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Re-evaluation of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) as food additives

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Abstract

The Panel on Food Additives and Flavourings (FAF) provided a scientific opinion re-evaluating the safety of Sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) as food additives. The Scientific Committee for Food (SCF) assigned these food additives together with other aluminium-containing food additives a provisional tolerable weekly intake (PTWI) of 7 mg aluminium/kg body weight (bw). In 2008, EFSA established a tolerable weekly intake (TWI) of 1 mg aluminium/kg bw per week. Sodium aluminium silicate was shown in rats to be absorbed to a limited extent at $0.12 \pm 0.011\%$. The Panel considered that potassium aluminium silicate would be absorbed and become systemically available similarly to sodium aluminium silicate. No information on the physicochemical characterisation of sodium aluminium silicate and potassium aluminium silicate when used as food additives has been submitted and only very limited toxicological data were available for sodium aluminium silicate. Exposure to E 554 was calculated based on the reported use levels in food supplements. Exposure to aluminium from this use of E 554 was calculated to exceed the TWI for aluminium. Based on the data provided by interested business operators, the Panel considered that E 555 is not being used as a carrier, but as an inseparable component of 'potassium aluminium silicate-based pearlescent pigments'. The Panel calculated the regulatory maximum exposure to E 555 as a carrier for titanium dioxide (E 171) and iron oxides and hydroxides (E 172). Exposure to aluminium from this single use at the maximum permitted level could theoretically far exceed the TWI. Considering that only very limited toxicological data and insufficient information on the physicochemical characterisation of both food additives were available, the Panel concluded that the safety of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) could not be assessed.

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Summary

Following a request from the European Commission, the Panel on Food Additives and Flavourings (FAF) was asked to deliver a scientific opinion on the re-evaluation of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) as food additives. Sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) are authorised food additives in the European Union (EU) according to Annex II and III of Regulation (EC) No 1333/2008 and specifications have been defined in Commission Regulation (EU) No 231/2012.

In 1990, the Scientific Committee for Food (SCF) assigned these food additives together with other aluminium-containing food additives a provisional tolerable weekly intake (PTWI) of 7 mg aluminium/kg body weight (bw). In 2008, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC Panel) established a tolerable weekly intake (TWI) of 1 mg aluminium/kg bw per week for dietary aluminium from all sources.

No information on the physicochemical characterisation of sodium aluminium silicate and potassium aluminium silicate when used as food additives E 554 and E 555, respectively, has been submitted. Sodium aluminium silicate was shown in rats to be absorbed to a limited extent at $0.12 \pm 0.011\%$. The Panel considered that potassium aluminium silicate would be absorbed and become systemically available similarly to sodium aluminium silicate. Only developmental toxicity studies with sodium aluminium silicate in mice, rats, hamsters and rabbits were available. No treatment-related maternal and developmental effects were observed. The reporting of the prenatal developmental studies was limited to allow the use of these data for hazard assessment.

Only use levels for sodium aluminium silicate (E 554) in food supplement (FC 17) were available. The exposure to E 554 based on the reported use levels could be up to 2.9 mg/kg bw per day at the mean level and 3.9 mg/kg bw per day at the high intake level (P95), both in children. In this assessment, it was assumed that all food supplements consumed contained sodium aluminium silicate (E 554) at the highest reported use level.

Based on the maximum amount of Al_2O_3 in sodium aluminium silicate (E 554) as stated in the EU specifications, E 554 contains up to 7.8% aluminium. Thus, the maximum exposure to aluminium from the use of E 554 could be up to 1.58 mg/kg bw per week at the mean and up to 2.13 mg/kg bw per week at the P95 for children. This alone would exceed the TWI of 1 mg/kg bw per week for dietary aluminium from all sources established by the European Food Safety Authority (EFSA).

Based on the data provided by interested business operators, the Panel considered that E 555 is not being used as a carrier but as an inseparable component of 'potassium aluminium silicate-based pearlescent pigments'. According to the Mintel Global New Products Database (GNPD), E 555 was labelled on 151 products, of which 146 were also labelled with iron oxide and hydroxides (E 172) or titanium dioxide (E 171).

