2.88	2.87–2.89	5
Fe_2O_3		0.84	0.83–0.87	5
Na_2O		1.05	1.03–1.06	5
Loss on ignition (%)		8.20	8.15–8.26	5

[7]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.

[8]Annex_II_1_2_XRD_Mineralogical_Composition.

[9]Annex_II_1_3 XRF_Chemical Composition.pdf.

[10]Annex_II_1_4 Heavy metals.pdf, Annex_II_1_5 Dioxins YELLOW.pdf, Annex_II_1_6 Search for asbestos YELLOW.pdf, Annex_II_1_7 Crystalline silica YELLOW.pdf, Annex_II_1_8 Nickel_Aluminium content YELLOW.pdf.

[11]Annex_II_1_9 PSD_rev YELLOW.pdf, Annex_II_1_12 Dusting potential_density report_REV Oct 2024 YELLOW.pdf, Annex_II_1_13 Dust analyses YELLOW.pdf, Annex_II_4_2 Homogeneity study_YELLOW.pdf.

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TABLE 1 (Continued)

Parameter	Specification	Analysis		
		Average	Range	No. of batches
Impurities (mg/kg)				
Lead			0.24–0.27	3
Mercury			< 0.01	3
Cadmium			< 0.01	3
Arsenic			< 0.01	3
Nickel			< 0.1	3
Fluorine			< 40	3
Dioxins and furans (upper bound)[1]				
PCDD/Fs (ng WHO_{2005}-TEQ/kg)			0.17–0.17	3
PCDD/Fs + PCBs (ng WHO_{2005}-TEQ/kg)			0.23–0.24	3
nDL-PCBs (µg/kg)			3.2–3.2	3
Crystalline silica (%)	≤ 0.1		0.007–0.044	5
Asbestos	Absent		Not detected	5

Note: <, means below the limit of quantification.

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, except for nickel and crystalline silica, which is addressed in the user safety section (see Section 3.2.5).

TABLE 2 Data on the physical properties of the additive.

		Analysis	
		Range	No. of batches
Physical properties			
Physical form	Powder/granules		
Bulk density (kg/m^3)		878–891	3
Tapped density		1060–1064	3
Solubility (mg/L) (20°C)		< 1	
Dusting potential (Stauber Heubach) (mg/m^3)		5410–5655	3
Nickel in dust (mg/kg)		1.8–5.2	3
Particle size distribution (laser diffraction) (% of particles below, v/v)			3
100 µm		[redacted]	
50 µm		[redacted]	
10 µm		[redacted]	
Homogeneity (coefficient of variation, %)			
Chicken, pig and cattle feed		7.7–8.5	1

Note: <, means below the limit of quantification.

The applicant investigated the presence of small/nanoparticles using scanning electron microscopy–energy dispersive X-ray spectroscopy (SEM–EDX) analysis and dynamic light scattering (DLS) technique in five batches of the additive. Qualitative SEM analysis showed that the samples contain agglomerates and that the constituent particles have a platelet-like shape. Quantitative analysis via DLS measurement showed the presence of small/nanoparticles; however, DLS is not considered adequate to accurately measure the size of the constituent particles of clinoptilolite because these are not spherical, and aggregated/agglomerated, resulting in biased measurements overestimating the minimal external dimension of the particles. The data provided allow concluding that a considerable fraction of small particles, including nanoparticles, is present in the samples.

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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, zearalenone, fumonisins B1/B2 and deoxynivalenol in three types of feeds (for dairy cows, chickens for fattening, piglets) supplemented with 20,000 mg clinoptilolite/kg complete feed. Aflatoxin B1 was introduced at the final concentration of 0.03 mg/kg feed, zearalenone at 0.5 mg/kg, fumonisins B1/B2 at 50 mg/kg and deoxynivalenol at 5 mg/kg.[12] No interference on the analytical determination of mycotoxins in feed was observed with the addition of the additive in complete feed.[13]

3.1.3 | Conditions of use

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

3.2 | Safety

3.2.1 | Genotoxicity studies

The FEEDAP Panel considers that clinoptilolite from volcanic origin, 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.

Bacterial reverse mutation test[14]

To evaluate the potential of clinoptilolite of volcanic origin to induce gene mutations, an Ames test was performed in accordance with the Organisation for Economic Co-operation and Development (OECD) Testing Guidelines (TG) 471, in a study claimed to be compliant with Good Laboratory Practices (GLP). *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 clinoptilolite of volcanic origin 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. The presence of a precipitate not interfering with the analysis was reported at 500 μg/plate and above. No cytotoxicity was observed, and the test item did not induce an increase in the number of revertant colonies under 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.

In vitro mammalian micronucleus test[15]

The test item was also tested for its potential to induce chromosomal damage applying an in vitro micronucleus test 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. A homogeneous water suspension of clinoptilolite of volcanic origin was used as a test item. Based on the results of a preliminary range-finding experiment, the additive was tested at: (i) 800, 2000 and 5000 μg/mL applying a short treatment (4 + 1.5 to 2 times the cell cycle of recovery) with metabolic activation; (ii) 224, 320 and 560 μg/mL in a short treatment (4 + 1.5 to 2 times the cell cycle of recovery) without metabolic activation; (iii) 51.2, 128, 320 μg/mL in a continuous treatment of about 1.5 to 2 times the cell cycle without metabolic activation. To measure cytotoxicity, the reduction of the relative increase in cell counts (RICC) was calculated. Values up to 47%, 50% and 43% were observed at the highest concentrations tested after short treatment in the presence of metabolic activation, and after 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 the clinoptilolite of volcanic origin did not induce structural and numerical chromosome aberrations in mammalian cells under the experimental conditions applied in this study.

3.2.1.1 | *Conclusions on genotoxicity*

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

[12]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).

[13]Annex_II_4_3 Non-Mycotoxin binding rev YELLOW.pdf.

[14]Annex_III_2_2 Final Report OECD 471 rev YELLOW.pdf.

[15]Annex_III_2_3 Final report OECD 487 rev YELLOW.pdf.

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3.2.2 | Safety for the target species

To support the safety for the target animals, the applicant submitted one tolerance trial in chickens for fattening, one in weaned piglets and one in dairy cows.[16] However, the trial conducted with dairy cows showed a great heterogeneity of the animals enrolled: at the start of the trial, the variability among animals within each group was about 20%–30% in milk yield, 15%–20% in dry matter intake and days in milk ranging from 70 to 235. 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.[17]

Tolerance trial in chickens for fattening[18]

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 meal were either not supplemented (control) or supplemented with the additive to provide 20,000 (1× maximum use level), 60,000 (3×) or 80,000 (4×) mg/kg complete feed. The recovery rates in the feeds were confirmed indirectly via the measurement of aluminium content as a marker (see Table 3). 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 for blood haematology[19] and biochemistry[20] analysis. The same 96 animals were killed, necropsied, and organs[21] sampled, weighed and evaluated for gross pathology. The experimental data were analysed with a generalised linear model, using the pen as the experimental unit and the diet as a fixed effect. Group means were compared by Tukey's test. Mortality data were assessed using non-parametric analysis. The significance level was set at 0.05 The main results are summarised in Table 3.

TABLE 3 Effects of the dietary supplementation of chickens for fattening with clinoptilolite of volcanic origin on selected safety parameters.

	Control	1×	3×	4×
Additive content (mg/kg feed)				
Intended	0	20,000	60,000	80,000
Analysed content of Al (starter/grower/finisher)	61/60/49	640/660/700	1700/1720/1770	2310/2350/2400
Calculated level of clinoptilolite[1] (starter/grower/finisher)	0	18,000/18,300/19,400	50,500/50,500/52,800	66,200/67,600/71,400
Mortality and culling (%)	1.7	0.9	2.5	2.5
Performance parameters				
Final body weight (kg)	2593^{b}	2689^{a}	2686^{a}	2661^{ab}
Average daily gain (g)	70.8^{b}	73.5^{a}	73.4^{a}	72.7^{ab}
Average daily feed intake (g)	102.1^{b}	104.0^{ab}	105.0^{ab}	105.7^{a}
Feed-to-gain ratio	1.44^{b}	1.42^{c}	1.43^{bc}	1.45^{a}
Blood parameters				
Red blood cells ($\times 10^{6}/\mu L$)	1.61^{b}	1.87^{a}	1.81^{ab}	1.77^{ab}
Heterophils ($\times 10^{3}/\mu L$)	8.02^{a}	6.43^{ab}	6.07^{ab}	6.05^{b}

(Continues)

[16]Annex_III_1_1 Dairy cows tol trial_YELLOW.pdf, Annex_III_1_1 Raw data_Clinoptilolite_DC TOL trial.xlsx, Annex_III_1_1 Dairy cows tol trial_REV JULY 2024 BLACK.pdf, Annex_III_1_1 Dairy cows tol trial_REV JULY 2024 YELLOW.pdf, Annex_III_1_1 DC tol trial_Appendix 7 REV JULY 2024.xlsx.

[17]Annex_III_1_1D ELS_Clinoptilolite_Dairy Cows_final YELLOW.

[18]Annex_III_1_3 Broiler tol trial B-671 YELLOW.pdf.

[19]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.

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

[21]Gross pathology evaluation was performed on the 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.

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TABLE 3 (Continued)

	Control	1×	3×	4×
Alkaline phosphatase (U/L)	1274[b]	1603[ab]	1995[a]	1808[ab]
Creatine kinase (U/L)	39,920[a]	32,615[ab]	23,005[a]	27,024[a]
Cholesterol (mg/dL)	111.2[a]	107.0[ab]	102.8[b]	100.9[b]
Organ's relative weight				
Liver (%)	2.77[a]	2.66[ab]	2.53[b]	2.57[b]

[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 clinoptilolite calculated from the analysed Al concentration are sufficient to confirm the intended concentrations.

Overall mortality (including culling) did not differ between the groups. The supplemented groups showed a dose-dependent linear increase in the average daily feed intake, which was significantly higher at 4× than the control. All supplemented groups showed higher final body weight and average daily gain than the control; however, the difference was only significant for the 1× and 3× groups. As a result, the feed-to-gain ratio was significantly improved at 1× and worsened at 4×. Considering the higher final body weight in the 4× group and the nature of the additive, the differences in the feed-to-gain ratio were not considered relevant to safety.

Regarding the blood data, in comparison with the control group, birds receiving clinoptilolite of volcanic origin showed higher red blood cell counts (significant at 1×) and alkaline phosphatase activity (significant at 3×) and lower heterophils counts (significant at 4×), creatine kinase activity (significant at 3× and 4×) and cholesterol concentration (significant at 3× and 4×). The differences in the creatine kinase activity and cholesterol concentration were not considered adverse effects. The effects observed on the other parameters did not show a clear trend, and all values were within normal physiological ranges for healthy chickens; thus, they were not considered clinically relevant.

Regarding the gross pathology evaluation, a dose-dependent linear reduction in the liver's relative weight was observed at higher levels of the additive, resulting in significant differences in 3× and 4× compared to the control. No histopathological examination was done. However, the Panel notes that the differences in relative weights between groups were small and that no macroscopic lesions were reported. Therefore, the absence of histopathological examination was not considered critical.

The results of the tolerance trial showed that clinoptilolite of volcanic origin is well tolerated by chickens for fattening at 80,000 mg/kg feed. Therefore, the FEEDAP Panel concludes that clinoptilolite of volcanic origin is safe at the proposed maximum safe 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[22]

A total of 144 mixed Piétrain × (Large White × Landrace) weaned piglets (28 day-old; initial bodyweight = 8.4 kg) were distributed in 36 pens in groups of four animals (two males and two females), which were randomly allocated, based on initial bodyweight, to four groups (representing nine replicates per group). Two basal diets (pre-starter, from day 1 to 14; starter, from day 15 to 43) based on barley, milk whey, maize and soybean meal (pre-starter phase) and maize, barley, soybean meal (starter phase) were either not supplemented (control) or supplemented with the product to provide 20,000 (1×), 60,000 (3×) or 80,000 (4×) mg clinoptilolite per kg complete feed. The recovery rates in the feeds were confirmed via the indirect measurement of aluminium content as a marker (see Table 3). The experimental diets were offered ad libitum as pellets for 43 days.

Mortality and health status were checked daily, and the most likely cause of death or reason for culling was recorded. Piglets were weighed at the start of the trial. Thereafter, body weight and feed intake were measured on days 7, 14, 28, and 42. 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 days 1 and 43 from the same two animals (one male and one female) per pen and treatment. The blood samples were analysed for haematology[23] and biochemistry[24] parameters. After finishing the trial, 36 piglets (one piglet per pen) were killed, organs[25] were sampled, weighed and evaluated for gross pathology. The experimental data were analysed using a generalised linear model, with the pen as the experimental unit and

[22]Annex_III_1_2 Piglets tol trial P-751_YELLOW.pdf.

[23]Total count for red blood cells, haematocrit, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total leukocytes, eosinophils, neutrophils (segmented/banded), lymphocytes, monocytes, fibrinogen and prothrombin time.

[24]Sodium, potassium, chloride, calcium, phosphate, magnesium, iron, total protein, albumin, globulin, glucose, urea, cholesterol, creatinine, bilirubin, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, gamma-glutamyltransferase, alkaline phosphatase, amylase, C-reactive protein and creatine kinase.

[25]Gross pathology evaluation was performed on the 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.

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the diet and block as fixed effects. When differences were observed, group means were compared with Tukey test. Significance level was set at 0.05. The main results are summarised in Table 4.

TABLE 4 Effects of the dietary supplementation of weaned piglets with clinoptilolite of volcanic origin on selected safety parameters.

	Control	1×	3×	4×
Additive content (mg/kg feed)				
Intended	0	20,000	60,000	80,000
Analysed content of Al (pre−/starter)	59/60	673/660	1635/1605	2184/2233
Calculated level of clinoptilolite[1] (pre−/starter)	0	19,400/18,900	49,800/51,800	67,200/68,700
Mortality and culling (%/n)	0 (0)	0 (0)	2.8 (1)	2.8 (1)
Performance parameters				
Final body weight (kg)	30.2	31.1	29.5	29.6
Average daily gain (g)	519	542	503	504
Average daily feed intake (g)	747	781	732	740
Feed-to-gain ratio	1.44	1.44	1.46	1.47
Blood parameters				
Alkaline phosphatase (U/L)	171.7^{b}	178.7^{ab}	203.7^{ab}	209.9^{a}
Phosphate (mg/dL)	9.86^{a}	9.64^{b}	8.84^{b}	8.39^{b}
Calcium (mg/dL)	10.4^{b}	10.5^{b}	10.7^{b}	11.3^{a}

[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 clinoptilolite calculated from the analysed Al concentration are sufficient to confirm the intended concentrations.

Overall mortality did not differ between groups. Zootechnical parameters improved in piglets receiving the 1×-diet compared to the control group, whereas performance worsened at levels of 60,000 and higher. These differences were not statistically significant. However, the Panel notes that the power of the study was below the minimum requested (< 0.80), which may prevent the identification of potential differences between groups.

Regarding the blood data, a dose-dependent increase in serum alkaline phosphatase activity and calcium concentration, along with a reduction in phosphate concentration at higher additive levels, was observed. This resulted in significant differences from 3× (phosphate) or at 4× (all parameters). No other significant differences were observed between the control and the supplemented groups in any of the blood haematology and biochemistry parameters analysed. The observed effects may suggest that the additive interferes with Ca/P metabolism, and thus, it was considered an adverse effect of the additive supplementation. The gross pathology evaluation, including organ relative weights, revealed no adverse effects of the additive supplementation.

The results from blood biochemistry and zootechnical performance data suggested that the inclusion of clinoptilolite in the diet of weaned piglets at 60,000 mg/kg or higher is not tolerated. Therefore, the Panel concluded that the clinoptilolite from volcanic origin is safe at 20,000 mg/kg complete feed, but no margin of safety can be established. 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. The lack of margin of safety prevents extrapolating the conclusion to other porcine species.

In vivo interaction with nutrients and other components of the diet[26]

An in vivo interaction/digestibility study in chickens for fattening was conducted in parallel with the corresponding tolerance trial to evaluate the interactions of clinoptilolite with other relevant dietary components over 18 days. Sixteen birds from the control and sixteen from the 1× group (20,000 mg clinoptilolite/kg feed) were distributed in pairs in 16 cages (8 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. Nitrogen retention (75.6% vs. 78.7%), the utilisation of total tocopherol (61.3% vs. 69.9%) and riboflavin (52.1% vs. 59.8%), and the disappearance of monensin (97.2% vs. 98.7%) were significantly decreased by the inclusion of clinoptilolite at 20,000 mg/kg complete feed compared to the control. No effects were observed on the utilisation of pyridoxine and manganese retention.

[26]Annex_III_1_3 Broiler tol trial B-671 YELLOW.

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3.2.2.1 | *Conclusion on the safety for the target species*

Based on the results of the tolerance trials submitted, the Panel concludes that clinoptilolite of volcanic origin 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, poultry reared for laying/reproduction and ornamental birds. No conclusion can be drawn for other terrestrial species/categories.

3.2.3 | Safety for the consumer

The FEEDAP Panel considers it unlikely that the additive, as with other clays, will be degraded during its passage through the gastrointestinal tract of target animals or absorbed to any measurable extent. It is also considered unlikely that harmful amounts of residues of any chemical component would occur in edible tissues/products from animals as a consequence of its use as a feed additive. Therefore, the use of the additive in animal nutrition is not considered to pose a risk for the consumer of tissues or products from animals fed the additive.

3.2.4 | Safety for the user

Based on the 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 OECD TG 403 with clinoptilolite of volcanic origin.[27] The lethal concentration 50 (LC_{50}) is greater than 1.18 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 industrial disease, silicosis. The European Directive 2017/2398[28] set an occupational exposure limit (OEL) of 0.1 mg/m^3 of air for respirable crystalline silica dust.

The FEEDAP Panel also notes that the additive contains nickel (the highest measured value in dust: 5.2 mg/kg). The European Directive 2022/431[29] set an OEL of 0.01 and 0.1 mg/m^3 for both respirable and inhalable fractions, respectively, as nickel meets the criteria for classification as carcinogenic (category 1A).

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

The skin irritation potential of clinoptilolite of volcanic origin was tested in a study conducted according to OECD TG 439,[30] which showed that the additive is not skin irritant (UN GHS No category).

The eye irritation potential of clinoptilolite of volcanic origin was tested in a study conducted according to OECD TG 438,[31] which showed that the additive is not an eye irritant (UN GHS No category).

The skin sensitisation potential of clinoptilolite of volcanic origin was tested in a local lymph node assay according to OECD TG 442-B,[32] which showed that the additive is not a skin sensitiser.

3.2.4.1 | *Conclusions on safety for the user*

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

3.2.5 | Safety for the environment

Clinoptilolite is a naturally occurring zeolite mineral that is 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 a binder and as an anticaking agent, the applicant submitted data from in vitro trials in which three different types of mash and/or pelleted feeds (for chickens, pigs and cattle) were supplemented with clinoptilolite at 0, 10,000, 20,000, 30,000 or 60,000 mg/kg complete feed.

[27]Annex_III_3_1 Final report OECD 403_rev Feb 2024 YELLOW.pdf.

[28]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.

[29]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.

[30]Annex_III_3_3 Final report OECD 439 rev YELLOW.pdf.

[31]Annex_III_3_2 Final report_OECD 438 rev YELLOW.pdf.

[32]Annex_III_3_4 Final report OECD 442B rev YELLOW.pdf.

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3.3.1 | Efficacy as a binder

The efficacy of the additive as a binder was assessed by measuring the pellet durability and hardness in three feed types (chicken, pig and cattle) supplemented with clinoptilolite of volcanic origin at 0, 10,000, 20,000, 30,000 or 60,000 mg/kg.[33] The feeds were pelleted at 65°C (output conditioner temperature), in a 4 mm diameter pellet matrix (24 mm thickness) to obtain pellets of 10mm in length. Durability was tested by sieving (3.15 mm pore size) before and after mechanical traction. Hardness was determined in a total of 36 pellets per feed using a hardness tester with a selected crushing length of 3 mm. The results were analysed with Kruskal-Wallis and followed by Dunn's post-test (durability) or with an analysis of variance (ANOVA) followed by Tukey test (hardness). The results are summarised in Table 5.

The durability of the pellets increased significantly with the inclusion of clinoptilolite of volcanic origin at 20,000 mg/kg feed or higher in the feed for cattle and at 30,000 mg/kg feed or higher in chicken and pig feeds. Clinoptilolite of volcanic origin significantly increased the hardness of the pellets when incorporated at 30,000 mg/kg feed or higher in the chicken and pig feeds and at 60,000 mg/kg in the cattle feed, compared to the respective controls.

TABLE 5 Pellet durability and hardness in feeds supplemented with clinoptilolite.

Type of feed	Inclusion level (mg/kg)	Mean durability (%)	Mean hardness (MPa)
Chicken	0	88.8^{b}	2.08^{c}
	10,000	89.2^{b}	2.10^{c}
	20,000	89.5^{ab}	2.02^{c}
	30,000	92.2^{a}	2.41^{b}
	60,000	90.3^{ab}	2.80^{a}
Pig	0	88.1^{b}	1.94^{c}
	10,000	87.9^{b}	2.26^{bc}
	20,000	87.8^{b}	2.10^{bc}
	30,000	91.4^{c}	2.27^{ab}
	60,000	90.1^{a}	2.46^{a}
Cattle	0	89.2^{c}	2.31^{b}
	10,000	88.8^{c}	2.27^{b}
	20,000	91.3^{ab}	2.51^{ab}
	30,000	91.1^{bc}	2.33^{b}
	60,000	92.4^{a}	2.53^{a}

Abbreviation: MPa, megapascal.

[a,b,c]Mean values within a group with a different superscript are significantly different ($p < 0.05$).

3.3.2 | Efficacy as an anticaking agent

The efficacy of the additive as an anticaking agent was evaluated by measuring the flowability of pelleted feeds and the angle of repose for mash feeds.[34] The results, analysed with Kruskal–Wallis and followed by Dunn's post-test, are presented in Table 6.

The inclusion of clinoptilolite of volcanic origin, starting at 10,000 mg/kg, significantly improved the flowability of all three feed types tested compared with the control. Clinoptilolite of volcanic origin also significantly increased the angle of repose when incorporated at 10,000 mg/kg feed in the chicken feed and at 20,000 mg/kg feed in the pig and cattle feeds, compared with the respective controls.

TABLE 6 Flowability and angle of repose in feeds supplemented with clinoptilolite.

Type of feed	Clinoptilolite inclusion level (mg/kg)	Mean flowability (kg/min)	Angle of repose (°)
Chicken	0	12.0^{a}	59.5^{ab}
	10,000	12.7^{bc}	61.0^{b}
	20,000	12.6^{ab}	58.4^{c}
	30,000	13.4^{c}	58.7^{ac}
	60,000	14.6^{d}	59.4^{abc}

(Continues)

[33]Annex_IV_1_1 Final report Efficacy YELLOW.pdf.

[34]Annex_IV_1_1 Final report Efficacy YELLOW.pdf.

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TABLE 6 (Continued)

Type of feed	Clinoptilolite inclusion level (mg/kg)	Mean flowability (kg/min)	Angle of repose (°)
Pig	0	12.6[a]	61.6[ac]
	10,000	13.7[b]	61.2[ab]
	20,000	13.9[b]	59.8[b]
	30,000	14.2[b]	61.1[ab]
	60,000	15.2[c]	65.1[c]
Cattle	0	12.0[a]	63.0[ab]
	10,000	13.1[b]	65.1[ac]
	20,000	13.4[bc]	62.1[b]
	30,000	13.9[bc]	65.6[c]
	60,000	14.4[d]	63.7[abc]

[a,b,c,d]Mean values within a group with a different superscript are significantly different ($p < 0.05$).

3.3.3 | Conclusions on efficacy

The FEEDAP Panel concludes that the additive clinoptilolite of volcanic origin is efficacious as a pellet binder and anticaking agent in feed for terrestrial animal species. The Panel notes that the efficacy as pellet binder has been shown at an inclusion level of 20,000–30,000 mg/kg complete feed, levels higher than the ones for which the safety has been supported.

4 | CONCLUSIONS

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

The use of clinoptilolite of volcanic origin in animal nutrition under the proposed conditions of use is of no concern for the safety of 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 efficacious as both a binder and an anticaking agent. The Panel notes that the efficacy as pellet binder has been shown at an inclusion level of 20,000–30,000 mg/kg complete feed.

5 | REMARK

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

ANOVA	analysis of variance
BW	body weight
CAS	Chemical Abstracts Service
DLS	dynamic light scattering
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GLP	Good laboratory practices
nDL-PCBs	non-dioxin-like polychlorinated biphenyls
PCB	polychlorinated biphenyls
PCDD	polychlorinated dibenzo-p-dioxins
PCDF	polychlorinated dibenzofurans
OECD	Organisation for Economic Co-operation and Development
OEL	occupational exposure limit
RICC	relative increase in cell counts
SEM–EDX	scanning electron microscopy–energy dispersive X-ray spectroscopy
TEQ	toxic equivalent factors
TG	Testing guidelines
XRF	X-ray fluorescence
XRPD	X-ray powder diffraction

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