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Safety and efficacy of a feed additive consisting of sodium aluminosilicate, synthetic, for all animal species (European Zeolites Producers Association (EUZEPA) & Association of Synthetic Amorphous Silica Producers (ASASP))

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of sodium aluminosilicate, synthetic, as a technological feed additive for all animal species. The additive sodium aluminosilicate, synthetic, is proposed to be manufactured in two different forms, amorphous and crystalline, characterised by different ratios among the main components, silica, aluminium and sodium. In the absence of adequate data, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was not in the position to conclude on the safety of the additive sodium aluminosilicate, synthetic, in both the amorphous and crystalline forms, for the target species, the consumer and the user. The use of sodium aluminosilicate, synthetic, as a feed additive was considered safe for the environment. In the absence of appropriate data, the FEEDAP Panel could not conclude on the efficacy of sodium aluminosilicate, synthetic, as a technological additive.

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Keywords: sodium aluminosilicate synthetic, technological additives, anti-caking agent, safety, efficacy

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from European Zeolites Producers Association (EUZEPA) & Association of Synthetic Amorphous Silica Producers (ASASP)² for the re-evaluation of the additive consisting of sodium aluminosilicate synthetic, when used as a feed additive for all animal species (category: technological additives; functional group: anti-caking agent).

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

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of sodium aluminosilicate synthetic, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

EFSA issued an opinion on the re-evaluation of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) as food additives (EFSA FAF Panel, 2020).

The additive is currently authorised for use in feed for all animal species (E 554).³

Sodium aluminium silicate, synthetic, is currently authorised for use as a food additive.⁴

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of sodium aluminosilicate, synthetic as a feed additive.

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.

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.⁶

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

² European Zeolites Producers Association (EUZEPA) & Association of Synthetic Amorphous Silica Producers (ASASP), Avenue E. van Nieuwenhuysse 4, B-1160, Brussels, Belgium. Companies: Arkema S.A., Colombes, France; Evonik Operations GmbH, Hanau, Germany; GRACE GmbH, Worms, Germany; IQE S.A., Zaragoza, Spain.

³ Commission Regulation (EC) No 2439/1999 of 17 November 1999 on the conditions for the authorisation of additives belonging to the group 'binders, anti-caking agents and coagulants' in feedingstuffs. OJ L 297, 18.11.1999, p. 8.

⁴ Commission Regulation (EU) No 380/2012 of 3 May 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for aluminium-containing food additives. OJ L 119, 4.5.2012, p 14.

⁵ FEED dossier reference: FAD-2010-0270.

⁶ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of sodium aluminosilicate, synthetic is in line with the principles laid down in Regulation (EC) No 429/2008⁷ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

The additive under assessment sodium aluminosilicate, synthetic, is to be used as a technological additive (functional group: anti-caking agents) for all animal species and categories.

3.1. Characterisation

The additive under assessment is defined as sodium aluminosilicate, synthetic. The applicant proposes to further classify the additive in two different products, based on their physical characteristics: sodium aluminosilicate amorphous, which is authorised also as a food additive, and sodium aluminosilicate crystalline. Data supporting the characterisation of sodium aluminosilicate amorphous were submitted by three manufacturers (a, b and c),⁸ those for sodium aluminosilicate crystalline were submitted by two manufacturers (c and d).⁹

3.1.1. Characterisation of the additive

3.1.1.1. Sodium aluminosilicate amorphous

The product sodium aluminosilicate amorphous is composed purely of the active substance sodium aluminosilicate (synonyms: sodium silicoaluminate, aluminium sodium silicate; International Union of Pure and Applied Chemistry (IUPAC) name: silicic acid, aluminium sodium salt; Chemical Abstracts Service (CAS) number: 1344-00-9, European Inventory of Existing Commercial Chemical Substances (EINECS) number: 215:684-8, molecular mass (calculated): 284-2,190 g/mol). The chemical formula is $\text{Na}_x[(\text{AlO}_2)_x(\text{SiO}_2)_y] \times \text{ZH}_2\text{O}$.

The additive is produced by chemical synthesis, using a wet process with Na_2SiO_3 and $\text{Al}_2(\text{SO}_4)_3$ as starting materials. The ratio of the elements in the starting materials expressed as $\text{Na}_2\text{O} : \text{Al}_2\text{O}_3 : \text{SiO}_2$ is on average approximately 1:1:13. After precipitation, filtration and washing, the additive is dried and milled at the desired dimension.

The additive is a white, odourless, free-flowing powder. The product specifications were set based on the specifications set for its use as food additive:¹⁰ SiO_2 : 66.0–88.0%, Al_2O_3 : 5.0–15.0% and Na_2O : 5.0–8.5% (on dry basis or anhydrous basis).

The results on the relative percentages of the main components, of at least ■■■ batches of the additive for each manufacturer showed compliance with the above specifications (Table 1).

Table 1: Composition of the additive sodium aluminosilicate amorphous (on dried basis) by elemental analysis. Results expressed as minimum and maximum content analysed

	SiO_2 %	Al_2O_3 %	Na_2O %
Specification	■■■■■	■■■■■	■■■■■
Manufacturer ■■■¹¹	■■■■■	■■■■■	■■■■■

⁷ 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.

⁸ Hereinafter referred to as manufacturers a, b and c.

⁹ Hereinafter referred to as manufacturers c and d.

¹⁰ 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.

		SiO ₂ %	Al ₂ O ₃ %	Na ₂ O %
Manufacturer	¹²	█	█	█
Manufacturer	¹³	█	█	█

The specifications set for the use in food include also: loss on drying < 8% and loss on ignition > 5% and < 11%, both on anhydrous base, and pH of a 5% slurry, > 6.5 and < 11.5; lead, arsenic and mercury concentrations in the additive are specified to be < 5, < 3 and < 1 mg/kg, respectively.¹⁰ At least █ of the additive from each manufacturer █ were analysed for impurities. The results of the analysis for heavy metals (lead, mercury and cadmium), arsenic and nickel, dioxins and the sum of dioxins plus dioxin-like PCBs and non-dioxin-like PCBs are summarised in Table 2. The results showed compliance with the specifications, where available. The detected amounts of the above described undesirable substances do not raise safety concerns. Loss on drying, loss on ignition and pH were in compliance with the specifications in all the batches analysed.

Table 2: Composition of the additive sodium aluminosilicate amorphous. Results expressed as minimum and maximum content analysed

		Lead mg/kg	Mercury mg/kg	Cadmium mg/kg	Arsenic mg/kg	Nickel mg/kg	Dioxins ^(a)	Sum of dioxins plus dioxin like PCBs ^(b)
Manufacturer	¹¹	█	█	█	█	█	█	█
Manufacturer	¹²	█	█	█	█	█	█	█
Manufacturer	¹³	█	█	█	█	█	█	█

(a): ng WHO-PCDD/F-TEQ/kg.

(b): ng WHO-PCDD/F-PCB-TEQ/kg.

(c): █

The dusting potential of the additive was determined using a modified rotating drum method, based on a continuous powder drop down onto two inclined plates in a fall shaft and particle size analysis by laser diffraction. █

█	█	█	█	█	█	█	█	█
█	█	█	█	█	█	█	█	█
█	█	█	█	█	█	█	█	█

Particle size of the additive was measured by laser diffraction. █

█	█	█	█	█	█	█	█	█
█	█	█	█	█	█	█	█	█
█	█	█	█	█	█	█	█	█

¹¹ Technical dossier/Supplementary information January 2021/Annex █ and Technical dossier/Supplementary Information April 2021/Part of Annex █.

¹² Technical dossier/Supplementary information January 2021/Annex █ and Technical dossier/Supplementary Information April 2021/Part of Annex █.

¹³ Technical dossier/Supplementary information January 2021/Annex █ and Technical dossier/Supplementary Information April 2021/Part of Annex █.

3.1.1.2. Sodium aluminosilicate, crystalline

The product sodium aluminosilicate crystalline is composed purely of the active substance sodium aluminosilicate (synonyms: sodium silicoaluminate, aluminium sodium silicate; IUPAC name: silicic acid, aluminium sodium salt; CAS n: 1318-02-1, EINECS n.: 215-283-8). The chemical formula is $\text{Na}_2\text{O}\cdot\text{Al}_2\text{O}_3\cdot 2\text{SiO}_2\cdot 4.5\text{H}_2\text{O}$.

The additive is produced by chemical synthesis with aqueous alkali metal silicate solutions and aluminate, or aluminium hydroxide and sodium hydroxide solutions, as starting materials. After hydrothermal crystallisation and filtration, the additive is dried and then activated (high temperature dehydration of the crystalline structure).

The additive, a white, odourless, fine powder or beads, is specified to contain, on dried basis, SiO_2 : 31.0–43.0%, Al_2O_3 : 26.0–36.5% and Na_2O : 16.0–25.5%.

The results on the relative percentages of the main components [redacted] showed compliance with the specifications for the additive from manufacturer [redacted], while the additive from manufacturer [redacted] did not meet the specifications [redacted] (Table 3).

Table 3: Composition of the additive sodium aluminosilicate crystalline (on dried basis) by elemental analysis. Results expressed as minimum and maximum content analysed

	SiO_2 %	Al_2O_3 %	Na_2O %
Specification	[redacted]	[redacted]	[redacted]
Manufacturer [redacted]	[redacted]	[redacted]	[redacted]
Manufacturer [redacted]	[redacted]	[redacted]	[redacted]

Regarding the purity of the additive, lead and cadmium concentrations¹⁵ are specified to be < 30 and < 2 mg/kg, respectively; concentrations of dioxins and dioxins-like PCBs are specified to be < 0.5 ng WHO PCDD/F-TEQ/kg and < 1.5 ng WHO-PCDD/F-PCB-TEQ/kg, respectively. [redacted] batches of the additive from each manufacturer were analysed for impurities. The results of the analysis for heavy metals (lead, mercury and cadmium), arsenic and nickel, dioxins and the sum of dioxins plus dioxin like PCBs and non-dioxin-like PCBs are summarised in Table 4. The results showed compliance with the specifications; the detected amounts of the above described undesirable substances do not raise safety concerns.

Table 4: Composition of the additive sodium aluminosilicate crystalline. Results expressed as minimum and maximum content analysed

	Lead mg/kg	Mercury mg/kg	Cadmium mg/kg	Arsenic mg/kg	Nickel mg/kg	Dioxins ^(a)	Sum of dioxins plus dioxin like PCBs ^(b)
Manufacturer [redacted]¹³	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Manufacturer [redacted]¹⁴	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

(a): ng WHO-PCDD/F-TEQ/kg.

(b): ng WHO-PCDD/F-PCB-TEQ/kg.

Particle size of the additive was measured by laser diffraction. [redacted]

[redacted] Technical dossier/Supplementary information January 2021/Annex [redacted] and Technical dossier/Supplementary Information April 2021/Part of Annex [redacted].

¹⁵ Expressed in mg/kg of complete feedingstuff at 12% moisture, according to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 11.

_____ No information on dusting potential of the additive was provided.

3.1.2. Stability and homogeneity

Stability studies are not required for mineral-based products, which can be reasonably assumed to be stable (EFSA FEEDAP Panel, 2017b). The stability of the effects over time in feedingstuffs has not been demonstrated.

No information on the capacity for homogeneous distribution of the additive in premixtures and/or feedingstuffs was provided.

3.1.3. Conditions of use

The additive is intended to be used in feedingstuffs and premixtures with no minimum or maximum content. The applicant reported a typical use level in the complete feed up to 50,000 mg/kg.

3.2. Safety

No specific studies or information on the safety of the additive for the target species have been provided. No specific information on the absorption, distribution, metabolism and excretion (ADME) and no specific toxicological studies, including genotoxicity studies and studies to support the safety for the user, done with the additive under assessment, were made available. Only an extract from the International Uniform Chemical Information Database (UICLID), summarising studies done with sodium aluminosilicate (specifications not reported), also reported as summary in the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset (SIDS) (OECD, 2004) and in a Human and Environmental Risk Assessment on ingredients of household cleaning products (HERA) report on Zeolite A (HERA, 2004) were submitted. However, the original reports of the studies cited were not submitted, consequently, the FEEDAP Panel was not able to assess them.

Therefore, in the absence of data, the Panel is not in the position to conclude on the safety of the additive, in both the amorphous and crystalline forms, for the target species, the consumer and the user.

The components of the additive 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 additive sodium aluminosilicate amorphous is authorised to be used as an anti-caking agent in a variety of foods. However, the chemical-physical characteristics (e.g. humidity, granulometry), of the food in which it is used and those of the feedingstuffs in which the additive is intended to be used may differ.

A summary of five *in vitro* studies _____

_____ However, in the absence of detailed results and statistical analysis of the results, these studies could not be further considered.

In the absence of appropriate data, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive sodium aluminosilicate, synthetic.

4. Conclusions

The feed additive sodium aluminosilicate, synthetic, is manufactured in two different forms, amorphous and crystalline, characterised by different ratios among the main components, silica, aluminium and sodium.

In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the safety of the additive sodium aluminosilicate, synthetic, in both the amorphous and crystalline forms, for the target species, the consumer and the user.

The use of sodium aluminosilicate, synthetic, as a feed additive is considered safe for the environment.

In the absence of appropriate data, the FEEDAP Panel cannot conclude on the efficacy of the additive.

5. Documentation provided to EFSA/Chronology

Date	Event
04/11/2010	Dossier received by EFSA. Sodium aluminosilicate, synthetic for all animal species. Submitted by European Zeolites Producers Association (EUZEPA) & Association of Synthetic Amorphous Silica Producers (ASASP)
16/10/2019	Reception mandate from the European Commission
28/11/2019	Application validated by EFSA – Start of the scientific assessment
18/02/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation/safety for the target species/safety for the consumer/safety for the user/efficacy</i>
21/02/2020	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
03/03/2020	Comments received from Member States
29/01/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
02/04/2021	Reception of spontaneous supplementary information from the applicant
	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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- 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, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J and Innocenti ML, 2017b. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023. <https://doi.org/10.2903/j.efsa.2017.5023>
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Abbreviations

ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
PCB	polychlorinated biphenyls
PCDD/F	polychlorinated dibenzo-p-dioxins and dibenzofurans
TEQ	toxic equivalent
WHO	World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of the Analysis for sodium aluminosilicate synthetic (E554)

In the current application an authorisation is sought under Article 10(2) for sodium aluminosilicate, synthetic (E 554) under the category/functional group 1(i) “technological additives”/“anti-caking agents”, according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the feed additive for all animal species.

The feed additive is to be marketed as two products, namely amorphous and crystalline synthetic sodium aluminosilicates. The amorphous synthetic sodium aluminosilicate is a white powder, consisting of 66–88% (w/w) of SiO_2 , 5–15% (w/w) of Al_2O_3 and 5–8.5% (w/w) of Na_2O based on anhydrous weight. The crystalline sodium aluminosilicate is a white fine powder or beads consisting of 31–43% (w/w) of SiO_2 , 26–36.5% (w/w) of Al_2O_3 and 16–25.5% (w/w) of Na_2O . The Applicant states that the specifications/purity criteria set in Commission Regulation (EU) 231/2012 for the food additive (sodium aluminium silicate, E554) are applicable also to one of the above mentioned products of the feed additive, namely amorphous synthetic sodium aluminosilicate.

The feed additive is intended to be used in premixtures and feedingstuffs, however the Applicant did not propose any limits of the feed additive in feedingstuffs.

For the characterisation of the feed additive, the Applicant submitted the FAO JECFA “Sodium Aluminium Silicate” monograph of the compendium for food additives and the dedicated Food Chemicals Codex (FCC) “Sodium Aluminosilicate” monograph. According to Commission Regulation (EU) 231/2012 the following methods are to be applied for the characterisation of sodium aluminium silicate, E554: qualitative and quantitative methods for aluminium, sodium and silicon; loss on drying; and loss on ignition. These methods are described in the FAO JECFA and FCC monographs mentioned above.

The EURL recommends for official control for the characterisation of the sodium aluminosilicate synthetic (E554) (feed additive) the methods mentioned above described in the FAO JECFA “Sodium Aluminium Silicate” and/or FCC “Sodium Aluminosilicate” monographs.

The Applicant did not provide experimental data or an analytical method for the determination of sodium aluminosilicate synthetic (E554) in premixtures and feedingstuffs as the unambiguous determination of the feed additive added to the matrices is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the determination of sodium aluminosilicate synthetic (E554) in premixtures and 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, as last amended by Regulation (EU) 2015/1761) is not considered necessary.