Based on the current authorisation for E 555 as a carrier for titanium dioxide (E 171) and iron oxides and hydroxides (E 172), where it can constitute '90% relative to the pigment' (Annex III of Regulation 1333/2008), the Panel calculated the theoretical regulatory maximum exposure to E 555 from this authorised use. Considering that potassium aluminium silicate (E 555) contains 20.4% aluminium (based on the molecular mass), the maximum exposure to aluminium from potassium aluminium silicate (E 555) as carrier for E 171 could be up to 388 mg/kg bw per week and the maximum exposure to aluminium from potassium aluminium silicate (E 555) as carrier for E 172 could be up to 297 mg/kg bw per week. The Panel noted that this single use at the maximum permitted level could theoretically far exceed the TWI for dietary aluminium from all sources established by EFSA.

Considering that only very limited toxicological data and insufficient information on the physicochemical characterisation of both food additives were available, the Panel concluded that the safety of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) could not be assessed.

The Panel recommended that data in line with the current Guidance document on evaluation of food additives is required for E 554 and E 555 to perform the risk assessment of these food additives and evaluate the potential exceedance of the TWI for aluminium resulting from their use as food additives.

According to the interested business operators, potassium aluminium silicate is only used for the manufacturing of 'potassium aluminium silicate-based pearlescent pigments' and the components – potassium aluminium silicate, titanium dioxide or iron oxides - are bound to each other by strong physical forces and cannot be separated from each other by standard methods. The interested business operators stated that 'without mica, a pearlescent effect is absent. The colour of the

pearlescent effect could not be achieved without titanium dioxide or iron oxide'. The description of the technological role of mica in 'potassium aluminium silicate-based pearlescent pigments' does not meet the definition of 'carrier' according to Regulation (EC) No 1333/2008. The Panel therefore considered that 'potassium aluminium silicate-based pearlescent pigments' is a new entity, not listed in the Regulation (EC) No 1333/2008 and not previously evaluated in the EU.

Therefore, the Panel concluded that potassium aluminium silicate in 'potassium aluminium silicate-based pearlescent pigments' does not meet the definition of a carrier according to Regulation (EC) 1333/2008 and 'potassium aluminium silicate-based pearlescent pigments' are not listed in Regulation (EC) 1333/2008. Consequently, 'potassium aluminium silicate-based pearlescent pigments' should be evaluated as a new food additive.

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1. Introduction

The present opinion deals with the re-evaluation of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) when used as food additives.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

Regulation (EC) No 1333/2008¹ of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under Regulation (EU) No 257/2010². This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted for groups of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the period of time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to a food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU³ of 2001. The report "Food additives in Europe 2000"⁴ submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below.

1.1.2. Terms of Reference

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

1.2. Information on existing authorisations and evaluations

Sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) are authorised food additives in the EU according to Annex II and III of Regulation (EC) No 1333/2008 and specifications have been defined in Commission Regulation (EU) No 231/2012⁵.

In 1990, the Scientific Committee for Food (SCF) considered sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555), together with other aluminium-containing food additives, as 'accepted additives' and indicated that the provisional tolerable weekly intake (PTWI) of 7 mg

¹ 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. 16–33.

² Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

³ COM(2001) 542 final.

⁴ Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.

⁵ 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.

aluminium/kg body weight (bw) from *all intake sources* previously established by JECFA, should be considered when setting conditions of use for these food additives (SCF, 1991).

In 2008, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC Panel) prepared a scientific opinion on the safety of aluminium from dietary intake. In view of the potential for accumulation of aluminium through dietary exposure, the Panel considered it more appropriate to establish a tolerable weekly intake (TWI) for aluminium rather than a tolerable daily intake (TDI). The Panel established a TWI of 1 mg aluminium/kg bw per week (EFSA, 2008).

In 2011, a statement on the evaluation of a new study related to the bioavailability of aluminium in food was published by EFSA (2011). EFSA concluded that this study did not provide any additional information on the bioavailability of aluminium from aluminium-containing compounds that would modify the conclusions reached in 2008 by the AFC Panel. Therefore, the previous safety evaluation of aluminium-based food additives authorised in the European Union was not reconsidered.

