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

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Guido Rychen, Gabriele Aquilina, Giovanna Azimonti, Vasilieios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Boris Kolar, Maryline Koub, Marta López-Alonso, Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace, Pieter Wester, Anne-Katrine Lundebye, Carlo Nebbia, Derek Renshaw, Matteo Lorenzo Innocenti and Jürgen Gropp

Abstract

The additive under assessment consists of a natural mixture, mainly composed of dolomite (~30%), magnesite (~20%) and magnesium-phyllosilicates (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-phyllosilicates. In this opinion, the Panel concluded that 20,000 mg additive/kg complete feed is considered safe for dairy cows and for piglets (weaned). This conclusion was extended to pigs for fattening while no conclusion could be drawn on the safety for poultry or any other 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 new tolerance studies submitted with cattle for fattening and chickens for fattening showed tolerance of these animal categories to the additive up to approximately fivefold the highest recommended use level. The FEEDAP Panel therefore concluded that 20,000 mg additive/kg complete feed is safe for cattle for fattening and chickens for fattening. The additive at the same dietary concentration was already considered safe in an earlier opinion for piglets and dairy cows. Since the additive at 20,000 mg/kg complete feed is considered safe for four animal categories (three major animal species) with a comparable margin of safety, the conclusion on safety is extrapolated to all animal species. At the safe dietary concentration the additive did not affect the digestibility of the feed (including feed additives).

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

Requestor: European Commission

Question number: EFSA-Q-2018-00010

Correspondence: feedap@efs.europa.eu
Panel members: Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

Acknowledgements: The Panel wishes to thank EFSA staff member(s): Montserrat Anguita, Jaume Galobart, Orsóly Holczknecht and Lucilla Gregoretti for the support provided to this scientific output.

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-Alonso M, López Puente S, 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, 2018. Scientific Opinion on the safety of natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species. EFSA Journal 2018;16(5):5272, 7 pp. https://doi.org/10.2903/j.efsa.2018.5272

ISSN: 1831-4732

© 2018 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Table of contents

Abstract .................................................................................................................................................... 1
1. Introduction ..................................................................................................................................... 4
1.1. Background and Terms of Reference as provided by the requestor ....................................................... 4
1.2. Additional information ....................................................................................................................... 4
1.3. Interpretation of the terms of reference ............................................................................................. 4
2. Data and methodologies ................................................................................................................... 5
2.1. Data ................................................................................................................................................ 5
2.2. Methodologies .................................................................................................................................. 5
3. Assessment ...................................................................................................................................... 5
3.1. Safety ............................................................................................................................................. 5
3.1.1. Safety for the target species ............................................................................................................. 5
3.1.2. Safety for chickens for fattening ........................................................................................................ 6
3.1.3. Interaction with nutrients and feed additives ...................................................................................... 6
4. Conclusions ...................................................................................................................................... 7
Documentation provided to EFSA ............................................................................................................... 7
References ................................................................................................................................................ 7
Abbreviations ............................................................................................................................................ 7
1. Introduction

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

Regulation (EC) No 1831/2003\(^1\) 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-phyllosilicates (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-phyllosilicates |
| Target animal category | All animal species |
| Applicant | IMI FABI S.p.A. |
| Type of request | New opinion |

On 25 January 2017, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority (“Authority”), in its opinion on the safety of the product, concluded that no reason was identified to modify the conclusions reached in the previous opinion.

Following the discussion at the Standing Committee on Plants, Animals, Food and Feed, Section-Animal Nutrition, on 24 April 2017, 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 1 September 2017, 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-phyllosilicates (Fluidol), when used as a feed additive for all animal species based on the additional data submitted by the applicant.

1.2. Additional information

In 2016, the FEEDAP Panel delivered an opinion on the safety and efficacy of a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) as a feed additive for all animal species (EFSA FEEDAP Panel, 2016). In this opinion, the Panel concluded that the additive is safe for the consumer, the user and the environment. The additive was also considered effective as an anticaking agent at a minimum inclusion level of 5,000 mg/kg feed. However, regarding the safety for the target animals, the Panel 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) and pigs for fattening but no conclusion could be drawn on the safety for poultry or any other species/categories.

