

ADOPTED: 25 January 2017

doi: 10.2903/j.efsa.2017.4711

Safety of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) for all animal species

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Abstract

The additive under assessment consists of a natural mixture, mainly composed of dolomite (~ 30%), magnesite (~ 20%) and magnesium-phyllsilicates (talc (~ 35%) and chlorite (~ 15%)). In 2016, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an opinion on the safety and efficacy of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates. The FEEDAP Panel concluded that the additive is safe in complete feed for dairy cows, piglets and pigs for fattening at a maximum concentration of 20,000 mg/kg. However, no conclusions could be drawn for all other animal species/categories. Following this opinion, the European Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the safety for all animal species. The applicant answered with a new submission, an analysis of the previous EFSA opinion, but without new data. The FEEDAP Panel considered the arguments made by the applicant, in relation to the tolerance studies with dairy cows and chickens for fattening. No reason was identified to modify the conclusions reached in the previous opinion.

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Keywords: dolomite, magnesite, magnesium-phyllsilicates, technological additives, anticaking agents, safety, target species

Requestor: European Commission

Question number: EFSA-Q-2016-00459

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Acknowledgements: The Panel wishes to thank the members of the Working Group on Technological additives, including Anne-Katrine Lundebye, Carlo Nebbia and Derek Renshaw, for the preparatory work on this scientific opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Kolar B, Kouba M, López Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Lundebye A-K, Nebbia C, Renshaw D, Innocenti ML and Gropp J, 2017. Scientific opinion on the safety of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) for all animal species. *EFSA Journal* 2017;15(2):4711, 7 pp. doi:10.2903/j.efsa.2017.4711

ISSN: 1831-4732

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, IMI FABI S.p.A., is seeking a Community authorisation of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol), when used as a feed additive for all animal species (category: technological additives; functional group: anticaking agents). (Table 1)

Table 1: Description of the substances

Category of additive	Technological additives
Functional group of additive	Anticaking agents
Description	mixture of dolomite plus magnesite and magnesium-phyllsilicates
Target animal category	All animal species
Applicant	IMI FABI S.p.A.
Type of request	New opinion

On 01 December 2015, the Panel on Additives and Products or Substances used in Animal Feed on the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, concluded that 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 other animal species/categories.

Following the discussion at the Standing Committee on Plants, Animals, Food and Feed, Section-Animal Nutrition, on 24 June 2016, the Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the safety and to allow a revision of Authority's opinion.

On 08 July 2016, the Commission has received new data from the applicant.

In view of the above, the Commission asks the Authority to deliver a new opinion for the natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol), when used as a feed additive for all animal species based on the additional data submitted by the applicant.

1.2. Additional information

The FEEDAP Panel, in 2016, delivered an Opinion on the safety and efficacy of a natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) as a feed additive for all animal species (EFSA FEEDAP Panel, 2016).

2. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information² following a previous application on the same product.³

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) is in line with the principles laid down in Regulation (EC) No 429/2008 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, 2011a), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008a), Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA, 2008b), Guidance 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 Dossier reference: FAD-2016-0042.

³ Dossier reference: FAD-2012-0043.

preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b), and Guidance on the assessment of additives intended to be used in pets and other non food-producing animals (EFSA FEEDAP Panel, 2011b).

3. Assessment

The product under assessment is a natural mixture mainly composed of dolomite (~ 30%), magnesite (~ 20%) and magnesium-phyllsilicates (talc (~ 35%) and chlorite (~ 15%)), subsequently referred to as MDMM.

The additive is intended to be used as a technological additive (functional group: (i) anticaking agents) 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.

The applicant did not submit any new data, only an analysis of the previous EFSA opinion. The FEEDAP Panel gives some comments to this analysis.

3.1. Safety

In its previous opinion (EFSA FEEDAP Panel, 2016), the FEEDAP Panel assessed three tolerance studies (one with piglets, one with chickens for fattening and one with dairy cows), and concluded that 'the proposed supplementation level of MDMM (20,000 mg MDMM/kg complete feed) is considered safe for 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'.