In 2011, JECFA evaluated aluminium-containing food additives (including sodium aluminium silicate and potassium aluminium silicate-based pearlescent pigments) and established a PTWI of 2 mg/kg bw for aluminium from all aluminium compounds in food including food additives based on a no-observed adverse effect level (NOAEL) of 30 mg/kg bw per day from a neurodevelopmental study (Poirier et al., 2011 as referred to by JECFA, 2012) and applying a safety factor of 100 (JECFA, 2012).

In 2017, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER, 2017) published an opinion on the tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys. The SCHEER used the same study of Poirier et al. (2011) and established a TDI of 0.3 mg aluminium/kg bw per day.

2. Data and methodologies

2.1. Data

The Panel on Food Additives and Flavourings (FAF) was not provided with a newly submitted dossier. EFSA launched public calls for data^{6,7} to collect information from interested business operators.

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to April 2020. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based; however, these were not always available to the Panel.

Food consumption data used to estimate the dietary exposure to sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database⁸).

The Mintel Global New Products Database (GNPD) was used to verify the use of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) in food and beverage products and food supplements within the EU market. The Mintel GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

2.2. Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency concerning scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidance from the EFSA Scientific Committee.

The FAF Panel assessed the safety of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) as food additives in line with the principles laid down in Regulation (EU) 257/2010 and in the guidance document 'Guidance on submission for food additive evaluations' by the Scientific Committee on Food (SCF, 2001).

When in animal studies, the test substance was administered in the feed or in drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption, the daily intake is calculated by the Panel using the relevant default values. In case of rodents, the values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific

⁶ Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (batch 5). Published 24 May 2016. Available online: <http://www.efsa.europa.eu/en/data/call/160524>

⁷ Call for scientific data on sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) authorised food additives in the EU. Published: 7 November 2018. Available online <https://www.efsa.europa.eu/en/consultations/call/181107>

⁸ Available online: <http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm>

Committee, 2012) are applied. In the case of other animal species, the default values used by JECFA (2000) are applied. In these cases, the dose was expressed as 'equivalent to mg/kg bw per day'. If a concentration in feed or drinking water was reported and the dose in mg/kg bw per day was calculated based on these reported concentrations and on reported consumption data for feed or drinking water, the dose was expressed as 'equal to mg/kg bw per day'.

Dietary exposure to sodium aluminium silicate (E 554) from its use as a food additive was estimated combining food consumption data available within the EFSA Comprehensive European Food Consumption Database with the reported use level (see Section 3.3.3). Dietary exposure to potassium aluminium silicate (E 555) was calculated based on the provisions of Regulation (EC) No 1333/2008 (Section 3.3.4).

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

Sodium aluminium silicate (E 554)

In Commission Regulation (EU) No 231/2012, sodium aluminium silicate (E 554) is defined by the chemical name and the content of SiO₂ (66–88%) and Al₂O₃ (5–15%).

Sodium aluminium silicate with a CAS No of 1344-00-9 is registered in REACH as 'silicic acid, aluminium sodium salt', but its Registrant did not express an interest in its use as a food additive (Documentation provided to EFSA No 4).

Potassium aluminium silicate (E 555)

According to Commission Regulation (EU) No 231/2012, the definition is 'natural mica consists of mainly potassium aluminium silicate (muscovite)'. Mica is a synonym for potassium aluminium silicate. The assay is defined as not less than 98% potassium aluminium silicate. The chemical formula given is KAl₂[AlSi₃O₁₀](OH)₂.

Interested business operators have not provided data on potassium aluminium silicate (E 555). According to them, potassium aluminium silicate is only used for the manufacturing process of a group of 'pearl pigments' (Documentation provided to EFSA No 2 and 3) (see Section 4).

3.1.2. Specifications

The specifications for sodium aluminium silicate (E 554) according to Commission Regulation (EU) No 231/2012 and JECFA (2017) are listed in Table 1.

Table 1: Specifications for sodium aluminium silicate (E 554) according to Commission Regulation (EU) No 231/2012 and JECFA (2017)

	Commission Regulation (EU) No 231/2012	JECFA (2017)
Synonyms	Sodium silicoaluminate; sodium aluminosilicate; aluminium sodium silicate	Sodium silicoaluminate; sodium aluminosilicate; aluminium sodium silicate; silicic acid, aluminium sodium salt; INS No 554
Definition		Sodium aluminium silicate is a series of amorphous hydrated sodium aluminium silicates with varying proportions of Na ₂ O, Al ₂ O ₃ and SiO ₂ . It is manufactured by reacting aluminium sulfate and sodium silicate followed by precipitation
Chemical name	Sodium aluminium silicate	Aluminium sodium silicate
CAS No		1344-00-9
Chemical formula		xSiO ₂ .yAl ₂ O ₃ .zNa ₂ O ₃

	Commission Regulation (EU) No 231/2012	JECFA (2017)
Assay	Content on the anhydrous basis: <ul style="list-style-type: none"> – as SiO₂ not less than 66% and not more than 88% – as Al₂O₃ not less than 5% and not more than 15% 	<ul style="list-style-type: none"> – SiO₂ not less than 66% and not more than 88% – Al₂O₃ not less than 5% and not more than 15% – Na₂O not less than 5% and not more than 8.5% All values expressed on the dried basis
Description	Fine white amorphous powder or beads	Odourless, fine, white amorphous powder or as beads
Identification		
Solubility		Insoluble in water
Test for sodium	Passes test	Passes test ^(a)
Test for aluminium	Passes test	Passes test ^(a)
Test for silicate	Passes test	Passes test ^(a)
pH	6.6–11.5 (5% slurry)	6.6–11.5 (5% slurry)
Purity		
Loss on drying	Not more than 8% (105°C, 2 h)	Not more than 8% (105°C, 2 h) ^(a)
Loss on ignition	Not less than 5% and not more than 11% on anhydrous basis (1,000°C to constant weight)	Not less than 5% and not more than 11% on anhydrous basis (1,000°C to constant weight)
Sodium	Not less than 5% and not more than 8.5% (as Na ₂ O) on the anhydrous basis	
Arsenic	Not more than 3 mg/kg	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg	Not more than 1 mg/kg

(a): More information about the test available at JECFA specifications (2017).

The specifications for potassium aluminium silicate (E 555) according to Commission Regulation (EU) No 231/2012 and JECFA (2014) are listed in Table 2.

Table 2: Specifications for potassium aluminium silicate (E 555) according to Commission Regulation (EU) No 231/2012

	Commission Regulation (EU) No 231/2012	JECFA (2014)
Synonyms	Mica	Mica, Muscovite, INS No 555
Definition	Natural mica consists of mainly potassium aluminium silicate (muscovite)	Potassium aluminium silicate is mined from natural sources and then further purified
Chemical name	Potassium aluminium silicate	Potassium aluminium silicate
EINECS No	310-127-6	
CAS No		12001-26-2
Chemical formula	KAl ₂ [AlSi ₃ O ₁₀](OH) ₂	KAl ₂ [AlSi ₃ O ₁₀](OH) ₂ (idealised)
Formula weight		398.31
Assay	Content not less than 98%	Not less than 98%
Description	Light grey to white crystalline platelets or powder	Light grey to white crystalline platelets or powder
Identification		
Solubility	Insoluble in water, diluted acids and alkali and organic solvents	Practically insoluble or insoluble in water, diluted acids and alkali and organic solvents
Test for aluminium and silicon		Passes test

	Commission Regulation (EU) No 231/2012	JECFA (2014)
Purity		
Loss on drying	Not more than 0.5% (105°C, 2 h)	Not more than 0.5% (105°C, 2 h)
Antimony	Not more than 20 mg/kg	Not more than 20 mg/kg
Zinc	Not more than 25 mg/kg	Not more than 25 mg/kg
Barium	Not more than 25 mg/kg	Not more than 25 mg/kg
Chromium	Not more than 100 mg/kg	Not more than 100 mg/kg
Copper	Not more than 50 mg/kg	Not more than 25 mg/kg
Nickel	Not more than 25 mg/kg	Not more than 50 mg/kg
Cadmium	Not more than 1 mg/kg	Not more than 2 mg/kg
Arsenic	Not more than 3 mg/kg	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg	Not more than 1 mg/kg

Based on the EU specifications, the Panel noted that impurities of the toxic elements arsenic, lead and mercury are tolerated up to 3, 5 and 1 mg/kg, respectively, for both sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) (Tables 1 and 2). Cadmium is tolerated up to 1 mg/kg for potassium aluminium silicate (E 555) (Table 2). The overall dietary exposure to these contaminants is close to the health-based guidance values or (lower confidence limits of the) benchmark doses (EFSA CONTAM Panel, 2009a,b, 2012a,b,c, 2014a). Moreover, the Panel noted the high limits for chromium, copper and nickel of 100, 50 and 25 mg/kg for potassium aluminium silicate (E 555), respectively, for which there are health-based guidance values established (EFSA CONTAM Panel, 2014b, 2015; ongoing EFSA assessment on copper⁹). The presence of all these impurities at these levels could have significant impacts on exposures to all these toxic elements from all dietary sources. The panel also noted that the oxidation state is not mentioned for chromium. The Panel further noted that chromium(VI) has been classified by the International Agency for Research on Cancer (IARC) as being carcinogenic to humans (Group 1) (IARC, 1990). Despite the fact that chromium from geological origin is mostly likely chromium(III), the Panel considered that the levels of chromium(VI) should be as low as possible and at least result in an adequate margin of exposure (EFSA, 2005).

The Panel noted that in the EU specifications for E 554, a 'passes test' is requested for sodium, aluminium and silica while the amounts for sodium (as Na₂O), silica (SiO₂) and aluminium (as Al₂O₃) are specified. Therefore, these parameters of 'passes test' are redundant and could be deleted.

3.1.3. Manufacturing process

No information on the manufacturing process of sodium aluminium silicate (E 554) or potassium aluminium silicate (E 555) was submitted or available from the literature.

3.1.4. Methods of analysis in food

No information on a specific method of analysis of both food additives in food was submitted or available from the literature.

3.1.5. Stability of the substances, and reaction and fate in food

No information on the stability of the two additives, and their reaction and fate in food was submitted or available from the literature.

3.2. Authorised uses and use levels

Maximum levels of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) have been defined in Annexes II and/or III to Regulation (EC) No 1333/2008 on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

⁹ <http://registerofquestions.efsa.europa.eu/rqFrontend/questionLoader?question=EFSA-Q-2019-00385>

According to Annex II, sodium aluminium silicate (E 554) is authorised with a maximum permitted level of 20 mg/kg carry over in cheese in the food category (FC) 12.1.1 Salt, with the restriction of 'Only for salt intended for surface treatment of ripened cheese, food category 01.7.2' (Table 3). Potassium aluminium silicate (E 555) is not authorised.

Table 3: MPLs of sodium aluminium silicate (E 554) in food according to Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	E-number/group	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
12.1.1	Salt	E 554	Only for salt intended for surface treatment of ripened cheese, food category 01.7.2	20 mg/kg ^(a) carry over in cheese

MPL: maximum permitted level.

(a): Expressed as aluminium.

According to Annex III, Part 5, section A of Regulation (EC) No 1333/2008, sodium aluminium silicate (E 554) is authorised as a food additive in nutrients except nutrients intended to be used in foods for infants and young children, at a maximum level of 15,000 mg/kg in fat-soluble vitamin preparations.

According to Annex III, Part 1, of Regulation (EC) No 1333/2008, potassium aluminium silicate (E 555) is authorised as a carrier in food additives titanium dioxide (E 171) and iron oxide and hydroxides (E 172) at a maximum level of 90% relative to the pigment.

3.3. Exposure data

3.3.1. Reported use levels or data on analytical levels

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call¹⁰ for occurrence data (use level and/or analytical data) on sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) in food. In response to this call, use levels were made available to EFSA by industry. No analytical data on the concentration of both additives in foods were made available.

Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with 12 use levels of sodium aluminium silicate (E 554). All levels were for food supplements (FC 17) (Appendix A). These use levels were provided by Food Supplements Europe (FSE) and referred to vitamin preparations for use in food supplements. No use levels were reported for FC 12.1.1, the only food category authorised according to Annex II to Regulation (EC) No 1333/2008.

Industry provided EFSA with 18 use levels of potassium aluminium silicate (E 555); however, after inquiry by EFSA, both interested business operators clarified that the reported use levels refer to 'potassium aluminium silicate-based pearlescent pigments' (Documentation provided to EFSA No 1 and 6). These levels were for food supplements; five were reported by FSE and 13 by Association of the European Self-Medication Industry (AESGP) (Appendix A) (see Section 4). The levels provided for the pearlescent pigments are indicated in Appendix A.

3.3.2. Summarised data extracted from the Mintel Global New Products Database

The Mintel GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 3 million food and beverage products of which more than 1,100,000 are or have been available on the European food market. Mintel started covering EU's

¹⁰ <http://www.efsa.europa.eu/sites/default/files/consultation/151012.pdf>

food markets in 1996, currently having 24 out of its 27 member countries and Norway and UK presented in the Mintel GNPD.¹¹

For the purpose of this Scientific Opinion, the Mintel GNPD¹² was used for checking the labelling of food and beverage products and food supplements for sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) within the EU food market as the database contains the compulsory ingredient information on the label.

According to the Mintel GNPD, sodium aluminium silicate (E 554) was labelled on 31 products between January 2015 and April 2020. These products were mainly noodles (n = 9), and vitamin and dietary supplements (n = 5). Some of these foods did not comply with the authorised use of the additive (i.e. in salt on ripened cheeses or in vitamin preparations). This was the case for noodles and snacks mixes as no ripened cheese nor vitamins are present on the ingredients list of these foods.

According to the Mintel GNPD, potassium aluminium silicate (E 555) was labelled on 151 products between January 2015 and April 2020, of which 146 were also labelled with iron oxide (E 172) or titanium dioxide (E 171). In the other five products, four were labelled with other colours. The subcategories with the highest number of food products labelled with aluminium silicate (E 555) were Vitamins & Dietary Supplements (n = 35) and Baking Ingredients & Mixes (n = 30).

Appendix B lists the percentage of the food products labelled with sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) out of the total number of food products per food subcategory according to the Mintel GNPD food classification. The percentages ranged from less than 0.1% in many food subcategories up to 0.9% in the Mintel GNPD food subcategory 'Frozen Desserts' for E 555 and up to 0.8% in the Mintel GNPD food subcategory 'Instants noodles' for E 554. The average percentage of foods labelled to contain sodium aluminium silicate (E 554) or potassium aluminium silicate (E 555) was 0.04% and 0.1% respectively.

3.3.3. Exposure to sodium aluminium silicate (E 554)

As the use of sodium aluminium silicate (E 554) was only reported in food supplements, the Panel only calculated the exposure to this food additive using the "food supplements" consumers only' exposure scenario. The methodology to calculate the exposure using this scenario is described in a statement of the EFSA ANS Panel (2017). As FC 17 Food supplements does not consider food supplements for infants and toddlers as defined in the legislation, exposure to sodium aluminium silicate (E 554) was not estimated for these two population groups.

The exposure estimates are listed in Table 4.

Table 4: Summary of dietary exposure to sodium aluminium silicate (E 554) from its use as a food additive according to the "food supplements" consumers only' exposure scenario in four population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Mean	0.28–2.90	0.22–0.67	0.09–0.70	0.27–0.77
95th percentile	1.04–3.90	0.51–0.85	0.60–3.48	0.82–2.96

bw: body weight.

The Panel considered that the exposure estimates of sodium aluminium silicate (E 554) were an overestimation of the exposure from its use as a food additive according to Annex III because:

- estimates were based on consumers' only of food supplements;
- it was assumed that all food supplements contained E 554, whereas information retrieved from the Mintel GNPD indicated that E 554 is only present in a very few number of the food supplements available on the European market;
- it was assumed that all food supplements consisted for 100% of a fat-soluble vitamin preparation with E 554 present at the highest reported use level.

¹¹ Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.

¹² <http://www.gnpd.com/sinatra/home/> accessed on 15/4/2020

Maximum exposure to aluminium resulting from the use of sodium aluminium silicate (E 554)

The use of sodium aluminium silicate (E 554) as a food additive is expected to contribute to the dietary exposure to aluminium for which a TWI of 1 mg/kg bw per week has been established (EFSA, 2008). As aluminium intakes from the diet may exceed the TWI (EFSA, 2008; Tietz et al., 2019), exposure to aluminium from the use of sodium aluminium silicate (E 554) at the reported use levels was calculated considering that the food additive could contain up to 7.8% of aluminium (from the maximum amount of 15% of Al₂O₃ according to EU specifications (Table 1)).

Based on these assumptions and those listed below Table 4, mean exposure to aluminium for children, adolescents, adults and the elderly would range from 0.05 mg/kg bw per week in adults up to 1.6 mg/kg bw per week in children. High level exposure to aluminium (P95) would range from 0.3 mg/kg bw per week in adolescents up to 2.1 mg/kg bw per week in children.

3.3.4. Exposure to potassium aluminium silicate (E 555)

According to Annex III of Regulation (EC) No 1333/2008, the use of potassium aluminium silicate (E 555) as carrier for titanium dioxide (E 171) and iron oxides and hydroxides (E 172) is permitted at a MPL of 90% relative to the pigment. Therefore, the Panel calculated the regulatory maximum exposure for E 555 as a carrier. However, because of lack of data on use and use levels a refined exposure scenario could not be calculated.

It is not clear what is actually meant by '90% relative to the pigment'. If 'pigment' is considered to be the resulting mixture, this might be a mixture containing 90% E 555 and 10% E 171 (or E 172) (scenario A). If 'pigment' is considered to only refer to E 171 (or E 172), the mixture might contain 90 g (47%) E 555 and 100 g (53%) E 171 (or E 172) (scenario B).

The Panel carried out a calculation of the theoretical regulatory maximum exposure to potassium aluminium silicate (E 555) from its authorised use as a carrier for E 171 based on the two scenarios mentioned above and assuming that E 555 is used always as a carrier for all uses of E 171 (Appendix C). The exposure to titanium dioxide (E 171) was calculated during its re-evaluation as a food additive and the refined non-brand-loyal scenario was considered the most appropriate and realistic scenario for risk characterisation (EFSA ANS Panel, 2016). The results of the exposure to potassium aluminium silicate (E 555) are presented in Appendix C. The Panel emphasises that this is a theoretical calculation.

The Panel noted that additional exposure to potassium aluminium silicate (E 555) would result from the use of E 555 as a carrier for iron oxides and hydroxides (E 172) for which refined exposure was also calculated during its re-evaluation as a food additive (EFSA ANS Panel, 2015). The Panel carried out a calculation of the theoretical regulatory maximum exposure to potassium aluminium silicate (E 555) from its authorised use as a carrier for E 172 based on the two scenarios mentioned above and assuming that E 555 is used always as a carrier for all uses of E 172 (Appendix E). The Panel emphasises that this is a theoretical calculation.

Regulatory maximum exposure to aluminium resulting from the use of potassium aluminium silicate (E 555)

Considering that potassium aluminium silicate (E 555) contains 20.4% aluminium (based on the molecular mass for the chemical formula assigned in the EU specifications (Table 2)), the maximum exposure to aluminium from potassium aluminium silicate (E 555) as a carrier for E 171 was also calculated. Results are presented in Appendix D. The Panel emphasises that this is based on a theoretical calculation. The Panel noted that these maximum exposure estimates exceeded the TWI for aluminium of 1 mg/kg bw per week (see Appendix D).

The Panel noted that an additional aluminium exposure can result from the use of E 555 as carrier for iron oxides and hydroxides (E 172) and that also these maximum exposure estimates exceeded the TWI for aluminium of 1 mg/kg bw per week (see Appendix F).

