Safety and efficacy of natural mixtures of talc (steatite) and chlorite (E 560) as a feed additive for all animal species

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Abstract

The additive is a natural mixture of talc and chlorite (NTMC) that contains at least 75% of talc and chlorite as main components. The additive is intended for use as a technological additive (functional groups: (i) anticaking agents) in premixtures and feedingstuffs for all animal species at use levels of 1,000–50,000 mg/kg. No safe dietary level of NMTC could be identified for piglets, chickens for fattening and dairy cows. The use of NMTC in animal nutrition is considered not to pose a risk for the consumer of animal tissues and products from animals fed the additive. Talc could cause serious lung disease if repeatedly inhaled in large quantities over a long period. Talc is not irritant to skin and eyes. In the absence of data, no conclusion can be drawn on the skin sensitisation potential of the product. The components of the additive (talc, chlorite, dolomite and magnesite) 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. The additive NMTC is efficacious as an anticaking agent.

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Keywords: talc, chlorite, safety, efficacy, technological additives, anticaking agent, binder

Requestor: European Commission

Question number: EFSA-Q-2014-00634

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Acknowledgements: The Panel wishes to thank EFSA staff members: Montserrat Anguita, Rosella Brozzi and Jaume Galobart 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 Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Lundebeye A-K, Nebbia C, Renshaw D, Innocenti ML and Gropp J, 2018. Scientific Opinion on the safety and efficacy of natural mixtures of talc (steatite) and chlorite (E 560) as a feed additive for all animal species. EFSA Journal 2018;16(3):5205, 15 pp. https://doi.org/10.2903/j.efsa.2018.5205

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
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 natural mixtures of talc (steatite) and chlorite (E 560) as a feed additive for all animal species.

The additive is a natural mixture of talc and chlorite that contain at least 75% of talc and chlorite as main components. The additive is intended for use as a technological additive (functional groups: (i) anticaking agents) in premixtures and feedingstuffs for all animal species at use levels of 1,000–50,000 mg/kg.

From the results of three tolerance studies, no safe dietary level of the additive could be identified for piglets, chickens for fattening and dairy cows.

The additive is essentially not adsorbed from the gut lumen. Therefore, the use of the additive in animal nutrition is considered not to pose a risk for the consumer of animal tissues and products from animals fed the additive.

Talc could cause serious lung disease if repeatedly inhaled in large quantities over a long period. Talc is not irritant to skin and eyes. In the absence of data, no conclusion can be drawn on the skin sensitisation potential of the product.

The components of the additive (talc, chlorite, dolomite and magnesite) 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.

The additive is efficacious as an anticaking agent.
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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003 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 received a request from Eurotalc a.i.s.b.l. for authorisation of the product natural mixtures of talc (steatite) and chlorite (E 560) for all target 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 9 March 2015.

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 mixtures of talc (steatite) and chlorite (E 560), when used under the proposed conditions of use (see Section 3.1.6).

1.2. Additional information

The additive is a natural mixture of talc and chlorite. The additive under assessment consists of natural mixtures mainly composed of talc (steatite) and chlorite, subsequently referred to as NMTC.

The additive is currently authorised for use as a feed additive in feedingstuffs for all animal species with no minimum and maximum content by the Council Directive 70/524/EEC. NMTC as a feed additive is defined as ‘Natural mixtures of steatite and chlorite, free of asbestos: minimum purity of the mixtures 85%’.

Talc is authorised for use as a food additive under Regulation (EC) No 1333/2008, with a specification established by Regulation (EU) No 231/2012. It is specified as ‘Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite’. The product should be free of asbestos.

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 in support of the authorisation request for the use of natural mixtures of talc (steatite) and chlorite (E 560) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008 and the applicable EFSA guidance documents.

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, and other scientific reports to deliver the present output.

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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 EUROTALC. Scientific Association of European Talc Industry A.I.S.B.L. Rue des Deux Eglises 26, Box 2, B – 1000 Brussels, Belgium. Companies: Luzenac Europe, 2 places E.-Bouilleres BP 33662 31036 Toulouse Cedex 1 France; Imi Fabi S.p.A., Viale dei Mille, 68 20129 Milano Italy; Mondo Minerals B.V, P.O. Box 59416 1040 HK Amsterdam, The Netherlands.
3 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).
4 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. (OJ L 83, 22.3.2012, p. 1–295).
5 FEED dossier reference: FAD-2010-0096.
6 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.
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.7

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of natural mixtures of talc (steatite) and chlorite (E 560) is in line with the principles laid down in Regulation (EC) No 429/20086 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 additive under assessment consists of natural mixtures mainly composed of talc and chlorite, and is subsequently referred to as NMTC.

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

3.1.1. Characterisation of the additive

The product is obtained by mining from different quarries and it is produced by three manufacturers. The production process may slightly vary among the manufacturers, but it is always based on mechanical process only, with no chemicals used during the manufacturing; as a general scheme, mining is followed by crushing, grinding, drying and packaging.

The product is specified to contain at least 75% of talc and chlorite as main components. The other components are dolomite and magnesite. The characteristics of the main constituents are listed in Table 1.

Table 1: Main constituents of the additive as provided by the applicant

|             | Talc | Chlorite | Dolomite | Magnesite |
|-------------|------|----------|----------|-----------|
| CAS number  | 14807-96-6 | 1318-59-8 | 16389-88-1 | 546-93-0 |
| EINECS number | 238-877-9 | 215-285-9 | 240-440-2 | 208-915-9 |
| Chemical formula | Mg₃Si₄O₁₀(OH)₂ | (Mg, Fe, Al)₆(Si, Al)₄O₁₀(OH)₈ | (CaMg)(CO₃)₂ | MgCO₃ |

CAS: Chemical Abstracts Service; EINECS: European INventory of Existing Commercial chemical Substances.

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 three batches each from the three manufacturers)8 is summarised in Table 2. The elemental composition (nine batches total, three from each manufacturer)9 is given in Table 3.

Table 2: Mineralogical composition of nine batches (three from each manufacturer) of the product (X-ray diffraction). The values represent the minimum and the maximum showed in the three batches analysed per manufacturer.

|             | Talc (%) | Chlorite (%) | Dolomite (%) | Magnesite (%) |
|-------------|----------|--------------|--------------|---------------|
| Manufacturer a | 56.5-59.0 | 37.0-39.0 | 2.5 | – |
| Manufacturer b | 49.0-66.0 | 12.0-25.0 | 13.0 | 9.0-13.0 |
| Manufacturer c | 96.8-97.9 | 0.1 | 0.3-2.3 | 0.5-2.7 |

Manufacturer + chlorite |

95.5-96.5
74.0-79.0
96.9-98.0

7 The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/firnrep-fad-2010-0096-steatite.pdf
8 Technical dossier/Section II/Annex 2-1-3; 2-1-4; 2-1-5.
9 Technical dossier/Section II/Annex 2-1-6; 2-1-7; 2-1-8.
Three batches each of additive from each manufacturer were also analysed for asbestos and crystalline silica (quartz). Asbestos was absent in all the batches analysed; quartz concentration was 0.5–0.7% for manufacturer a, and below the respective limits of detection (0.5% and 0.1%, respectively) for manufacturers b and c.

The product is further characterised by pH values (10% solution) of 9.0–9.5. Loss of ignition (900°C) was evaluated in nine batches (three batches each form the three manufacturer) and varied from 5.7% to 8.8% for manufacturers a and c, and 16.6% to 18.6% for manufacturer b.

3.1.2. Purity

Nine batches of the product (three batches each from each manufacturer) showed concentrations of lead, cadmium, mercury and arsenic of ≤3.3 mg/kg, ≤0.15 mg/kg, ≤0.005 mg/kg and ≤1.8 mg/kg, respectively, which do not raise safety concerns.

Dioxins (polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/F) in nine batches (three batches each from each manufacturer) were ≤0.09 ng World Health Organization (WHO) PCDD/F-TEQ/kg, sum of dioxins and dioxins-like polychlorinated biphenyls (dl-PCBs) ≤0.1 ng WHO-PCDD/F-dl-PCB-TEQ/kg. These concentrations comply with the limits set in the Commission Directive 2002/32/EC and are considered of no concern.

3.1.3. Physical state of the product

The bulk density of the three products varies from 343 to 523 kg/m³, depending on the grinding process.

Particle size distribution, analysed by laser diffraction in nine batches of the additive (three batches each from each manufacturer), showed that 100% of particles (v/v) were ≤100 μm, 95–97% ≤50 μm and 25–44% ≤10 μm.

The additive showed a dusting potential (analysed by Stauber–Heubach method in three batches from only one manufacturer (a)) of about 4.5 g/m³.

3.1.4. Stability and homogeneity

Stability studies are not required for mineral-based products, which can be reasonably assumed to be stable. One of the manufacturers (b) analysed one batch of the additive, immediately after manufacturing and after 8 years of storage, for bulk density, moisture content, particle size distribution, XRD and loss on ignition. No differences were reported for any of the parameters considered.

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

3.1.5. Physicochemical interactions in feed

An in vitro trial was performed to study the effect of the additive on the analytical determination of different diet components. The additive was added at concentrations of 0%, 1%, 1.5% or 2% to feeds.

Table 3: Elemental composition of 11 batches (three from two manufacturers and five from the third one) of the product (expressed as oxide). The values represent the minimum and the maximum showed in the batches analysed.

| Manufacturer | SiO₂ (%) | MgO (%) | Al₂O₃ (%) | Fe₂O₃ (%) | CaO (%) |
|--------------|----------|---------|-----------|-----------|---------|
| a            | 49.0–49.6| 30.6–30.7| 7.1–7.3   | 1.4       | 1.3     |
| b            | 43.2–44.8| 28.7–29.3| 2.9–4.1   | 3.8–4.6   | 2.3–3.5 |
| c            | 60.7–62.8| 31.7–32.0| 0.02–0.2  | 0.1–0.2  | 0.1–0.7 |

Three batches each of additive from each manufacturer were also analysed for asbestos and crystalline silica (quartz). Asbestos was absent in all the batches analysed; quartz concentration was 0.5–0.7% for manufacturer a, and below the respective limits of detection (0.5% and 0.1%, respectively) for manufacturers b and c.

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Dioxins (polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/F) in nine batches (three batches each from each manufacturer) were ≤0.09 ng World Health Organization (WHO) PCDD/F-TEQ/kg, sum of dioxins and dioxins-like polychlorinated biphenyls (dl-PCBs) ≤0.1 ng WHO-PCDD/F-dl-PCB-TEQ/kg. These concentrations comply with the limits set in the Commission Directive 2002/32/EC and are considered of no concern.

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3.1.4. Stability and homogeneity

Stability studies are not required for mineral-based products, which can be reasonably assumed to be stable. One of the manufacturers (b) analysed one batch of the additive, immediately after manufacturing and after 8 years of storage, for bulk density, moisture content, particle size distribution, XRD and loss on ignition. No differences were reported for any of the parameters considered.

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

3.1.5. Physicochemical interactions in feed

An in vitro trial was performed to study the effect of the additive on the analytical determination of different diet components. The additive was added at concentrations of 0%, 1%, 1.5% or 2% to feeds.

Table 3: Elemental composition of 11 batches (three from two manufacturers and five from the third one) of the product (expressed as oxide). The values represent the minimum and the maximum showed in the batches analysed.

| Manufacturer | SiO₂ (%) | MgO (%) | Al₂O₃ (%) | Fe₂O₃ (%) | CaO (%) |
|--------------|----------|---------|-----------|-----------|---------|
| a            | 49.0–49.6| 30.6–30.7| 7.1–7.3   | 1.4       | 1.3     |
| b            | 43.2–44.8| 28.7–29.3| 2.9–4.1   | 3.8–4.6   | 2.3–3.5 |
| c            | 60.7–62.8| 31.7–32.0| 0.02–0.2  | 0.1–0.2  | 0.1–0.7 |

Three batches each of additive from each manufacturer were also analysed for asbestos and crystalline silica (quartz). Asbestos was absent in all the batches analysed; quartz concentration was 0.5–0.7% for manufacturer a, and below the respective limits of detection (0.5% and 0.1%, respectively) for manufacturers b and c.

The product is further characterised by pH values (10% solution) of 9.0–9.5. Loss of ignition (900°C) was evaluated in nine batches (three batches each form the three manufacturer) and varied from 5.7% to 8.8% for manufacturers a and c, and 16.6% to 18.6% for manufacturer b.

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Nine batches of the product (three batches each from each manufacturer) showed concentrations of lead, cadmium, mercury and arsenic of ≤3.3 mg/kg, ≤0.15 mg/kg, ≤0.005 mg/kg and ≤1.8 mg/kg, respectively, which do not raise safety concerns.

Dioxins (polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/F) in nine batches (three batches each from each manufacturer) were ≤0.09 ng World Health Organization (WHO) PCDD/F-TEQ/kg, sum of dioxins and dioxins-like polychlorinated biphenyls (dl-PCBs) ≤0.1 ng WHO-PCDD/F-dl-PCB-TEQ/kg. These concentrations comply with the limits set in the Commission Directive 2002/32/EC and are considered of no concern.

3.1.3. Physical state of the product

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The additive showed a dusting potential (analysed by Stauber–Heubach method in three batches from only one manufacturer (a)) of about 4.5 g/m³.

3.1.4. Stability and homogeneity

Stability studies are not required for mineral-based products, which can be reasonably assumed to be stable. One of the manufacturers (b) analysed one batch of the additive, immediately after manufacturing and after 8 years of storage, for bulk density, moisture content, particle size distribution, XRD and loss on ignition. No differences were reported for any of the parameters considered.

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

3.1.5. Physicochemical interactions in feed

An in vitro trial was performed to study the effect of the additive on the analytical determination of different diet components. The additive was added at concentrations of 0%, 1%, 1.5% or 2% to feeds.
for pigs and ruminants before pelleting. The feeds (control and treated with the additive) were then analysed for vitamins (A and E),\textsuperscript{19} veterinary drugs (oxytetracycline and sulfadimethoxine)\textsuperscript{20} and trace elements (Cu, Fe, Mn and Zn).\textsuperscript{21} The results showed variability between the feedingstuffs for pigs and ruminants. It appeared that the analytical recovery of veterinary drugs and trace elements was reduced in both feedingstuffs, particularly at the highest inclusion level of the additive, whereas that of vitamins was not affected.

The FEEDAP Panel notes that under the conditions of analysis performed (extraction of the soluble ash with 0.075 M HCl), (i) iron added by the additive was not found, and (ii) the extractability of trace elements originally contained in a feed by the HCl solution was reduced by the additive. This may indicate that the analysis of trace elements for official control purposes could be impaired when the feed is supplemented with the additive.

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 1,000–50,000 mg/kg, with an average of 20,000 mg/kg.

3.2. Safety

3.2.1. Absorption, distribution, metabolism and excretion

No absorption, distribution, metabolism and excretion (ADME) studies with the additive were made available. However, the WHO International Agency for Research on Cancer (IARC) reported in its monograph on talc (WHO, 1987a) that ‘In studies in rats, mice, guinea-pigs and hamsters using radioactive tracer techniques, no intestinal absorption or translocation of ingested talc to the liver and kidneys was detected (Wehner et al., 1977; Phillips et al., 1978)’. The FEEDAP Panel assumes that the same conclusions would apply to chlorite, a phyllosilicate with similar chemical composition and physical structure as talc.

3.2.2. Toxicological studies

No specific studies with additive under assessment were made available. However, some information on the toxicology of talc was provided. This consisted of review articles (including WHO, 1987a) plus a full report of one study: a study of the carcinogenicity of talc given to mice and rats by the inhalation route (NTP, 1993) and articles discussing the results of this study (Goodman, 1995; Oberdoerster, 1995). The review articles reported that talc was not carcinogenic in two lifespan oral studies in rats that each used only a single dose level (50 mg talc/kg body weight (bw) per day and 100 mg talc/rat per day). These articles also reported that oral doses of talc did not produce developmental toxicity in mice (up to 1,600 mg/kg bw per day), rats (up to 1,600 mg/kg bw per day), hamsters (up to 1,200 mg/kg bw per day) and rabbits (up to 900 mg/kg bw per day). Aspects of reproduction toxicity of talc other than developmental toxicity had not been investigated. No other repeat dose toxicity studies were reported.

The IARC (WHO, 1987a, 2010) also assessed all the available \textit{in vitro} and \textit{in vivo} genotoxicity studies, concluding that there is no evidence that talc is genotoxic. The Panel is unaware of any subsequent genotoxicity studies made with talc.

The FEEDAP Panel concludes that the limited range of oral toxicity studies available give no evidence to suggest that the additive is hazardous by this route of exposure.

3.2.3. Safety for the target species

To support the safety of NMTC for all animal species, the applicant submitted three tolerance studies, one with piglets, one with chickens for fattening and one with dairy cows.
3.2.3.1. Safety for weaned piglets

A total of 96 male and female weaned piglets (Large white × Landrace) of about 25 days of age was fed pelleted diets supplemented with 0, 50,000 (1 × the highest recommended use level) or 100,000 (2 ×) mg NMTC (74% talc and 21% chlorite)/kg for 42 days.22 The diets consisting mainly of barley, maize, and soybean meal were isonitrogenous (about 19% crude protein (CP)) and isocaloric (about 10 MJ net energy (NE)/kg, by an increase of full fat extruded soybean and animal fat with increasing content of the additive at the expense of barley). The concentrations of the additive were confirmed (by analysis of magnesium). Group size was eight replicates with four piglets each (initial body weight: 6.3 kg). Body weight 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 one piglet per pen for haematology23 and clinical chemistry analyses.24 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 analysis of variance (ANOVA) and by a set of linear contrasts. Group differences were analysed by Duncan's multiple range test.

No mortality occurred. A significant reduction of feed intake was observed leading to a reduced final body weight (23.7 and 24.0 vs 25.0 kg) and average daily gain (0.41 and 0.42 vs 0.44 kg) in the treated groups with 1× and 2× groups, compared to control. Feed to gain ratio was not affected by the treatment.

The blood biochemical parameters were not influenced by the treatment, whereas among the haematological parameters the number of erythrocytes (5.98 and 5.97 vs 6.38 × 10¹²/µL) was lower in the groups treated with the additive at either concentration without accompanying effects on haemoglobin (Hb), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), packed cell volume (PCV) and mean corpuscular haemoglobin concentration (MCHV). An increased number of segmented neutrophils was seen in the overdose group.

3.2.3.2. Safety for chickens for fattening

A total of 791 one-day-old male chickens (Ross 308) was fed pelleted diets supplemented with 0, 50,000 (1 × the highest recommended use level) or 100,000 (2 ×) mg NMTC (74% talc and 21% chlorite)/kg for 35 days. Group size was eight replicates with 32/33 birds each.25 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 21.0% CP; grower: about 20% CP) and isocaloric (starter: about 12.3 MJ ME/kg; grower: about 12.8 MJ ME/kg), by an increase of full fat extruded soybeans and animal fat with increasing content of the additive at the expense of maize and soybean meal. The concentration of the additive was confirmed (by analysis of magnesium). The diets were supplemented with a coccidiostat (monensin sodium); the starter diets of the control and the 50,000 mg NMTC group contained 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 haematology23 and clinical chemistry analyses.26 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 ANOVA and a set of linear contrasts. Group differences were analysed by Duncan's multiple range test.

Mortality was low (1.14%, 0.76% and 0% in the control group and in the 1× and 2× groups, respectively). Final weight of the control group was 2.28 kg, average daily feed intake (ADFI) was 100 g. No significant differences in body weight gain were seen between the three groups. The feed to gain ratio of the 1× group was statistically inferior (1.63) to the one of the control group (1.57) and the 2× group (1.59). Significant differences in body weight and average daily gain (ADG) were

22 Supplementary Information October 2016/Annex_1_1_A; Annex_1_1_B; Annex_1_1_C.
23 Haemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), platelets, white blood cell count (WBC), white blood cell differentials (segmented neutrophils, banded neutrophils, lymphocytes, monocytes, eosinophils).
24 Alanine aminotransferase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatinine phosphokinase (CPK), gamma-glutamyl transpeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), albumins, globulins, total protein, glucose, urea, phosphate.
25 Supplementary Information October 2016/Annex_1_3_A; Annex_1_3_B; Annex_1_3_C.
26 Alanine aminotransferase (ALT), alkaline phosphatase (AP), aspartate aminotransferase (AST), creatinine phosphokinase (CPK), gamma-glutamyl transpeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), albumins, globulins, total protein, glucose, uric acid, phosphate.
obtained in the starter period (bw: 846, 791 and 800 g for the groups with 0, 50,000 and 100,000 mg NMTC/kg). These differences might have resulted from differences in feed intake. In the grower period, a tendency for compensatory feed intake was observed, leading to equal growth rate of the groups. Consequently, feed to gain ratio in the grower period was significantly inferior for both treated groups compared to the control (1.67, 1.67 vs 1.58). However, the magnitude of difference obtained in the starter period remained, even if final body weight was not significantly different. At the end of the trial, the feed to gain ratio of the use level was negatively affected compared to the control and the 2x groups (1.63 vs 1.57 and 1.59, respectively).

No effects were seen in the haematological and blood biochemical parameters with the exception of reduced uric acid and AST in the 2x group and increased AP in the use level group.

3.2.3.3. Safety for dairy cows

A total of 45 Holstein multiparous cows was fed total mixed ration (TMR) mainly composed of maize silage, maize, soybean meal and a concentrate supplemented with 0, 50,000 (1× the highest recommended use level), or 100,000 (2×) mg NMTC (77.5% talc and 19.5% chlorite)/kg for 56 days.27 Group size was 15 cows fed together in one pen. No details on the allocation of cows to the pens were provided (e.g. milk yield, age, parity). The diets were calculated to be isonitrogenous (about 15% CP) and isocaloric (about 6.7 MJ net energy for lactation (NEL)/kg), the additive added at expenses of alfalfa, straw and cereal silage. The concentration of the additive was not analytically confirmed. Group feed intake, individual milk production and milk composition (fat and protein analysed by Fourier transform infrared spectroscopy) were recorded daily. At the end of the experiment, a blood sample was taken from seven animals per treatment for haematology28 and clinical chemistry analyses.29 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.

Average dry matter intake was 23.8, 25.2 and 23.8 kg/day for the control group and the, 1x and 2x groups, however, the data could not be statistically analysed.

Average body weight during the trial was 641, 640 and 639 kg (body weight of the groups at start not given). Average milk yield was 31.6, 31.5 and 30.9 kg/day for the groups with 0, 50,000 and 100,000 mg NMTC/kg feed (not significantly different). Milk fat content was significantly reduced by the treatment in a dose-dependent manner (p < 0.01). Average values were 3.99% for the control, 3.79% and 3.54% for the groups with 50,000 and 100,000 mg NMTC, respectively. Milk protein content was significantly higher in the 100,000 mg NMTC group (3.34%) compared to the control (3.22%) and the 50,000 mg NMTC group (3.27%). Overall, there were no differences in any of the analytes that were measured in haematology and blood clinical chemistry. There was a tendency (p = 0.09) for cows on NMTC for lower blood P levels (5.57 and 5.81 vs 6.42 mg/dL).

3.2.3.4. Interactions in vivo (chicken study)

The study of the interactions in vivo was performed during the tolerance trial in chickens. On days 18 to 21, excreta samples were collected from 24 chickens per group (8 replicates per treatment) for the determination of nitrogen and uric acid, vitamin E (tocopherol acetate, alpha tocopherol and total tocopherols), riboflavin, zinc and monensin, and the digestibility/absorption was calculated for the groups receiving 0 and 50,000 mg NMTC/kg feed. The excretion of total nitrogen was reduced by the supplementation of 50,000 mg NMTC/kg in diets for chickens for fattening, however, no changes were observed on the apparent faecal nitrogen digestibility. The excretion of riboflavin was increased by about 19%. No effects were observed on the digestibility/absorption of tocopherol acetate, alpha tocopherol and total tocopherols. Monensin measurement was not affected by the presence of the additive. It was not possible to conclude on the effect on zinc, due to potential contamination of the samples with zinc from the floors of metabolism cages.
3.2.3.5. Conclusions on safety for the target species

No dietary concentration of NMTC without negative effects on body weight, body weight gain and feed intake could be identified for piglets; a safe level could consequently not be established.

In chicken for fattening, it could not be excluded that the highest recommended use level of NMTC (50,000 mg/kg) would impair feed to gain ratio. Therefore, a safe level of NMTC could not be identified.

The dose-dependent reduction of milk fat observed in the tolerance study with dairy cows is considered as a potential adverse effect. The limitations of the study design (no replicates for feed intake) and reporting does not allow this effect to be clearly ascribed to the additive. A safe level for dairy cows could consequently not be established.

3.2.4. Safety for the consumer

Talc is authorised as a food additive with no maximum content and without any restrictions on the presence of other phyllosilicates. The Joint Food and Agriculture Organization (FAO)/WHO Expert Committee on Food Additives (JECFA) evaluated talc and concluded that an acceptable daily intake (ADI) is not necessary (WHO, 1987b).

The FEEDAP Panel considers it unlikely that NMTC, 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 from animals as a consequence of the use of the product as a feed additive.

Therefore, the use of NMTC in animal nutrition is considered not to pose a risk for the consumer of animal tissues and products from animals fed the additive.

3.2.5. Safety for the user

3.2.5.1. Effects of inhalation

A study of respiratory toxicity was provided (Jakubowska and Szafarska-Stojko, 1992). The effects of two forms of talc (Italian and Austrian) on the respiratory tract were investigated in rats. A total of 120 Wistar rats were divided into five groups. Rats in treated groups were each given a single intratracheal dose of 50 mg of talc in normal saline and observed for 6 or 9 months. Both forms of talc caused chronic inflammatory changes in the bronchi and lungs at both observation periods.

The IARC reported in its monograph on talc (WHO, 1987b) data from studies which confirmed that inhalation of large amounts of fine dusts of insoluble materials such as talc can lead to deposition in the respiratory tract. It was noted that talc pneumoconiosis in exposed workers was most prevalent and severe in those exposed to forms of talc containing asbestiform minerals. On the basis of animal carcinogenicity studies and of human epidemiological and case studies, the IARC concluded that inhalation of forms of talc containing asbestiform fibres is carcinogenic to humans. However, this conclusion does not apply to the forms of talc that do not contain asbestiform fibres.

Talc did not induce pleural tumours in rats following intrapleural injection (Stanton et al., 1981).

Small amounts of quartz were detected in the product from one manufacturer but not in the products from two other manufacturers. Repeated occupational exposure to large air concentrations of quartz has been associated with lung disease: silicosis and lung cancer (WHO, 1997).

3.2.5.2. Effects on skin and eyes

Talc was not irritant in a test for primary irritation to the skin of rabbits (IFREB, 1983). The test was performed before the introduction of OECD methodological guidelines for testing of skin irritancy. Talc (0.3 g/area) was placed under an occlusive dressing on clipped skin (an intact area of skin and a scarified area) of each of six rabbits. The exposed areas of skin were examined after 24 and 72 h. There were no signs of any irritation at intact or scarified sites on any of the rabbits at either examination time.

Talcum powder was one of a large number of substances screened for skin irritancy in humans using a chamber-scarification test (Frosch & Kligman, 1976). Five pale-skinned Caucasian volunteers were used. Talcum powder (0.1 mg) was applied to normal and scarified fore-arm skin in aluminium chambers once daily for 3 days and skin was examined 30 min and 72 h after removal of the chambers. The irritancy of talcum powder was classified as ‘low’ (the lowest classification used) with a score of 0–0.4 out of a possible maximum of 4.
Three mineral samples were tested for irritancy to the eyes of rabbits (Lauressergues, 1978). The minerals tested were a commercial talc, reference talc (‘quite similar to the theoretical mineral’) and chlorite. Each test material was tested on 12 consecutive days by application as a 10% suspension in water to the conjunctiva sac of six male rabbits. No eye irritancy was caused by application of chlorite or either of the samples of talc.

### 3.2.5.3. Conclusions on safety for the user

The additive is a fine powder and, owing the high dusting potential and the high proportion of respirable particles, it has the potential to be inhaled by users. Talc could cause serious lung disease if repeatedly inhaled in large quantities over a long period. Talc is not irritant to skin and eyes. No information is available on the possible skin sensitisation potential of the product. The quartz content of the additive could pose an additional health risk to the user exposed by inhalation.

### 3.2.6. Safety for the environment

The components of the additive (talc, chlorite, dolomite and magnesite) 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

Four studies were provided to support the efficacy of the additive NMTC as an anticaking substance in feedingstuffs.

In the first study, the efficacy of the additive as an anticaking agent was tested in 10 subsamples each of a complete mash feed for chickens for fattening.\(^{30}\) The feed was supplemented with 0, 10,000 or 20,000 mg/kg of either a NMTC with a talc and chlorite content of about 75% or a NMTC with a talc and chlorite content of about 85%. Each subsample (2,000 g) was loaded in a standard cone with an orifice of 20 mm and left to fall. The flow time of each sample was measured. The inclusion of 10,000 and 20,000 mg of both NMTC/kg feed reduced significantly the flow time of the feeds compared to the unsupplemented feedingstuffs.

In the second study, a mash pig feed was mixed with 0, 10,000, 15,000 or 20,000 mg/kg NMTC with a talc and chlorite content of about 75\(^{\circ}\).\(^{31}\) The feeds (10 subsamples each) were loaded in a plastic cylinder (diameter: 100 mm; height: 140 mm), turned upside down on the end of a smooth surface, which was then raised on one side with a hydraulic piston, forming an angle with the floor, up to the height at which the cylinder started moving. This height was then measured. The inclusion of the additive significantly reduced the height compared to the control (values of h for the three concentrations vs control), and therefore improved the flowability of the feed.

In the third study, a mash pig feed was mixed with increasing levels (0, 2,000, 3,000, 4,000, 5,000, 6,000, 7,000, 10,000, 15,000 and 20,000 mg) of a NMTC with a talc and chlorite content of about 85\(^{\circ}\).\(^{32}\) Subsamples (12) of 75 g of each supplemented feed were poured into a test tube (diameter 40 mm), and laid on an horizontal wood plank, which was raised slowly until the feed started to flow out. At a certain angle, the run-off occurs quite abruptly; this measured angle is called ‘angle of flowability’. The sine of such angle was then compared. The results showed that the inclusion of NMTC at concentrations of 3,000 mg/kg feed and above significantly improved the flowability of the feed.

In the fourth study, three subsamples of each of the mash pig feed used in the third study (90 g each) were stored for 1 h in a moisture saturated atmosphere, then loaded in a steel cylinder and put under a 25 kg of pressure for 24 h.\(^{33}\) The strength (N) needed to break the cake was measured with a dynamometer. The results showed that the inclusion of NMTC significantly reduced the strength resistance, improving flowability, at concentrations of 5,000 mg/kg feed and above.

### 3.3.1. Conclusions on efficacy

The results of four \textit{in vitro} studies showed that the additive NMTC is efficacious as an anticaking agent.

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\(^{30}\) Technical dossier/Section IV/Annex 4-1-1.

\(^{31}\) Technical dossier/Section IV/Annex 4-1-2.

\(^{32}\) Technical dossier/Section IV/Annex 4-1-3.

\(^{33}\) Technical dossier/Section IV/Annex 4-1-4.
4. Conclusions

No safe dietary level of NMTC could be identified for piglets, chickens for fattening and dairy cows. The use of NMTC in animal nutrition is considered not to pose a risk for the consumer of animal tissues and products from animals fed the additive. Talc could cause serious lung disease if repeatedly inhaled in large quantities over a long period. Talc is not irritant to skin and eyes. In the absence of data, no conclusion can be drawn on the skin sensitisation potential of the product. The components of the additive (talc, chlorite, dolomite and magnesite) 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. The additive NMTC is efficacious as an anticaking agent.

5. Recommendations

The FEEDAP Panel notes that one of the NMTC products described does not comply with the existing authorisation for E 560 natural mixtures of steatites and chlorite. The FEEDAP Panel supports the proposal of the applicant concerning the specification for the sum of talc and chlorite (minimum 75%).

Documentation provided to EFSA

1) Natural mixture of talc and chlorite for all animal species. August 2010. Submitted by Scientific Association of European Talc Industry A.I.S.B.L.
2) Natural mixture of talc and chlorite for all animal species. Supplementary Information October 2016. Submitted by Scientific Association of European Talc Industry A.I.S.B.L.
3) Comments for the Member states.

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**Abbreviations**

| Abbreviation | Definition |
|--------------|------------|
| AAS | atomic absorption spectrometry |
| ADG | average daily gain |
| ADI | acceptable daily intake |
| ADFI | average daily feed intake |
| ADME | absorption, distribution, metabolism and excretion |
| ALT | alanine aminotransferase |
| ANOVA | analysis of variance |
| AP | alkaline phosphatase |
| AST | aspartate aminotransferase |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CP | crude protein |
| CPK | creatine phosphokinase |
| d-l-PCB | dioxins-like polychlorinated biphenyl |
| EINECS | European INventory of Existing Commercial chemical Substances |
| EURL | European Union Reference Laboratory |
| FEEDAP | EFSA Panel on Additives and Products or Substances used in Animal Feed |
| GGT | gamma-glutamyl transeptidase |
| GLDH | glutamate dehydrogenase |
| GSH-Px | glutathione peroxidase |
| Hb | haemoglobin |
| IARC | International Agency for Research on Cancer |
| IFREB | Institut Français de Recherches et Essais Biologiques |
| JECFA | Joint Food and Agriculture Organisation (FAO)/WHO Expert Committee on Food Additives |
| LDH | lactate dehydrogenase |
| MCH | mean corpuscular volume |
| MCHC | mean corpuscular haemoglobin concentration |
| MCV | mean corpuscular haemoglobin |
| ME | metabolisable energy |
| NE | net energy |
| NEL | net energy lactation |
| NMT | natural mixture of talc and chlorite |
| NTP | National Toxicology Program |
| OECD | Organisation for Economic Co-operation and Development |
| PCDD/F | polychlorinated dibenzo-p-dioxins and dibenzofurans |
| PCV | packed cell volume |
| RBC | red blood cell count |
| TEQ | TEQ toxic equivalent |
| TGA | thermo gravimetric analyses |
| TMR | total mixed ration |
| WBC | white blood cell count |
| WHO | World Health Organization |
| XRD | X-ray diffraction |
| XRF | X-ray fluorescence |
Annex A – Evaluation Report on the Analytical Methods submitted in connection with the Application for Authorisation of a Feed Additive according to Regulation (EC) No 1831/2003

In the current application authorisation is sought under articles 10(2) for natural mixtures of talc and chlorite, under the category/functional group 1(i) ‘technological additives’/‘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. The feed additive is a white to light grey powder obtained by crushing and milling natural rocks. This natural mixture contains a minimum of 75% of talc (steatite) and chlorite, and a maximum of 25% of dolomite, magnesite and quartz. The feed additive is intended to be used directly in feedingstuffs or through premixtures at inclusion levels in feedingstuffs ranging from 0.1% to 5% with an average at 2%. For the characterisation of the feed additive the Applicant submitted a set of complementary methods: (i) X-ray diffraction (XRD), (ii) thermo gravimetric analyses (TGA) and (iii) X-ray fluorescence (XRF), or (iv) atomic absorption spectrometry (AAS) for chemical analyses. Even though no performance characteristics are provided, the EURL recommends for official control the combined set of well-established mineralogical methods (XRD, TGA, XRF and AAS) for the characterisation of natural mixtures of talc and chlorite. The Applicant provided no experimental data or any analytical method for the determination of the natural mixtures of talc and chlorite in premixtures or feedingstuffs as the unambiguous determination of the feed additive added to the matrixes is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the direct determination of natural mixtures of talc and chlorite in premixtures or feedingstuffs. 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.