The applicant provided a different interpretation of the results of two tolerance studies (one with dairy cows and one with chickens for fattening) assessed in the previous opinion (EFSA FEEDAP Panel, 2016) allowing, in his view, the potential authorisation of the additive for all animal species. The following arguments were raised by the applicant:

Study with dairy cows

- The absence of replicates for feed intake (owing the difficulties to register individual feed intake with cows) does not impair the validity of the study, since for tolerance the primary outcome should be milk production.
- Diets should be considered equivalent only if they are isocaloric and isonitrogenous, without considerations to the type and the amount of the ingredients included in the formulation. The diets are also considered equivalent if the outcome is an equal ratio dry matter (DM) intake/milk yield (kg/day), without consideration to the absolute milk yield.
- Dairy and meat-producing ruminants share the same digestive system, have the same physiology, and the feed formulation for meat-producing animals is not too far from the one for dairy animals. Therefore, any conclusion drawn for dairy cows can be applied to other ruminants (i.e. cattle for fattening).

Chickens for fattening

- Although the differences in feed-to-gain ratio are significantly different, they are minimal, and are to be attributed to unbalanced diet formulation.

3.1.1. Safety for the target species

3.1.1.1. Safety for cows

In the cow study, all animals of one treatment group were taken together in one pen; individual feed intake data could not be recorded. This deficiency reduces the precision of the study; the potential relation of individual performance data with feed intake could not be examined. The techniques to measure individual feed intake for penned animals are readily available, and not 'difficult' as considered by the applicant.

When diets are formulated for a tolerance test, the test item, and its quantity should be the only variable in the feed to be given. Only under this condition, all effects observed in the study can be doubtlessly traced back to the variable, the test item. This principle is somewhat difficult to follow, when additives occupy a considerable part of the diet (e.g. 5% or 10%). Calculations for isocaloric diets remain calculations; standard (tabulated) figures, which must be used for these calculations, may not be consistent under more extreme dietary conditions, interactions between nutrients, which cannot

be predicted in its magnitude, may lead to different values. Anyway, the inclusion of 2%, 5% and 10% of a calorie-free test item requires large changes in diet composition by feed materials. But these changes should be 'linear', showing the application of the same logic when adding increasing amounts of the test item and reducing the number of feed materials with a varying feed concentration. After reconsideration of the data, the Panel confirms its previous conclusion that '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'.

However, the applicant concluded based on essentially equal amounts of milk produced per kilogram of feed 'that the formulations, whatever the group, are identical'. In fact, feed intake and milk yield were lower (the latter significantly) in the high-dose group (30.8 vs 29.4 kg milk, $p < 0.05$); therefore, this level (10%) could not be considered as tolerated. The applicant's explanation that this effect would result from a reduced feed palatability is speculation.

The FEEDAP Panel considers that any extrapolation of results from one animal species or category carries a certain degree of uncertainty. This uncertainty is considered to be reduced by the requirement for a (wide) margin of safety of the safe use level of the test item. This margin of safety could not be derived from the cow study; consequently any extrapolation is not possible.

3.1.1.2. Safety for chicken for fattening

In its previous opinion, the FEEDAP Panel concluded that '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'.

With increasing amount of MDMM, feed-to-gain ratio increased related to the dose of the test item. The applicant proposed to use a system in which only certain levels of impairment would allow a conclusion on adverse effects. A scientific assessment uses generally for this decision statistical parameters; a significant difference is taken as a difference to be considered. Feed-to-gain ratio was significantly affected in a dose-dependent manner, with even the lowest dose (2% MDMM in the diet) showing a significant difference. In case of dose-related changes, the difference (even if small or not statistically significant) observed at the lowest dose is of concern.

The applicant also argued (in contrast to its considerations for the cow study) that an effect on feed-to gain ratio conversion could be 'very likely due to the high amount of fat we added in order to make the diets isocaloric'. In fact, high amounts of fat (necessary for isocaloric diets with high ash content) may not be fully utilised by the animal (e.g. because of soap formation in the intestine, which are excreted as such, and the fatty acids contained escape absorption). These findings support the requirement for tolerance studies to keep dietary changes as small as possible.

4. Conclusions

The FEEDAP Panel does not see any reason to modify its former position and reiterates its previous conclusion: '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'.

Documentation provided to EFSA

- 1) Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) for all animal species. July 2016. Submitted by IMI FABI S.p.A.

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Abbreviations

DM	dry matter
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
MDMM	Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates