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Safety and efficacy of a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) as feed additive for all animal species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

Abstract

The additive, a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates, is intended to be used as a technological additive (functional groups: anticaking agents) in feedingstuffs for all animal species. The additive is safe in complete feed for dairy cows, piglets and pigs for fattening at a maximum concentration of 20,000 mg/kg. No conclusions can be drawn for all the other animal species/categories. The additive is not genotoxic. As the additive is essentially not absorbed from the gut lumen, the Panel on Additives and Products or Substances used in Animal Feed considers that use of the additive in animal nutrition is safe for consumers of food products from animals fed diets containing the additive. The additive is not an irritant to the eyes and the skin, it is not a skin sensitiser and it is of low toxicity by the inhalation route. The components of the additive (dolomite, magnesite, talc and chlorite) are natural constituents of soil. Consequently, the use of the additive in animal nutrition will not pose a risk to the environment. The additive is effective as an anticaking agent at a minimum inclusion level of 5,000 mg/kg feed.

Keywords: dolomite, magnesite, talc, chlorite, technological additive, safety, anticaking agent

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Summary

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 the a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates.

The additive is safe in complete feed for dairy cows, piglets and pigs for fattening at a maximum concentration of 20,000 mg/kg. No conclusions can be drawn for all the other animal species/categories.

The additive is not genotoxic. As the additive is essentially not absorbed from the gut lumen, the FEEDAP Panel considers that use of the additive in animal nutrition is safe for consumers of food products from animals fed diets containing the additive.

The additive is not an irritant to the eyes and the skin, it is not a skin sensitiser and it is of low toxicity by the inhalation route.

The components of the additive (dolomite, magnesite, talc and chlorite) are natural constituents of soil. Consequently, the use of the additive in animal nutrition will not pose a risk to the environment.

The additive is effective as an anticaking agent at a minimum inclusion level of 5,000 mg/kg feed.

Table of contents

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

The European Commission (EC) received a request from IMI FABI S.p.A.[2] for authorisation of the product natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol), when used as a feed additive for all animal species (category: technological additives; functional group: anticaking agents).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 6 August 2013.

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 natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol), when used under the proposed conditions of use (see Section 3.1.6).

1.2. Additional information

The additive Fluidol is a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (chlorite and talc). This product has not been previously authorised in the Community.

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 natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003 and the applicable EFSA guidance documents.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies and peer-reviewed scientific papers, to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.[4]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of natural mixture of dolomite plus magnesite and magnesium-phyllosilicates is consistent with the principles laid down

[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] IMI FABI S.p.A. Viale dei Mille, 68, 20129 Milano, Italy.
[3] FEED dossier reference: FAD-2012-0043.
[4] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2012-0043%20Fluidol.doc_.pdf

in Regulation (EC) No 429/2008[5] and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012b) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012c).

3. Assessment

The product under assessment is a natural mixture mainly composed dolomite, magnesite, and magnesium-phyllosilicates (talc and chlorite), subsequently referred to as MDMM. Talc is authorised for use as food additive under Regulation (EC) No 1333/2008,[6] with a specification established by Regulation (EU) No 231/2012.[7]

The applicant is seeking an authorisation for the use of the product as a technological additive (functional groups: (i) anticaking agents) in feedingstuffs for all animal species.

3.1. Characterisation

References to the dossier in the footnotes should read as in the examples below.

3.1.1. Characterisation of the additive

The product is obtained by mining from a quarry located in Italy. Extraction is followed by crushing, drying and packaging. It is a grey fine powder clay with a bulk density of about 820 kg/m^3.[8]

The product is specified to contain at least 40% of dolomite plus magnesite as main components; the other components are magnesium-phyllosilicates (hydrated silicates of magnesium (talc) and of aluminium–magnesium (chlorite)). The additive is further specified to contain at least 24% carbonates and to be free of quartz and asbestos. The characteristics of the main constituents are listed in Table 1.

Table 1: Main characteristics of the additive dolomite plus magnesite and magnesium-phyllosilicates as provided by the applicant.

	Dolomite	Magnesite	Talc	Chlorite
CAS number	16389-88-1	546-93-0	14807-96-6	1318-59-8
EINECS number	240-440-2	208-915-9	238-877-9	215-285-9
Chemical formula	$(CaMg)(CO_3)_2K(Al,Fe)_2AlSi_3O_{10}(OH)_2.H_2O$	$MgCO_3Na_x[(Al_{2-x}Mg_x)Si_4O_{10})(OH)_2]$	$Mg_3Si_4O_{10}(OH)_2Al_2(OH)_4(SiO_5)$	$(Mg, Fe, Al)_6(Si, Al)_4O_{10}(OH)_8$

X-ray diffraction (XRD) is commonly used to provide a full mineralogical analysis of clays, which can also be characterised by their elemental composition, usually determined/expressed as the corresponding oxides. Both mineralogical and chemical approaches have been used to characterise the additive. The mineralogical composition (XRD of six batches)[9] is summarised in Table 2. The

[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.
[6] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)
[7] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. (O J L 83, 22.3.2012, p. 1–295)
[8] Technical dossier/Section II/Annex 2-1-10
[9] Technical dossier/Section II/Annex 2-1-1 and Supplementary Information July 2014/Annex i_1

elemental composition (six batches)[10] is given in Table 3. Asbestos[11] and crystalline silica (quartz, tridymite and cristobalite)[12] were absent in three batches of the additive.

Table 2: Mineralogical composition of six batches of the product (X-ray diffraction).

	Dolomite (%)	Magnesite (%)	Talc (%)	Chlorite (%)
Mean	29	18	36	17
Minimum	26	14	35	16
Maximum	33	21	37	18

Table 3: Elemental composition of five batches of the product (expressed as oxide)

	SiO_2 (%)	MgO (%)	Fe_2O_3 (%)	CaO (%)	Al_2O_3 (%)
Mean	28.4	27.8	8.1	5.1	2.5
Minimum	27.9	27.0	7.8	4.9	2.1
Maximum	28.8	28.4	8.4	5.4	2.7

The product is further characterised by (average of three batches) loss of ignition (900°C): 27.1%;[13] pH (10% solution): 8.5 – 9.0;[14] moisture (4 h at 105°C): 0.15%;[15] carbonates: > 24%.[16]

3.1.2. Purity

Three batches of the product[17] showed concentrations of lead, cadmium, mercury and arsenic below the respective limit of detections (≤ 5 mg/kg, ≤ 1 mg/kg, ≤ 0.1 mg/kg and ≤ 1 mg/kg, respectively) and that do not raise safety concern.

Dioxins in four batches were ≤ 0.06 ng WHO PCDD/F-TEQ/kg, sum of dioxins and dioxins-like polychlorinated biphenyls (PCBs) ≤ 0.09 ng WHO-PCDD/F-PCB-TEQ/kg and of non-dioxin-like PCBs (ICES = 6) ≤ 0.33 µg/kg.[18] These concentrations are below the limits set in the Commission Directive 2002/32/EC.[19]

3.1.3. Physical state of the product

Particle size distribution, analysed by laser diffraction in three batches of the additive,[20] showed that about 97% of particles (v/v) were ≤ 100 µm, 85% ≤ 50 µm and 45% ≤ 10 µm. The mean diameter of the particles of the additive was about 12 µm.

The additive showed a dusting potential (analysed by Stauber–Heubach method in three batches)[21] of about 10 g/m^3.

3.1.4. Stability and homogeneity

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

[10] Technical dossier/Section II/Annex 2-1-2
[11] Technical dossier/Section II/Annex 2-1-5
[12] Technical dossier/Section II/Annex 2-1-6
[13] Technical dossier/Section II/Annex 2-2-1
[14] Technical dossier/Section II
[15] Technical dossier/Section II/Annex 2-2-2
[16] Technical dossier/Section II
[17] Technical dossier/Section II/Annex 2-1-3
[18] Technical dossier/Section II/Annex 2-1-4
[19] Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls (OJ L 140, 30.5.2002, p.10)
[20] Technical dossier/Section II/Annex 2-1-8
[21] Technical dossier/Section II/Annex 2-1-9

For an additive intended as an anticaking agent, no homogeneity studies are considered necessary if the efficacy can be demonstrated (see Section 3.3).

3.1.5. Physico-chemical interactions in feed

An *in vitro* trial was performed[22] to study the effect of the additive on the analytical determination of different diet components. The additive was added at concentrations of 1.6% to mash and pelleted feeds for poultry, piglets and cattle for fattening. The feeds (control and treated with the additive) were then analysed for concentrations of basic nutrients of the diets,[23] macro and trace elements,[24] vitamins and amino acids[25], and of coccidiostats.[26] The results showed that the analytical recovery of the tested constituents was not affected by the additive. No physico-chemical incompatibilities with feed materials, other additives or medicinal substances in feed are therefore expected.

3.1.6. Conditions of use

The additive is intended to be used in premixtures and feedingstuffs for all animal species and categories, with no minimum and maximum content. The applicant suggested use levels in premixtures and feedingstuffs of 5,000 – 20,000 mg/kg.

3.2. Safety

3.2.1. Safety for the target species

Safety for weaned piglets

A total of 96 male piglets (Pietrain × (Large white × Landrace)) of about 26 days of age was fed pelleted diets supplemented with 0, 20,000 (1 × the highest recommended use level) or 100,000 (5×) mg MDMM/kg for 42 days.[27] Group size was eight replicates with four piglets each (initial body weight: 8.3 kg). The diets consisting mainly of barley, maize, biscuit meal and soybean meal were isonitrogenous (about 18% crude protein (CP)) and isocaloric (about 10 MJ net energy (NE)/kg, by an increase of animal fat with increasing content of the additive). The concentrations of the additive were analytically confirmed (by analysis of iron). Body weight (bw) and feed intake were recorded fortnightly. Feed-to-gain ratio was calculated for the different periods. At the end of the experiment, a blood sample was taken from two piglets per pen for haematology[28] and clinical chemistry.[29] The experiment was statistically considered as a randomised complete block design with the pen as experimental unit. The effects of the additive were evaluated by a set of linear contrasts. Group differences were analysed by Duncan's multiple range test.

No mortality occurred. Final body weight of the control was 30.7 kg and average daily weight gain was 511 g, both not being significantly different from the two MDMM treated groups. Feed-to-gain ratio of the control and of the groups receiving 20,000 and 100,000 mg MDMM/kg feed was 1.43, 1.44 and 1.46, respectively.

Among the blood biochemical parameters, differences between groups were seen for serum phosphorus, for AP, ALT and for β-globulins. They were not treatment related. Haematology did not show differences between the groups except the relative white blood cell

[22] Technical dossier/Section II/Annex 2-4-2
[23] Moisture, ash, crude cellulose, crude protein, crude fat, starch, total sugar, metabolisable energy
[24] Calcium, sodium, phosphorus, iron, zinc, copper, manganese, cobalt, iodine, selenium
[25] Vitamin A, vitamin E, vitamin D3, lysine, methionine, methionine hydroxy analogue
[26] Monensin sodium, narasin, salinomycin sodium, decoquinate, diclazuril, halofuginone, lasalocid a sodium, maduramycin ammonium alpha, nicarbazin, robenidine hydrochloride, semduramicin sodium.
[27] Supplementary Information July 2014/Annex_ii_2 A-D.
[28] Haemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), platelets, white blood cell count (WBC), white blood cell differentials (segmented neutrophils, banded neutrophils, lymphocytes, monocytes, eosinophils).
[29] Alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyltranspeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), albumins, globulins, total protein, glucose, urea, phosphate.

differentials, where minor and not treatment related differences were observed. In total, there was evidence that 100,000 mg MDMM/kg feed was tolerated by piglets.

Safety for chickens for fattening

A total of 960 one-day-old male chickens (Ross 308) was fed pelleted diets supplemented with 0, 20,000 (1 × the highest recommended use level), 50,000 (2.5 ×) or 100,000 (5 ×) mg MDMM/kg for 35 days.[30] Group size was 6 replicates with 40 birds each. The diets (starter, from day 0 to day 21; grower, from day 22 to day 35) consisting mainly of maize and soybean meal, were isonitrogenous (starter: about 21.5% CP; grower: about 19.5% CP) and isocaloric (starter: about 12.3 MJ ME/kg; grower: about 12.8 MJ/kg, by an increase of full fat extruded soybeans with increasing content of the additive). The concentration of the additive was analytically confirmed (by analysis of iron). The diets contained 0.05% of a coccidiostat (monensin sodium); the starter diet included also 0.5% titanium oxide, used as an inert marker for the digestibility measurements. Body weight and feed intake were recorded at day 21 and at day 35. Feed-to-gain ratio was calculated for the different periods. At the end of the experiment, a blood sample was taken from one chicken per pen for haematology[31] and clinical chemistry.[32] On days 18 to 21, excreta samples were collected for the determination of nitrogen and uric acid, vitamin E (tocopherol acetate, alpha tocopherol and total tocopherols), riboflavin, pyridoxine, zinc and monensin, and the digestibility was calculated for the groups receiving 0 and 20,000 mg MDMM/kg feed. The experiment was statistically considered as a randomised complete block design with the pen as experimental unit. The effects of the additive were evaluated by a set of linear contrasts. Group differences were analysed by Duncan's multiple range test.

Overall mortality was low but it increased from 1.2% in the control to 4.0% in the 100,000 mg MDMM/kg group. A linear trend was not significant ($p = 0.052$). The mean final body weight of the control was 2.64 kg, average daily feed intake 109 g. The significant differences observed within the final body weight, average daily gain refer to lower values for the high dose group compared to the mid dose group, but not to the control group. Feed intake was significantly higher in the mid dose group compared to the control group. With increasing amount of MDMM, feed-to-gain ratio increased too. The control group (1.44) was significantly better than all treated groups, the low and mid dose groups (1.46 and 1.48, respectively) were not different, the highest value (1.51) was calculated for the highest level group, and was significantly different from all the other groups.

The only haematological parameter which appeared to be affected by MDMM was the increased number of leucocytes and basophils, both showing a significant trend. However, these differences reached significance only in the highest group (26.2×10^3/µL vs. 19.3×10^3/µL for leucocytes, 2491 vs. 684 for basophils). No safe level of MDMM for chickens for fattening could be identified since feed-to-gain ratio was higher in all treated groups compared to control.

The excretion of nitrogen, tocopherol acetate, alpha tocopherol and total tocopherols, riboflavin, pyridoxine, zinc was not significantly affected by the additive in concentration of 20,000 mg MDMM/kg. Monensin sodium showed a small but significant reduction in digestibility (95% vs 94%).

Safety for dairy cows

A total of 60 Holstein multiparous cows (initial average days in milk: 178 days) was fed total mixed ration (TMR) mainly composed of alfalfa hay, sorghum silage and concentrate supplemented with 0, 20,000 (1 × the highest recommended use level), 50,000 (2.5 ×) or 100,000 (5 ×) mg MDMM/kg for 58 days.[33] Group size was 15 cows fed together in one pen. The diets were calculated to be isonitrogenous (about 15.5% CP) and isocaloric (about 6.7 MJ net energy for lactation (NEL)/kg), the increasing content of the additive was compensated by an increase of soybean meal and maize grain. It is noted that the incorporation 10% MDMM in an isonitrogenous and isocaloric diet involved many changes in the diet composition that the comparability of this diet with the three others is

[30] Supplementary Information July 2015/Annex_ii_1_A-D

[31] Haemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), platelets, white blood cell count (WBC), white blood cell differentials (segmented neutrophils, banded neutrophils, lymphocytes, monocytes, eosinophils).

[32] Alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyltranspeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), albumins, globulins, total protein, glucose, uric acid, phosphate.

[33] Supplementary Information July 2015/Annex_i_1_A-D

questionable. The concentration of the additive was analytically confirmed (by analysis of iron). Group feed intake and individual milk production were recorded daily. Milk composition (fat and protein) were analysed at day 20 and 56. At the end of the experiment, a blood sample was taken from seven animals per treatment for haematology[34] and clinical chemistry.[35] All data, with the exception of group feed intake, were analysed with a mixed model considering the data from the different periods and the effect of the animal, with the animal as experimental unit.

No significant difference in milk yield between the control and the 20,000 and 50,000 mg MDMM/kg feed group was observed, but there was a significant reduction ($p < 0.05$) in the group given the highest dose (control: 30.8 kg; 100,000 mg MDMM/kg feed group: 29.4 kg). Although the group determination of feed intake did not allow a statistical analysis, the reduction in milk yield appeared to be associated with a reduction in the dry matter (DM) intake (control: 23.4 kg DM/day; 100,000 mg MDMM/kg feed group: 22.3 kg DM/day). In general, milk fat (control: 4.03%) and protein (control: 3.50%) were not influenced by the treatment, although there were some significant group differences.

No differences were found among haematological parameters. Blood electrolytes showed some significant differences. Significant differences in blood magnesium are limited to differences between the control value and the mid dose group (2.6 and 2.78 mg/100 mL, respectively); as well as the significant differences observed in sodium and chloride, they are not considered treatment related. Blood urea concentration was nearly the same in the control and in the low-dose groups (26.0 and 26.7 mg/100 mL, respectively). Similar values were found for the mid- and the high-dose groups (23.5 and 23.1 mg/100 mL). The differences between the two pairs of groups are considered to be diet related and not treatment related. Blood creatinine increased with MDMM addition in a dose-dependent manner. The absence of difference in any of the other parameters of clinical biochemistry would suggest that the changes in the creatinine level observed are not related to tissue damage.

Significant decrease in milk yield in the high-dose group compared to the control group, and the low- and mid-dose groups is considered adverse. The evident differences in the rations formulation between control and low-dose groups on one side, and the mid- and high-dose group on the other make it difficult to conclude on the safety of 50,000 mg MDMM/kg feed. Therefore, only an MDMM concentration of 20,000 mg/kg complete feed for dairy cows is considered safe.

Interactions *in vivo*

The excretion of nitrogen, tocopherol acetate, alpha tocopherol and total tocopherols, riboflavin, pyridoxine, zinc was not significantly affected by the additive in concentration of 20,000 mg MDMM/kg in diets for chickens for fattening. It is expected that the additive, up to a concentration of 50,000 mg/kg complete feed, will not interfere with the nutrient/micronutrients supply of animals.

Conclusions on the safety for target species

All three studies had deficiencies in their design. The chicken and the piglet study did not include data on plasma electrolytes, although an interaction with the mineral clay might be anticipated. In the study on dairy cows, feed intake could not be replicated and the efforts to formulate isocaloric diets resulted in substantially different diets. Therefore, only limited conclusions on the safety of the additive could be drawn from these studies.

MDMM in chickens for fattening up to 20,000 mg/kg feed did not influence the absorption of nutrients/micronutrients.

The proposed supplementation level of MDMM (20,000 mg MDMM/kg complete feed) is considered safe dairy cows and for piglets (weaned). This conclusion is extended to pigs for fattening. No conclusion can be drawn on the safety for poultry or any other species/categories.

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

[35] Alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyltranspeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), calcium, phosphorous, magnesium, potassium, chlorine, cholesterol, lactate, albumins, total protein, urea, creatinine and non-esterified fatty acids.

3.2.2. Safety for the consumer

The FEEDAP Panel considers it unlikely that dolomite, magnesite, talc and chlorite, in common with other clays, will be degraded during their 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 as a consequence of the use of the additive.

The applicant has provided some reports of toxicological studies performed with the additive.

The additive was tested for mutagenicity in a bacterial reverse mutation test. The study was good laboratory practice (GLP) compliant and conformed to OECD Guideline 471.[36] It used concentrations of the additive of up to 5,000 µg/plate in two independent experiments, using strains TA1537, TA1535, TA98, TA100 and TA102 of *Salmonella* Typhimurium in the presence and absence of S9 from the livers of rats treated with Aroclor 1254. None of the strains showed any evidence of mutagenesis in either the presence or absence of metabolic activation. Positive control chemicals gave the expected results for each tester strain.

MDMM was tested in an *in vitro* chromosome aberration test in human lymphocytes. The study was GLP compliant and conformed to OECD Guideline 473 (version 1997).[37] Based on the results of a preliminary cytotoxicity test, 1,500 µg/mL was selected as the highest concentration to be tested, both in the presence and in the absence metabolic activation (S9 mix from liver of rats treated with Aroclor 1254). Fluidol did not induce any statistically significant increase in the number of cells with chromosome aberrations, polyploidy or endoreduplication, in any experimental condition at treatment levels causing evident cytotoxicity (52% reduction of mitotic index at 1,000 µg/mL without S9 mix; 54% at 1,300 µg/mL with S9 mix). Positive control chemicals produced the expected results.

The micronucleus test was GLP compliant and conformed to OECD Guideline 474.[38] Five male and five female Swiss albino mice were used per experimental groups. Animals were treated orally (by gavage) with the limit dose of 2,000 mg/kg body weight using two treatments separated by 24 h. Toxicity to bone marrow (as indicated by the polychromatic to total erythrocytes ratio) was not seen in the group treated with the additive, therefore, there was no evidence of target exposure. There was no increase in the number of micronucleated polychromatic erythrocytes seen in the bone marrow of the additive-treated group. The positive control group responded as expected.

Conclusions on safety for the consumer

The additive is not genotoxic. As the additive is essentially not absorbed from the gut lumen, the FEEDAP Panel considers that use of MDMM in animal nutrition is safe for consumers of food products from animals fed diets containing the additive.

3.2.3. Safety for the user

Effects on the respiratory system

The additive has a high dusting potential (10 g/m^3) and contains a high proportion of fine particles (85% ≤ 50 µm diameter; 45% ≤ 10 µm). Therefore, there is a potential for all parts of the respiratory tract of workers to be exposed by inhalation of dust generated as a result of handling of the additive.

An acute inhalation toxicity study was performed with the additive using groups of three male and three female Wistar rats exposed to 0 or 4.2 mg additive/L air for 4 h followed by a recovery period of 14 days, using a protocol that conformed to OECD Guideline 403.[39] No adverse effects on signs of toxicity, body weight or gross pathology were found. Therefore, the additive is considered to be of low toxicity by the inhalation route.

[36] Technical dossier/Section III/Annex 3-2-2
[37] Technical dossier/Section III/Annex 3-2-3
[38] Technical dossier/Section III/Annex 3-2-4
[39] Technical dossier/Section III/Annex 3-3-1

Effects on eyes and skin

An acute dermal toxicity study conforming to OECD Guideline 402 was performed on the additive using groups of 10 male and 10 female Wistar rats.[40] No mortality was observed. No adverse effects on signs of toxicity, body weight or gross pathology were found. Therefore, the additive is considered to be of low toxicity by the dermal route.

Acute dermal irritation and eye irritation studies with MDMM were performed in New Zealand White rabbits conforming to OECD Test Guideline 404 and 405.[41,42] Both the studies were GLP compliant. In the dermal study, slight erythema and very slight oedema were seen in all animals at 24 and 48 h but all application sites were normal at 72 h. The control application sites remained normal throughout the study. The only reaction in treated eyes was a slight transient redness. All eyes appeared normal at 72-h postdosing. The results of these tests indicate that the additive does not require labelling as a skin or an eye irritant.

Skin sensitisation was investigated in male Hartley strain guinea-pigs using a Magnusson and Kligman test that conformed to OECD Test Guideline 406.[43] The study was GLP compliant. There were no signs of toxicity in any animals and body weight was unaffected by treatment. No skin reactions were seen in any of the animals at 24 or 48 h after patch removal. Thus the study results indicated that Fluidol is not a skin sensitiser.

Conclusions on safety for the user

The additive is not an irritant to the skin or the eyes, it is not a dermal sensitiser and it is of low toxicity by the inhalation route.

3.2.4. Safety for the environment

The components of the additive (dolomite, magnesite, talc and chlorite) are ubiquitous in the environment, being natural components of soil. Therefore, it is not expected that its use as a feed additive would adversely affect the environment.

3.3. Efficacy

The efficacy of the additive as anticaking agent was tested in five subsamples each of a laying hen[44] and a cattle[45] pelleted feed (pellet dimensions 3 × 8 and 4 × 23 mm, respectively) and a crumbled pig[46] feed. After mixing the feeds with the additive at concentrations of 0, 5,000, 10,000 and 20,000 mg/kg, samples of 500 g each were loaded in a standard cone with an orifice of 18 mm (laying hens and pig feed) or 43 mm (cattle feed) and left to fall from a standard height of 80 mm (laying hens and cattle feed) and 95 mm (pig feed). Below the cone the sample formed a small pile, forming an angle of response α, calculated as a quotient of the height (h) and the diameter (D) of the pile ($\tan \alpha = h/0.5D$). The measure of the angle gives the tendency of the material to be cohesive or free-flowing, with lower values (25–30°) for very flowing materials and higher values (> 66°) for cohesive materials (Carr, 1965). The speed of flow through the cone (S) gives an indication of the flowability; the data were statistically analysed using Student's t-test to compare the series.

In the three feedingstuffs tested, the addition of 0, 5,000, 10,000 and 20,000 mg MDMM/kg improved the flowability of feed (Table 4) as indicated by lower values for the angle of response α and the reduced flow time (speed S).

[40] Technical dossier/Section III/Annex 3-3-3
[41] Technical dossier/Section III/Annex 3-3-4
[42] Technical dossier/Section III/Annex 3-3-2
[43] Technical dossier/Section III/Annex 3-3-5
[44] Technical dossier/Section IV/Annex 4-1-A and Annex 4-1-B
[45] Technical dossier/Section IV/Annex 4-3-A and Annex 4-3-B
[46] Technical dossier/Section IV/Annex 4-2-A and Annex 4-2-B

Table 4: Efficacy of the additive as an anticaking agent in feedingstuffs for laying hens, cattle and pigs.

Feedingstuffs	Inclusion level (mg/kg)			
	0	5,000	10,000	20,000
Laying hens				
Angle of response α (°)	41.6	41.3*	39.2**	37.2**
Speed of flow *S* (s)	11.2	10.8*	10.4**	9.9**
Cattle				
Angle of response α (°)	31.6	30.3*	29.9*	29.2**
Speed of flow *S* (s)	14.3	13.3*	13.4*	12.5**
Pigs				
Angle of response α (°)	42.6	41.9*	41.3**	40.4**
Speed of flow *S* (s)	22.9	22.2**	21.9**	21.7**

*,** Means within a row with stars are significantly different from the control (*p ≤ 0.05; **p ≤ 0.01)

In the three feedingstuffs tested, the addition of 5,000, 10,000 and 20,000 mg/kg of the additive improved the flowability of feed as indicated by lower values for the angle of response α and the reduced flow time (speed *S*).

4. Conclusions

The additive is safe in complete feed for dairy cows, piglets and pigs for fattening at a maximum concentration of 20,000 mg/kg. No conclusions can be drawn for all the other animal species/categories.

The additive is not genotoxic. As the additive is essentially not absorbed from the gut lumen. The FEEDAP Panel considers that use of MDMM in animal nutrition is safe for consumers of food products from animals fed diets containing the additive.

The additive is not an irritant to the eyes and the skin, it is not a skin sensitiser and it is of low toxicity by the inhalation route.

The components of the additive (dolomite, magnesite, talc and chlorite) are natural constituents of soil. Consequently, the use of the additive in animal nutrition will not pose a risk to the environment.

The additive is effective as an anticaking agent at a minimum inclusion level of 5,000 mg/kg feed.

5. Remark

The FEEDAP Panel notes that the iron content of the product (average 5.7% and ranges between 5.5% and 5.9%) would limit its use in compound feedingstuffs for which a maximum content for iron is set by the EU legislation.[47]

Documentation provided to EFSA

1. Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species. November 2012. Submitted by IMI FABI S.p.A.

2. Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species. Supplementary information. July 2014. Submitted by IMI FABI S.p.A.

3. Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species. Supplementary information. July 2015. Submitted by IMI FABI S.p.A.

4. Evaluation report of the European Union Reference Laboratory for Feed Additives on the

[47] Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11)

Methods(s) of Analysis for natural mixture of dolomite plus magnesite and magnesium-phyllosilicates.

5. Comments from Member States.

References

Carr RL, 1965. Evaluating flow properties of solids. Chemical Engineering, 72, 163-168.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. doi:10.2903/j.efsa.2011.2175

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for technological additives. EFSA Journal 2012;10(1):2528, 23 pp. doi:10.2903/j.efsa.2012.2528

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance for establishing the safety of additives for the consumer. EFSA Journal 2012;10(1):2537, 12 pp. doi:10.2903/j.efsa.2012.2537

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. doi:10.2903/j.efsa.2012.2539

Abbreviations

AAS	atomic absorption spectrophotometry
ADFI	average daily feed intake
ADG	average daily gain
ADI	average daily intake
BW	body weight
CAS	Chemical Abstracts Service
CP	Crude Protein
CV	Coefficient of variation
DM	Dry matter
EC	European Commission
EFSA	European Food Safety Authority
EURL	European Union Reference Laboratory
EINECS	European Inventory of Existing Commercial Chemical Substances
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
GLP	Good laboratory practice
HACCP	hazard analysis and critical control points
ICDD	International Center for Diffraction Data
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
ME	Metabolisable energy
MDMM	Natural mixture of dolomite, magnesite, and magnesium-phyllosilicates (talc and chlorite)
NE	Net energy
OECD	Organisation for Economic Co-operation and Development
PCBs	Polychlorinated biphenyl
PCDD/F	Polychlorinated dibenzodioxins/dibenzofurans
TEQ	Toxic equivalent
WHO	World Health Organisation
XRD	X-ray diffraction

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for mixture of dolomite plus magnesite and magnesium-phyllosilicates

In the current application, authorisation is sought under article 4(1) *Fluidol,* natural mixture of *dolomite* plus *magnesite* and *magnesium-phyllosilicates* (later referred as *DMM),* under the category/functional group and 1(i) 'technological additives'/'binders' and 'anticaking agents' according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species. *DMM* is an odourless grey powder obtained by crushing and milling natural rocks. The *feed additive* consists mainly of *dolomite, magnesite* and *magnesium-phyllosilicates* and other minerals such as hydrated silicates. According to the Applicant, the *feed additive* contains a minimum of 40% of *dolomite* and *magnesite.* The *feed additive* is intended to be used in *premixtures* and *feedingstuffs.* The Applicant did not specify any maximum or minimum concentration of *DMM* in *feedingstuffs* but recommends a dosage of 0.5–2% for all animal species.

For the determination of mineralogical composition of the *feed additive* the Applicant submitted experimental data obtained using X-ray diffraction (XRD) method. Furthermore, the chemical composition of the *feed additive* was characterised by the Applicant using atomic absorption spectrophotometry (AAS). Based on the experimental evidence provided, the EURL recommends for official control the two methods (XRD and AAS) for the characterisation of *Fluidol.*

As the quantification of *DMM* in *premixtures* and *feedingstuffs* is not achievable experimentally, the EURL cannot recommend any method for official control in these matrices.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.