In 2017, the FEEDAP Panel was requested to assess additional information submitted by the applicant. In its opinion (EFSA FEEDAP Panel, 2017), the Panel analysed a different interpretation given by the applicant of the results of the tolerance studies with dairy cows and chickens for fattening assessed in the previous opinion (EFSA FEEDAP Panel, 2016). In the absence of any new data, the Panel concluded that ‘no reason was identified to modify the conclusions reached in the previous opinion’.

1.3. Interpretation of the terms of reference

In the view of the above, the current opinion will focus on the assessment of the safety of the additive for the target species.

---

\(^1\) 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. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information following two previous applications on the same product.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (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, 2012) and the Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

3. Assessment

The product under assessment is a natural mixture mainly composed of dolomite (~30%), magnesite (~20%) and magnesium-phyllosilicates (talc (~35%) and chlorite (~15%)), subsequently referred to as MDMM. It was described and properly characterised in a previous opinion (EFSA FEEDAP Panel, 2016).

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 proposed use levels in premixtures and feedingstuffs of 5,000–20,000 mg/kg.

The FEEDAP Panel delivered two opinions on the additive under assessment (EFSA FEEDAP Panel, 2016, 2017). In the current application, the applicant submitted two new tolerance studies, one in cattle for fattening and one in chickens for fattening.

3.1. Safety for the target species

In its previous opinion (EFSA FEEDAP Panel, 2016), the Panel concluded that the additive is safe for dairy cows at a concentration of 20,000 mg/kg complete feed, however, a margin of safety could not be identified. Consequently, this conclusion could not be extrapolated to other ruminants. In the same opinion, the safety for chickens for fattening could not be shown, because the data indicated a worsening effect on feed to gain ration in all the treated groups. In order to complete the assessment of the safety for all animal species, the applicant submitted two new tolerance studies, one in cattle for fattening and one in chickens for fattening.

3.1.1. Safety for cattle for fattening

A total of 63 Holstein bulls (average age: 146 days; average body weight: 201 kg) was fed mash concentrates supplemented with 0, 20,000 (1× highest proposed use level), 50,000 (2.5×) or 100,000 (5×) mg MDMM/kg and straw for 49 days. The concentrate and straw were offered ad libitum. Group size was four replicates with four bulls each (except one with three bulls in the 1× group). The concentrates were isonitrogenous (about 15.8% CP) and isocaloric (about 8.5 MJ NE/kg), achieved by an increase of corn gluten feed, beet pulp and palm oil with increasing content of the additive. It is noted that the incorporation of 100,000 mg MDMM/kg in an isonitrogenous and isocaloric diet involved many changes in the diet composition that makes the comparability of this diet with the three others questionable. The concentration of the additive was analytically confirmed (by analysis of iron as the marker). Individual body weight and pen feed intake (including straw consumption) were recorded at day 0, 14, 28, 42 and 49. Feed to gain ratio was calculated for the different periods. At start and end of the experiment, blood samples were obtained from the same eight animals per treatment (two pens per...
treatment) and analysed for haematology\(^5\) and clinical chemistry.\(^6\) Data on feed consumption, growth and feed efficiency were analysed using a linear mixed-effects model with repeated measurements. The model accounted for the fixed effects of treatment, time and the interaction between these two factors; pen was considered a random effect. Initial body weight was used as a covariate. Data on blood parameters of days 0 and 49 were analysed using a linear model with the fixed effects of treatment.

No mortality occurred in the trial. Mean final body weight was 290 kg without differences between the groups. No adverse effects of the additive on the intake of concentrate and total feed dry matter (DM), on the total feed DM to gain ratio were observed (control group: concentrate intake 6.16 kg/day, total DM intake 6.64 kg/day, total DM to gain ratio 3.60). No differences were seen in the haematological and clinical biochemistry parameters among the groups, with the exception of glucose (lower in the control group compared to the 1× and the 2.5×, but not the 5× groups) and total protein (higher in the control group compared to the 1× and the 5×, but not the 2.5× groups).

The results show that complementary feed for cattle for fattening containing up to 100,000 mg MDMM/kg, corresponding to approximately 93,000 mg MDMM kg complete feed\(^7\) can be formulated and fed without causing adverse effects to the cattle.

### 3.1.2. Safety for chickens for fattening

A study in chickens was provided,\(^8\) in which a total of 32 one-day birds was distributed to 16 cages (2 birds per cage) and the same starter diets as described in the tolerance study for the control group and the group receiving 20,000 mg MDMM/kg (representing 8 replicates per treatment).

Overall mortality was low (0 birds in the 1× group, 3 birds each in groups 0 and 5× and 5 animals in the 2.5× group). No differences were observed on the performance parameters among the groups (control group: final body weight 2.29 kg, average daily feed intake 94 g and feed to gain ratio 1.46).

The only haematological parameters which were affected by MDMM, but not in a dose-dependent manner, were haematocrit (higher in the 5× group compared to the 1× group) and haemoglobin (higher in the 2.5× group compared to the control group). No differences were observed in any of the clinical biochemistry parameters.

The results show that complete feed for chickens for fattening containing up to 100,000 mg MDMM/kg can be formulated and fed without causing adverse effects to chickens for fattening.

### 3.1.3. Interaction with nutrients and feed additives

A study in chickens was provided,\(^8\) in which a total of 32 one-day birds was distributed to 16 cages (2 birds per cage) and fed the same starter diets as described in the tolerance study for the control group and the group receiving 20,000 mg MDMM/kg feed (representing 8 replicates per treatment).
Titanium dioxide (0.5%) was used as an inert marker for the digestibility/adsorption measurements. Excreta were collected from days 18 to 21. Nitrogen, uric acid, vitamin E (alpha-tocopherol and alpha-tocopherol acetate), riboflavin, pyridoxine, zinc and monensin (and titanium) were analysed and the digestibility/absorption calculated. The data were evaluated by a one-way ANOVA.

None of the end-points selected for assessing the potential influence of the additive on the digestibility/absorption of nutrients and feed additives (faecal nitrogen, alpha tocopherol and alpha-tocopherol acetate, riboflavin, pyridoxine, zinc and monensin) indicated an effect of the additive at the concentration of 20,000 mg/kg complete feed.

4. Conclusions

The tolerance studies with cattle for fattening and chickens for fattening showed tolerance of these animal species/categories to the additive MDMM up to approximately fivefold the highest recommended use level. The FEEDAP Panel therefore concludes that 20,000 mg MDMM/kg complete feed is safe for cattle for fattening and chickens for fattening. The Panel notes that MDMM at the same dietary concentration was already considered safe in an earlier opinion for piglets and dairy cows (EFSA FEEDAP Panel, 2016). Since MDMM at 20,000 mg/kg complete feed is considered safe for four animal categories and shows a comparable margin of safety in three major animal species, the conclusion on safety is extrapolated to all animal species.

At the safe dietary concentration, MDMM does not affect the digestibility of the feed components (including feed additives).

Documentation provided to EFSA

1) Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species. December 2017. Submitted by IMI FABI S.p.A.

References

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. https://doi.org/10.2903/j.efsa.2011.2175

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

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) as feed additive for all animal species. EFSA Journal 2016;14(1):4341, 16 pp. https://doi.org/10.2903/j.efsa.2016.4341

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017. Scientific opinion on the Safety of natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species. EFSA Journal 2017;15(2):4711, 7 pp. https://doi.org/10.2903/j.efsa.2017.4711

Abbreviations

ANOVA analysis of variance
CP crude protein
DM dry matter
FEEDAP Panel on Additives and Products or Substances used in Animal Feed
MDMM Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates