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SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of Kieselguhr (diatomaceous earth) for all animal species (Imerys France)

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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, EFSA was asked to deliver a scientific opinion on the safety and efficacy of Kieselguhr (diatomaceous earth, three forms: natural, purified calcined and purified flux-calcined) as a technological additive (functional group: anticaking and binder) for all animal species. Kieselguhr is predominantly amorphous silica (non-crystalline silicon dioxide (SiO_2)). Based on the information submitted, Kieselguhr natural, purified calcined and purified flux-calcined are safe when used at 5000 mg/kg of complete feed in all terrestrial animals. No conclusions can be reached on the safety of its use in aquatic animals. The use of Kieselguhr natural, purified calcined and purified flux-calcined in animal nutrition under the proposed conditions of use is safe for the consumer and the environment. Kieselguhr natural and purified flux-calcined are not irritant to the skin. All the three forms of the additive are irritant to the eyes and should be considered dermal and respiratory sensitisers. Any exposure is considered a risk. The FEEDAP Panel concluded that the additive is effective as a pellet binder. Kieselguhr is efficacious as an anticaking agent at a minimum concentration of 15,000 mg/kg.

KEYWORDS

anticaking agent, binder, diatomaceous earth purified, efficacy, kielselguhr, safety, technological additive

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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 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Imerys France[2] for re-evaluation of the authorisation of Kieselguhr (diatomaceous earth, three forms: natural, purified calcined and purified flux calcined), when used as a feed additive for all animal species (category: technological additive; functional groups: binders, anticaking agents).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 28 November 2019.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Kieselguhr (diatomaceous earth, three forms) when used under the proposed conditions of use (see Section 3.1.4).

1.2 | Additional information

Kieselguhr (diatomaceous earth, purified) is authorised in the European Union (EU) as feed additive under the category 'technological additives' and the functional groups 'binders, anticaking agents and coagulants' for all animal species 'without a time limit' and is subject of re-evaluation following the provisions of Article 10(1) of Regulation (EC) No 1831/2003.

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 Kieselguhr (diatomaceous earth, three forms) as a feed additive. The dossier was received on 16/10/2019 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2019-00662.

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' 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 diatomaceous earth purified in animal feed.[4]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the product is in line with the principles laid down in Regulation (EC) No 429/2008[5] 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

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

[2]Original application submitted by IMA-Europe aisbl, Twin gardens (6° Floor) – Rue des Deux Eglises, 26 -Box 2, Brussel, Belgium. During the risk assessment (6th July 2020) the applicant changed into Imerys Industrial Minerals S.A, Place E.-Bouillères - B.P. 33662–31036 Toulouse Cedex 1.

[3]FEED dossier reference: FAD-2010-0284.

[4]The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/finrep-fad-2010-0284_diatomaceous_earth.pdf.

[5]Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024).

3 | ASSESSMENT

The present assessment concerns the re-evaluation of Kieselguhr (diatomaceous earth) as a technological feed additive (functional groups: binders and anticaking agents) for all animal species. The applicant requested the authorisation of three different forms of Kieselguhr (diatomaceous earth): natural, purified, calcined and purified and flux-calcined.

3.1 | Characterisation

Kieselguhr (diatomaceous earth) is a fine-grained siliceous sediment of biogenic origin (synonyms: diatomite, diatomaceous silica, kieselgur, infusorial earth). It is composed of the skeletal remains of microscopic single-celled aquatic plants called diatoms. Kieselguhr is predominantly amorphous silica (non-crystalline silicon dioxide (SiO_2). It may also contain small amounts of crystalline silica (quartz and cristobalite), insoluble oxides of calcium, magnesium, iron and aluminium and certain trace elements. In some cases, diatomaceous earth is closely associated with surrounding chalk or clay deposits which can lead to significant calcium carbonate or smectite contents.

3.1.1 | Manufacturing process

The additive is obtained after excavation of the ore using surface mining methods and, depending upon the processing applied,[6] three different forms are obtained, which are described below.

- Kieselguhr (natural, N): [redacted].
- Kieselguhr (purified calcined, C): [redacted].
- Kieselguhr (purified flux-calcined, FC): [redacted].

For the purpose of this assessment the three forms will be abbreviated as follows: Kieselguhr N, Kieselguhr C and Kieselguhr FC.

3.1.2 | Characterisation of the additive

Amorphous silicon dioxide is the primary quantitative component in all three forms, with its quantity varying as shown by the data on the mineralogical analysis,[7] elemental analysis[8] and impurities[9,10] (see Table 1). Based on these analyses, the applicant proposed the following specifications for Kieselguhr N, Kieselguhr C and Kieselguhr FC: ≥ 60% SiO_2, ≥ 70% SiO_2 and ≥ 75% SiO_2, respectively.[11] Kieselguhr is insoluble in water and appears as an odourless whitish powder or granulate.

[6]Technical dossier/Kieselgur_SIn3 dossier_March 2023.pdf.
[7]Using X-ray diffraction (XRD) methodology.
[8]Using X-ray fluorescence (XRF) methodology.
[9]Technical dossier/Annex_SIn_Q4_1.
[10]Technical dossier/Annex_SIn_Q4_2.
[11]Technical dossier/Annex_SIn_Q3_1, Annex_SIn_Q3_2, Annex_SIn_Q3_3.

TABLE 1 Analytical data on the batch-to-batch variation and impurities for the three forms of Kieselguhr.

	Analysis			
	Kieselguhr (natural)	Kieselguhr (purified calcined)	Kieselguhr (purified flux-calcined)	# batches
Parameter	**Range**			
Mineralogical analysis (%)				
Amorphous Silica	63–69	71–75	76–81	5
Montmorillonite (smectite)	27.5–30.5	19–25	Traces	5
Feldspars (Albite)	2–4	2–4	1–2	5
Quartz (crystalline silica)	1.9–3.1	1.8–3.2	1.51–1.83	5
Calcite	1.20–1.96	0.33–0.5	nd	5
Mica	< 1	< 1	nd	5
Anatase	0.12–0.22	0.15–0.21	Traces	5
Cristobalite (crystalline silica)	0.10–0.19	0.11–0.18	4.30–5.31	5
Amorphous phase (containing SiO_2 and Al_2O_3)	–	–	9–14	5
Haematite	–	–	1–2	5
Elemental analysis (%)[a]				
SiO_2	70.43–71.02	72.35–72.98	75.01–76.62	5
Al_2O_3	9.38–10.04	9.76–10.98	9.48–10.03	5
Fe_2O_3	6.11–6.69	6.82–7.33	6.42–6.91	5
CaO	0.96–1.70	1.10–1.75	1.54–1.65	5
MgO	1.59–1.65	1.50–1.70	1.70–1.77	5
K_2O	1.34–1.45	1.30–1.58	1.25–1.41	5
Na_2O	0.50–0.69	0.51–0.71	1.67–1.82	5
TiO_2	1.17–1.22	1.09–1.25	1.15–1.25	5
P_2O_5	0.20–0.21	0.21–0.27	0.20–0.22	5
Loss on ignition	6.34–6.92	3.14–3.82	0.10–0.22	5
Impurities (mg/kg)				
Lead	7.10–7.21	0.01–10[b]	0.61 – 0.86	3
Mercury	< 0.1	< 0.1	< 0.1	3
Cadmium	0.30–0.32	0.28–0.29	0.04–0.05	3
Arsenic	13.36–13.6	14.40–14.60	3.20–3.35	3
Nickel	8.6–8.8	9.3–9.6	5.40–6.0	3
Dioxins and furans (upper bound)[c]				
PCDD/Fs (ng WHO_{2005}-TEQ/kg)	0.16–0.17	0.15	0.16	3
PCDD/Fs + PCBs (ng WHO_{2005}-TEQ/kg)	0.22–0.24	0.2	0.21–0.24	3
nDL-PCBs (µg/kg)	1.6–3.7	2.9–3.2	1.6–5.1	3

Abbreviations: PCDDs, polychlorinated dibenzo-*p*-dioxins; PCDFs, polychlorinated dibenzofurans; nDL-PCBs, non-dioxin-like PCBs; 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.

[a]Expressed as oxides.

[b]Analysed in eight batches.

[c]Upper bound concentrations calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

<: below the limit of quantification (LOQ).

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, except for the presence of nickel, which will be addressed in the user safety section.

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

3.1.3 | Physico-chemical and technological properties

The physico-chemical properties of kieselguhr are determined mainly by its primary structure: the skeletal remains of microscopic single-celled aquatic plants called diatoms create a three-dimensional structure with nano-size cavities leading to a very large surface area.

Sieving and milling leads to different grades of products in terms of particle size ranges. The applicant provided data on the particle size distribution for different products of each form of Kieselguhr obtained using laser diffraction analysis (see Table 2 below).[12]

The additive is reported to be not soluble in water (solubility < 2%).

TABLE 2 Physico-chemical characteristics on the three forms of Kieselguhr.

Parameter	Analysis			
	Kieselguhr (natural)	Kieselguhr (purified calcined)	Kieselguhr (purified flux-calcined)	# batches
Physical properties	**Range**			
Physical form	Powder or granulates	Powder or granulates	Powder	
Colour	Off-white to pink	White	White	
Bulk density (kg/m^3)				
Powder	267–291	275–306	256–297	3
Granulate	510–516	437–442	–	
Dusting potential (Stauber Heubach) (mg/m^3)	4285–4360	4515–4605	5620–6240	3
Particle size distribution (laser diffraction) (% of particles below, v/v)				
< 100 µm	71.78–77.78	55.55–70.65	72.41–78.53	3
< 50 µm	59.81–65.62	42.37–51.35	46.04–57.30	
< 10 µm	27.61–30.55	14.47–16.94	5.77–8.98	

Additional data on the particle size generated with dynamic light scattering (DLS)[13] and scanning electron microscopy (SEM) with energy dispersive X-ray spectroscopy (EDX)[14] confirmed the presence of nano sized constituent particles. All three types of Kieselguhr showed a fraction below 250 nm representing more than 10%. [redacted]

The applicant provided evidence of the stability and homogenous distribution in feed in the efficacy studies done with several feedingstuffs/feed materials. The studies are described in the efficacy section (see Section 3.3).

3.1.4 | Conditions of use

The additive is intended to be used as a technological additive (functional groups: binders; anticaking agents) in premixtures and feedingstuffs for all animal species and categories, with a minimum content of 5000 mg/kg and no maximum content in feed.

3.2 | Safety

3.2.1 | Toxicological studies

The applicant submitted genotoxicity studies and a sub-chronic repeated dose oral toxicity study performed with Kieselguhr N and FC.

[12]Technical dossier/Annex_SIn_Q6_1 IFF Report No. 3.773–2_Dusting_Natural DE, Annex_SIn_Q6_2 IFF Report No. 3.773–3_Dusting_Calcined DE, Annex_SIn_Q6_3 IFF Report No. 3.773-1_Dusting_Flux-calcined DE, Annex 2–1-26, 2–1-27, 2–1-28, 2–1-29, 2–1-30, Annex_SIn_Q5_1 Natural DE CoAs_PSD results.pdf, Annex_SIn_Q5_2 Calcined DE CoAs_PSD results.pdf, Annex_SIn_Q5_3 Flux-Calcined DE CoAs_PSD results.pdf, 2–1-27 Damolin, 2–1-29 Imerys.

[13]Technical dossier/Annex_SIn3_Q2_1.

[14]Technical dossier/Annex_SIn3_Q2_2 and Supplementary information November 2024.

3.2.1.1 | *Genotoxicity studies*

3.2.1.1.1 | *Kieselguhr natural*

3.2.1.1.1.1 | Bacterial reverse mutation test

To investigate the potential of Kieselguhr N to induce gene mutations, an Ames test was performed in Salmonella Typhimurium strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* strain WP2 (uvrA-) (pKM101).[15] The study was performed according to the OECD TG 471 and was claimed to be compliant with the principles of GLP. Two independent experiments were performed applying the plate incorporation and pre-incubation methods both in the presence and absence of metabolic activation. Kieselguhr N, insoluble in water, was suspended in NaCl 0.9% and tested at 50, 150, 500, 1500 and 5000 μg/plate. No toxicity was observed in any experimental condition. A slight precipitate was visible at the highest concentration not interfering with the analysis. No increase in the number of revertant colonies was observed in any strain, at any tested concentration with or without metabolic activation. Therefore, the soluble part of the test item, if any, is non-mutagenic in the Ames test under the experimental conditions employed in this study.

3.2.1.1.1.2 | In vitro mammalian micronucleus test

To evaluate the potential of Kieselguhr N to induce chromosomal damage, an in vitro micronucleus test was carried out in Chinese Hamster Ovary cells according to OECD TG 487, in a study claimed to be compliant with the principles of GLP.[16] The test item was insoluble in water and a suspension was obtained in NaCl 0.9% by continuous stirring. Based on the results of a preliminary cytotoxicity test, three concentrations of the suspension were selected for the analysis of the frequency of micronuclei applying a short treatment (4 + a recovery period of 1.5–2 times the cell cycle) in the absence (224, 320, 560 μg/mL) and presence (800, 1400, 2000 μg/mL) of metabolic activation and a continuous treatment (1.5–2 times the cell cycle) in the absence of metabolic activation (128, 224, 320, 560 μg/mL). No cytotoxicity was observed after treatment with the test item, as measured by the relative increase in cell count (RICC). No increase in the frequency of micronucleated cells was observed in the treated cultures compared to the vehicle control cultures. Therefore, the soluble part of the test item, if any, does not induce structural and numerical aberrations in mammalian cells under the experimental conditions employed in this study.

3.2.1.1.2 | *Kieselguhr purified flux-calcined*

3.2.1.1.2.1 | Bacterial reverse mutation test

In order to investigate the potential of Kieselguhr FC (purity 100%) to induce gene mutations in bacteria, an Ames test was performed according to OECD TG 471 and claimed to be GLP compliant, in S. Typhimurium TA98, TA100, TA1535, TA1537 and *E. coli* WP2uvrA, in the presence or absence of metabolic activation.[17] The test material was suspended in polyethylene glycol 400 and tested up to 5000 μg/plate, the maximum recommended concentration for non-toxic substances. A fine, black particulate precipitate was observed at the highest concentration, not preventing the analysis of revertant colonies. No toxicity and no increase in the mean number of revertant colonies were induced by the test item in any bacterial strain. Therefore, the soluble part of the test item, if any, is non-mutagenic in the Ames test under the experimental conditions employed in this study.

3.2.1.1.2.2 | Chromosomal aberration test

To evaluate the potential of Kieselguhr FC (purity 100%) to induce chromosome damage, an in vitro chromosomal aberration test was performed in whole blood human lymphocytes according to OECD TG 473 and claimed to be GLP compliant.[18] Three concentrations (10, 20 and 40 μg/mL) were selected for the analysis of micronucleus frequency applying a short treatment (4 h plus 20 h of recovery) in the presence and absence of metabolic activation and a continuous treatment (24 h plus 0 h recovery) in the absence of metabolic activation. The test material was suspended in culture medium. Precipitation was observed at 37.5 μg/mL and above and determined the selection of the top concentration. No significant cytotoxicity was induced by treatment with the test item compared to the vehicle controls. No significant increase in the frequency of aberrations or polyploidy was observed at any dose and sampling time. Therefore, test item does not induce structural chromosome aberrations and polyploidy in cultured human peripheral blood lymphocytes under the experimental conditions employed in this study.

[15]Technical dossier/Annex_SIn5_Q2_2.

[16]Technical dossier/Annex_SIn5_Q2_3 Micronucleus test_OECD 487.pdf.

[17]Technical dossier/3–2-3 Ames test (3018–0008) final.

[18]Technical dossier/3–2-2 Chromosome Aberration test (3018–0009).

3.2.1.1.2.3 | Mouse Lymphoma Assay

To assess the mutagenic potential of Kieselguhr FC (purity 100%) in a mammalian cell system, the L5178Y TK +/– mouse lymphoma assay was performed in accordance with OECD Guideline 476 applying a short treatment (4 h) in the absence and presence of S9-mix and a continuous treatment (24 h) in the absence of S9-mix.[19] The study was claimed to be performed following the GLP principles. The test material was suspended in culture medium and tested at six concentrations ranging from 2.5 to 40 μg/mL. The maximum dose level applied was limited by precipitation observed at 5 μg/mL and above.

Comparable values of mutant frequency (MF) were observed in the treated and vehicle control cultures in the absence of metabolic activation, while a statistically significant increase in MF was induced by the highest concentration tested in the presence of metabolic activation. The MF did not exceed the Global Evaluation Factor value, was within the range of historical vehicle control values and, therefore, the Panel considered it not biologically relevant. Therefore, the soluble part of the test item, if any, does not induce gene mutations in mammalian cells under the experimental conditions applied in this study.

3.2.1.2 | *Sub-chronic repeated dose oral toxicity study*

Groups of 20 Sprague–Dawley (Crl:CD®BR) rats of each sex received diets containing no Kieselguhr (control) or Kieselguhr N at 50,000 mg/kg or Kieselguhr FC at 10,000 mg/kg or 50,000 mg/kg, for 13 weeks.[20] These dietary levels corresponded to: (i) 3533 and 3998 mg Kieselguhr N/kg body weight (bw) per day), for males and females, respectively; or (ii) 656 and 741 mg Kieselguhr FC/kg bw per day (males and females, respectively) and (iii) 3543 and 3932 mg Kieselguhr FC/kg bw per day (males and females, respectively). The study was claimed to follow the GLP principles.

There was no effect of treatment on mortality, clinical signs, ophthalmoscopic findings body weight, food intake, haematology or serum analyses. Gross pathology, organ weights and microscopic histopathology showed no treatment-related effects.

The FEEDAP Panel considers that the no observed adverse effect level (NOAEL) from this study is 3533 mg/kg bw for Kieselguhr N and 3543 mg/kg for Kieselguhr FC.

3.2.1.3 | *Conclusions on toxicology*

The Panel concludes that Kieselguhr N and Kieselguhr FC are not genotoxic under the tested conditions. A NOAEL of 3533 mg/kg bw (highest dose tested) is derived from the 90-day sub-chronic oral toxicity study. Considering the composition of the different forms of the additive, the Panel considers that the conclusions reached for the natural form can be extended to the purified calcined form.

3.2.2 | Safety for the target species

The applicant provided three tolerance studies, one in chickens for fattening,[21] one in weaned piglets[22] and one in dairy cows.[23] All the studies tested the form Kieselguhr N.

3.2.2.1 | *Chickens for fattening*

A total of 960 one-day-old male Ross 308 chickens were distributed in 48 pens (20 birds each) and randomly allocated to four groups.[24] Three basal diets (starter 1–10 days, grower 11–21 days and finisher 22–35 days), based on maize and soybean meal and calculated to be isoenergetic (starter: 2900 ME Kcal/kg; grower: 2950 ME Kcal/kg; finisher: 3000 ME Kcal/kg), were either not supplemented (control) or supplemented with Kieselguhr N at an inclusion level of 20,000 (4× minimum use level), 50,000 (10×) or 100,000 (20×) mg/kg complete feed. The experimental diets were offered ad libitum as crumbs (starter) or pellets (grower/finisher) for 35 days.

Birds were monitored throughout the study. The birds were weighed at start of the trial. Thereafter, the BW and the feed intake were recorded on a pen basis on days 21 and 35. The average daily feed intake, average daily weight gain and

[19]Technical dossier/3–2-4 Mouse Lymphoma Assay 3018–0010 (final).
[20]Technical dossier/Annex_SIn_Q9_1.
[21]Technical dossier/Annex_SIn_Q8_3.
[22]Technical dossier/Annex_SIn_Q8_2a.
[23]Technical dossier/Annex_Sin_Q8_1.
[24]Technical dossier/Annex_SIn_Q8_3.

feed-to-gain ratio were calculated and corrected for mortality for the whole period. At the end of the study, blood was sampled from two chickens per pen and analysed for biochemical[25] and haematological[26] parameters.

Data were analysed with a two-way analysis of variance (ANOVA) with the diet and block as fixed effect. When differences were observed, group means were compared with Tukey's test. The pen was the experimental unit for all parameters. The significance level was set at 0.05.

Two pens (one from 4× and one from 20× groups) were removed from the statistical analysis due to an impaired performance caused by an infection with *Mycoplasma gallisepticum*). Mortality rates were 1.25, 0.91, 1.25 and 2.73% for the control, 4×, 10× and 20× groups, with no statistical differences between them.

No significant differences were observed in the final body weight (range of values across treatments: 2.3–2.4 kg), average daily gain (range of values across treatments: 64.4–67.4 g) or average daily feed intake (range of values across treatments: 90–94.5 g) between groups. However, the feed-to-gain ratio was significantly worsened in the 20× group compared to the control (1.43 vs. 1.38). This effect seems to follow a trend related to the concentration of the additive in the feed; therefore, the Panel considers it as an adverse effect of the additive.

None of the clinical chemistry or haematological parameters showed significant differences between groups, except for the alkaline phosphatase, which showed higher serum activity in the 20× group compared to the control (829.1 vs. 611.5 U/L).

Based on the results of this study in which no adverse effects were observed on the performance and health of chickens for fattening supplemented with Kieselguhr N at 50,000 mg/kg, the Panel concludes that the additive is safe in chickens for fattening at 5000 mg/kg, with a margin of safety of approximately 10.

3.2.2.2 | *Weaned piglets*

A total of 144 piglets ((Large White × Landrace) × Piétrain), 32 days of age and 8.2 kg initial body weight) ca. were distributed in 36 pens (four piglets per pen), which were randomly allocated to one of four groups (nine replicates per group).[27] Two basal diets (pre-starter 1–14 days and starter 15–42 days) were either not supplemented (control) or supplemented with Kieselguhr N at 20,000 (4×), 50,000 (10×) or 100,000 (20×) mg/kg complete feed. The concentration of the additive in the feed was estimated based on the analysis of aluminium as a marker.[28] The experimental diets were offered ad libitum in mash form for 42 days.

Mortality and health status were checked every day. The piglets were weighted at the start of the trial. Thereafter, BW and feed intake were recorded on days 14, 28 and 42. The Average Daily Feed Intake (ADFI), Average Daily Gain (ADG) and the Feed/Gain ratio (F/G) were calculated and corrected for mortality for the whole period. Blood from the same two piglets per pen were sampled at the start and at the end of the trial and analysed for biochemical[29] and haematological[30] parameters.

The data were analysed with a generalised linear model, with the diet and block (based on weight and room location) as fixed effects. When differences were observed, group means were investigated using Tukey's test. The significance level was set at 0.05.

No significant treatment effects were observed for blood biochemical values at day 42, except for cholesterol which showed a significantly higher value in the piglets of the 20× group, although within the physiological range and values of all treatments were in the normal range.

Some differences were observed in phosphorus levels, however these were not dose-related. A treatment effect was also observed in the percentage of lymphocytes which showed a lower value in the piglets receiving the control than in the piglets of 4× group, but in all cases the values in number and percentage were in the normal range.

Based on the results of the tolerance trial, in which no adverse effects were observed on the zootechnical performance and the blood haematology and biochemistry parameters monitored at 100,000 mg/kg complete feed, the Panel concludes that the additive is safe for weaned piglets at the minimum use level of 5000 mg/kg complete feed with a margin of safety of 20.

[25]Biochemical parameters: alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyl transpeptidase, lactate dehydrogenase (LDH), bilirubin, creatine, cholesterol, albumin, globulin, total protein, glucose, urea, sodium, potassium, chloride, calcium, phosphate, magnesium.

[26]Haematological parameters: haemaglobin (Hb), red blood count (RBC), packed cell volume (MCV), mean cell haemoglobin (MCH), white blood cell differentials (segmented neutrophils, lymphocytes, monocytes, eosinophils) prothrombin time, fibrinogen.

[27]Technical dossier/Annex_SIn_Q8_2a.

[28]Estimated concentration of the additive in the feed (based on AI).

[29]Biochemical parameters: alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyl transpeptidase, lactate dehydrogenase (LDH), bilirubin, creatine, cholesterol, albumin, globulin, total protein, glucose, urea, sodium, potassium, chloride, calcium, phosphate, magnesium.

[30]Haematological parameters: haemaglobin (Hb), red blood count (RBC), packed cell volume (MCV), mean cell haemoglobin (MCH), white blood cell differentials (segmented neutrophils, lymphocytes, monocytes, eosinophils) prothrombin time, fibrinogen.

3.2.2.3 | *Dairy cows*

A total of 48 multiparous Holstein cows (BW 642 ± 79 kg) were housed in collective barns equipped with automatic feed bins, allowing for individual feed intake monitoring and randomly allocated to four groups (12 replicates per group).[31] The cows received a total mixed ration (TMR),[32] including a concentrate which was either not supplemented (control) or supplemented with Kieselguhr N at 20,000, 50,000 or 100,000 mg/kg. These levels of Kieselguhr in the concentrate would correspond to 4800 (0.96×), 12,000 (2.4×) and 23,000 (4.6×) mg/kg complete feed (88% dry matter). The concentration of the additive in the feed was estimated based on the analysis of aluminium as a marker.[33] The experimental diets were offered ad libitum for 56 days.

The health status of the animals was monitored daily. Individual feed intake, body weight, milk production and milk composition (protein, fat, lactose and total solids) were recorded daily, and the dry matter intake, the energy-corrected milk yield (ECM)[34] and the feed efficiency[35] were calculated for the whole period. Milk samples were collected from each cow on days 7, 21 and 56 to determine milk urea and on days 1, 14, 28 and 56 to determine somatic cell counts. At the start (day 1) and end (day 56) of the experiment, blood was sampled from all animals and analysed for haematological[36] and biochemical[37] parameters.

The productive performance and milk quality data were analysed with a mixed model for repeated measures, considering the diet, time and their interaction as fixed effects and the cow as a random effect. Data for blood parameters were analysed with one-way ANOVA, considering the diet as a fixed effect The individual cow was used as experimental unit in all cases. The significance level was set at 0.05.

No mortality occurred throughout the experiment. The supplementation of the cow's diet with Kieselguhr N at any level showed no significant effect on the productive performance (average values for the control: BW = 641 kg, dry matter intake = 24.1 kg/day, milk yield = 29.8 kg/day and feed efficiency = 1.39) or on the milk quality (fat content = 3.87% for control, protein = 3.34%, lactose = 4.64%, total non-fat solids = 8.60% and somatic cell counts = 153×10^3), except for the content of urea in milk, which was significantly higher in 2.4× (304 mg/kg) and 4.6× (305 mg/kg) compared to the control (268 mg/kg).

Regarding the blood haematology and biochemistry parameters, the only difference between the animals from the supplemented groups and the control was the concentration of phosphate in the blood. The group supplemented with the additive at 4.6× (4.66 mg/dL) showed lower serum phosphate concentration in comparison with the control (5.66 mg/dL), 0.96× (5.79 mg/dL) and 2.4× (6.00 mg/dL) groups. The concentration of serum phosphate in the 4.6× group was below the physiological range for cows (5.6–6.5 mg/dL; Kaneko et al., 2008). Therefore, the Panel considered it an adverse effect.

The Panel concludes that the use of Kieselguhr N in dairy cows' feed is safe at 5000 mg/kg complete feed, with a margin of safety of 2.4.

3.2.2.4 | *Interaction of the additive with other components of the diet*

A total of 32 one-day-old male Ross 308 chickens for fattening were placed on 16 cages at two per pen from day one till day 18 for collection of faeces for the interference study.

Digestibility measurements were carried out by comparing the control group and the group fed with 20,000 mg additive/kg feed between 16 and 18 days, with a separate group of birds placed in cages (8 cages of 2 birds per treatment). On day 15, animals were deprived of feed for 16 h and after the amount of feed consumed and the weight of fresh excreta were recorded for 3 days. Feed and excreta samples were collected for determination of nitrogen (total and non-protein nitrogen), α-tocopherol and α-tocopherol acetate (vitamin E), riboflavin (vitamin B_2), pyridoxin (vitamin B_6), zinc[38] and monensin, and the retention was calculated. No significant differences were observed among treatments in the nitrogen retention or in the measured concentrations of tocopherol, pyridoxin and monensin. The digestibility of ribloflavin was higher in supplemented group compared to the control (55.9% vs. 44.7%). The results of the study suggest that Kieselguhr N does not adversely interfere with the availability of nutrients to the animals and does not interact with monensin.

3.2.2.5 | *Conclusions on the safety for the target species*

The applicant did not propose a maximum use level of the additive in complete feed for the target species, but only a minimum (5000 mg/kg complete feed). The Panel notes that the minimum proposed use level was not included in the

[31]Technical dossier/Annex_Sin_Q8_1.

[32]Total mixed ration composition: alfalfa hay, fescue hay, ryegrass hay, straw, soyabean meal, orange, vitamin-mineral premix and concentrate (based on maize, wheat, sunflower meal and palm oil.

[33]Estimated concentration of the additive in the feed (based on Al).

[34]Energy-corrected milk yield (kg/d) = 0.3246 × milk yield +12.86 × fat yield +7.4 × protein yield.

[35]Feed efficiency = ECM/dry matter intake.

[36]Haemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean cell volume (MCV), mean cell haemoglobin (MCH), platelets, white blood cell count (WBC), white blood cell differentials (neutrophils, lymphocytes, basophils, monocytes, eosinophils), prothrombin time and fibrinogen.

[37]Alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyltranspeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), bilirubin, creatinine, cholesterol, albumin, globulin, total protein, glucose, urea, sodium, potassium, chloride, calcium, phosphate and magnesium.

[38]Results of zinc showed negative values; in the report it was acknowledged that this could be due to the galvanised cages in which the animals were kept during the digestibility study.

studies in chickens for fattening and weaned piglets, in which the lowest level tested was 20,000 mg/kg. In these studies, no adverse effects were observed when the additive was supplemented at 50,000 and 100,000 mg/kg, for chickens and piglets, respectively. The Panel considers that, even if the minimum use level was not tested, the studies would still allow reaching conclusions on the safety of the additive at this level.

Based on the tolerance studies assessed, the Panel concludes that the use of Kieselguhr N in chickens for fattening, weaned piglets and dairy cows at the proposed minimum use level of 5000 mg/kg complete feed is safe, with a margin of safety of at least 2.4. Considering that the safety of the additive has been demonstrated in three terrestrial major target species with different metabolic capacities and with a similar margin of safety, the FEEDAP Panel concludes that the use of Kieselguhr N at the proposed use level of 5000 mg/kg complete feed is safe for all terrestrial animal species.

The Panel notes that only the N form of the additive was tested in the tolerance studies. Considering the outcome of the genotoxicity studies and the sub-chronic oral toxicity study in which the N and FC forms were used, and taking into account that it is not expected that the additive is absorbed in the gastrointestinal tract of the animals, the FEEDAP Panel considers that the conclusions reached with Kieselguhr N can be extended to the other two forms (C and FC). In the absence of data, no conclusions can be reached on the safety of the additive in aquatic species.

3.2.3 | Safety for the consumer

The FEEDAP Panel considers it unlikely that the additive 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.

3.2.4 | Safety for the user

Based on the highest dusting potential measured (4360, 4605 and 6240 mg/m^3 for Kieselguhr N, C and FC, respectively), the FEEDAP Panel considers that the exposure of users through inhalation is likely.

The applicant submitted two acute inhalation toxicity studies performed according to the OECD TG 403, one performed with Kieselguhr N and the other one with Kieselguhr FC.

In the first study,[39] three males and three female Wistar rats were exposed to Kieselguhr N for 4 h at the maximum achievable breathing zone concentration of 2.8 mg/L air. The acute inhalation LC_{50} was greater than the maximum attainable concentration of 2.8 mg/L air.

In the second study,[40] five males and five female Wistar rats were exposed to Kieselguhr FC for 4 h at the maximum achievable breathing zone concentration of 2.6 mg/L air. The acute inhalation LC_{50} was greater than the maximum attainable concentration of 2.6 mg/L air.

The FEEDAP Panel notes that all the forms of the additive contain nickel (see Table 1). Directive (EU) 2022/431[41] set an occupational exposure limit (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). Therefore, to reduce the risk, the FEEDAP Panel considers that the exposure of the users should be minimised.

The FEEDAP Panel also notes that all the forms of the additive contain crystalline silica (see Table 1). Inhalation of crystalline silica is known to be hazardous and is associated with increased risk of lung cancer and the industrial disease, silicosis. Directive (EU) 2017/2398[42] 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.

Considering the content of nickel, the additive should be considered a skin and respiratory sensitiser.

The skin irritation potential of Kieselguhr N was tested in a study performed according to OECD TG 439 which showed that the test item is not a skin irritant (UN GHS 'No Category').[43]

The eye irritation potential of Kieselguhr N was tested in a study performed according to OECD TG 438 which showed that the test item should be classified according to the UN GHS as 'No prediction can be made'.[44]

The skin sensitisation potential of Kieselguhr N was tested in a study performed according to OECD TG 442B which showed that the test item is not a skin sensitiser.[45]

[39]Technical dossier/Annex_SIn_Q10_1.

[40]Technical dossier/Annex_SIn_Q10_5.

[41]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.

[42]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.

[43]Technical dossier/Annex_SIn_Q10_3.

[44]Technical dossier/Annex_SIn_Q10_2.

[45]Technical dossier/Annex_SIn_Q10_4.

The skin irritation potential of Kieselguhr FC was tested in a study performed according to the OECD TG 439. The results showed that the test item is not a skin irritant (UN GHS as 'No Category').[46]

The skin corrosion potential Kieselguhr FC was tested in a study performed according to the OECD TG 431. The results indicated that the test item is not corrosive to skin.[47]

Based on the information present in the safety data sheets (SDS), the three forms of Kieselguhr are irritant to the eyes.[48]

3.2.4.1 | *Conclusions on safety for the user*

Kieselguhr N and Kieselguhr FC are not irritant to the skin. All the three forms of the additive are irritant to the eyes and should be considered dermal and respiratory sensitisers. Any exposure is considered a risk.

3.2.5 | Safety for the environment

The components of the three forms of Kieselguhr are normal components of the soils and widely distributed in the environment. Its use in animal nutrition is not expected to increase the load of the components in the environment. Therefore, the use of the three forms of Kieselguhr in animal nutrition is considered safe for the environment.

3.3 | Efficacy

The applicant provided two studies with Kieselguhr N in feed-to-support the efficacy of diatomaceous earth as a binder and anti-cacking agent.

In the first study,[49] complete feeds for chickens for fattening, pigs and cattle were supplemented with 0 (control), 5000, 15,000, 30,000 or 50,000 mg Kieselguhr N/kg. Pellet durability, pellet hardness, flowability and angle of repose of the feed either before and after pelleting were measured and statistically analysed with one-way ANOVA followed by a post-hoc Tukey test or a Kruskal–Wallis test followed by a post-hoc Dunn test. The results are reported in Table 3.

TABLE 3 Results of pellet durability, hardness, flowability and angle of repose in pelleted feeds and angle of repose in mash feed in feeds supplemented with 0, 5000, 15,000, 30,000 and 50,000 mg/kg Kieselguhr N.

Type of feed	Kieselguhr natural inclusion level (mg/kg)	Mean hardness (MPa)	Pellet durability (%)	Flowability (kg/min) of pelleted feed	Angle of repose (°) of mash feed	Angle of repose (°) of pelleted feed
Chickens	0	1.77^{a}	88.2^{a}	13.4^{a}	64.7	27.8^{a}
	5000	2.08^{b}	90^{a}	13.6^{ab}	65.2	31^{b}
	15,000	2.34^{b}	91.7^{ab}	13.9^{bc}	65.4	31.3^{b}
	30,000	2.56^{c}	92.2^{b}	14.4^{cd}	66.1	31^{bc}
	50,000	2.91^{c}	93.4^{b}	15.1^{d}	63.1	30.3^{c}
Pigs	0	1.85^{a}	87^{a}	13^{a}	66.6^{ab}	28.7^{a}
	5000	1.88^{a}	88.2^{ab}	13.2^{ab}	69.4^{a}	29.9^{ab}
	15,000	2.18^{b}	90.5^{ab}	13.1^{ab}	66^{abc}	30.4^{bc}
	30,000	2.61^{b}	92^{c}	13.4^{b}	63.5^{bc}	30.2^{bc}
	50,000	3.64^{c}	93.1^{c}	13.7^{c}	62.6^{c}	30.6^{c}
Cattle	0	1.67^{a}	86.5^{a}	11.4^{a}	64.5^{ab}	30.6
	5000	2.04^{b}	87.6^{a}	11.8^{ab}	65.4^{a}	30.9
	15,000	2.02^{b}	87.9^{ab}	12^{bc}	66.2^{ab}	30.9
	30,000	2.28^{c}	90.2^{bc}	12.5^{c}	63.9^{bc}	31
	50,000	2.28^{c}	90.7^{c}	13.2^{d}	61.5^{c}	31

^{a,b,c}Mean in a column not sharing a common letter are statistically different ($p < 0.05$).

Kieselguhr N improved pellet hardness at all levels tested in feed for chickens for fattening and cattle, and in feed for pigs at concentrations starting from 15,000 mg/kg. Pellet durability was improved in all feeds at concentrations of 30,000 mg/kg and above. Pellet flowability was improved in feed for chicken for fattening and cattle starting at 15,000 and in feed for pigs at 30,000 mg/kg feed.

[46]Technical dossier/Annex 3-3-2.
[47]Technical dossier/Annex 3-3-3.
[48]Technical dossier/Annex 2.5.2, Annex 2.5.4 and Annex 2.5.9.
[49]Technical dossier/Annex_SIn_Q11_1.

The results of the angle of repose showed contrasting effects. When the additive was added to mash feed, no effects were observed in chicken for fattening and an improvement was observed in feed for pigs and cattle only at 50,000 mg/kg. Instead, in pelleted feed for pigs and chicken for fattening, the additive had a opposite effect, increasing the angle of repose starting respectively at 5000 and 15,000 mg/kg. No differences were observed in pelleted feed for cattle.

In the second study, the anticaking effects of Kieselguhr N was tested in mash feed supplemented either with 0 (control), 50,000, 100,000 or 150,000 mg Kieselguhr N/kg feed.[50] Results (10 replicated analysis for each measurement) were analysed with one-way ANOVA. The significance level was established at 0.05. The results are reported in the Table 4.

TABLE 4 Results of the anticaking effect in feeds supplemented with 0, 50,000, 100,000 and 150,000 mg Kieselguhr N/kg.

Kieselguhr natural (mg/kg feed)	Angle of repose (°)
0	36.2[b]
50,000	34.8[a]
100,000	36.3[b]
150,000 mg/kg	38.3[c]

[a,b,c]Mean in a column not sharing a common letter are statistically different ($p < 0.05$).

The angle of repose resulted statistically lower at the inclusion level of 50,000 mg/kg. At an inclusion of 100,000 mg/kg no differences were observed with the control, while at 150,000 mg/kg an inversion of the effect was observed.

3.3.1 | Conclusions on efficacy

Based on the studies in feed for chickens for fattening, pigs and cattle, in which Kieselguhr N significantly improved the pellet hardness/durability, and the flowability of feeds, the FEEDAP Panel concludes that the additive is efficacious as pellet binder and anticaking agent. These conclusions are extended to the other forms of Kieselguhr (C, FC).

4 | CONCLUSIONS

The FEEDAP Panel concludes that Kieselguhr natural, purified calcined and purified flux-calcined are safe when used at 5000 mg/kg of complete feed in all terrestrial animals. No conclusions can be reached on the safety of its use in aquatic animals.

The use of Kieselguhr natural, purified calcined and purified flux-calcined in animal nutrition under the proposed conditions of use is safe for the consumer and the environment.

Kieselguhr natural and purified flux-calcined are not irritant to the skin. All the three forms of the additive are irritant to the eyes and should be considered dermal and respiratory sensitisers. Any exposure is considered a risk.

The FEEDAP Panel concludes that the three forms of Kieselguhr are effective as pellet binders and anticaking agents.

5 | REMARKS

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

6 | RECOMMENDATIONS

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

ABBREVIATIONS

ADFI	Average Daily Feed Intake
ADG	Average Daily Gain
ALT	alanine transaminase
ANOVA	analysis of variance
AST	aspartate aminotransferase

[50]Technical dossier/Annex 4-1-4.

bw	body weight
CPK	creatine phosphokinase
DLS	dynamic light scattering
ECM	energy-corrected milK
EDX	energy dispersive X-ray spectroscopy
EURL	European Union Reference Laboratory
F/G	Feed/Gain ratio
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
GGT	gamma-glutamyltranspeptidase
GLDH	glutamate dehydrogenase
GLP	Good Laboratory Practice
GSH-Px	glutathione peroxidase
Hb	haemoglobin
LDH	lactate dehydrogenase
MCH	mean cell haemoglobin
MCV	packed cell volume
MF	mutant frequency
nDL-PCBs	non-dioxin-like PCBs
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
OEL	occupational exposure limit
PCDDs	polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzofurans
RBC	red blood count
RICC	relative increase in cell count
SDS	safety data sheets
SEM	scanning electron microscopy
TEQ	toxic equivalent factors
TG	Testing Guideline
TMR	total mixed ration
WHO	World Health Organization
XRD	X-ray diffraction
XRF	X-ray fluorescence

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