3.4. Biological and toxicological data

3.4.1. ADME

The data on the toxicokinetics of silicates have been described in the Scientific opinion on the re-evaluation of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii))

and talc (E 553b) as food additives (EFSA ANS Panel, 2018). The following text summarises these data: 'The Panel considered that calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) dissociate to a limited extent in the gastrointestinal tract into silicates and their corresponding cations. Overall, the Panel considered that the silicate anion from calcium silicate or magnesium trisilicate is absorbed to a limited extent in rats with evidence that absorption is saturable. No data were available for magnesium silicate. Based on a 2-year study with calcium silicate incorporated in the diet in rats, the Panel considered that at high doses (up to 5,000 mg/kg bw per day), there is evidence of silicon accumulation in the liver and kidney. The Panel considered that data in humans with magnesium trisilicate indicated that silicate anion is absorbed to a limited extent (less than 5%) similarly to rodents, becomes systemically available and silicon is excreted in the urine. No human data were available for calcium silicate or magnesium silicate. The Panel considered that a read-across approach from magnesium trisilicate was appropriate and considered that silicate anion from both calcium silicate or magnesium silicate would be absorbed and excreted similarly in man'.

In an unpublished study evaluated by EFSA (EFSA, 2011), sodium aluminium silicate was shown in rats to be absorbed to a limited extent at $0.12 \pm 0.011\%$. The Panel considered that potassium aluminium silicate would be absorbed and become systemically available similarly to sodium aluminium silicate.

3.4.2. Toxicological data on sodium aluminium silicate

No new studies were submitted following the call for data.¹³ The data on genotoxicity was available in the previous EFSA evaluation on aluminium (EFSA, 2008). In addition, a prenatal developmental toxicity study was available (FDRL, 1973, Documentation provided to EFSA No 5).

Under REACH toxicological studies for 'silicic acid, aluminium sodium salt', the synonym for sodium aluminium silicate, are listed¹⁴ but the full study reports were not available to EFSA.

Genotoxicity

Bacterial gene mutation assays with sodium aluminium silicate were reported to be negative in the EFSA opinion on the safety of aluminium from dietary intake (EFSA, 2008). The Panel, however, noted that these studies were not fully compliant with the OECD TG 471.

Developmental toxicity

The only available studies for sodium aluminium silicate were prenatal developmental toxicity studies in four species (FDRL, 1973, Documentation provided to EFSA No 5). In all studies described below, body weights were recorded at regular intervals during gestation and all animals were observed daily for appearance and behaviour. All dams were subjected to caesarean section, and the number of implantation sites, resorption sites, live and dead fetuses, and body weights of live fetuses were recorded. All fetuses were examined for sex and for external abnormalities (one-third detailed visceral examination and two-third stained and examined for skeletal defects). For the rabbits, all live pups were placed in an incubator for 24 hours to evaluate the postnatal survival prior to sacrifice. All pups were examined for external, visceral and skeletal abnormalities.

Mice

Groups of pregnant CD-1 mice received on gestation day (GD) 6–15 sodium aluminium silicate (FDA 71-45) at dose levels of 0, 16, 74.3, 345 or 1,600 mg/kg bw per day by gavage (water solution) (FDRL, 1973, Documentation provided to EFSA No 5). Except for the high dose, 24–25 mated females were used of which 21–24 females were pregnant at term. In the high-dose group, 32 females were mated of which 19 females were pregnant at term and 1 female died on GD 16. No explanation for this low number of pregnant females in the high-dose group was presented. Body weight was determined at GD 0, 6, 11, 15 and 17. All dams were subjected to Caesarean section at GD 17. No maternal or developmental toxicity was detected up to the highest dose tested.

Rats

Groups of 21–23 pregnant Wistar rats received on GD 6–15 sodium aluminium silicate via gavage at dose levels of 0, 16, 74.3, 345 or 1,600 mg/kg bw per day (water solution) (FDRL, 1973,

¹³ Call for scientific data on sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) authorised food additives in the EU. Published: 7 November 2018. Available online <https://www.efsa.europa.eu/en/consultations/call/181107>

¹⁴ <https://echa.europa.eu/brief-profile/-/briefprofile/100.014.259>

Documentation provided to EFSA No 5). Body weight was determined at GD 0, 6, 11, 15 and 20. On GD 20 caesarean section was carried out. No treatment-related maternal or developmental toxicity was detected up to the highest dose tested.

Hamsters

Groups of 22 pregnant golden hamsters received on GD 6–10 sodium aluminium silicate via gavage at dose levels of 0, 16, 74.3, 345 or 1,600 mg/kg bw per day (water solution) (FDRL, 1973, Documentation provided to EFSA No 5). Body weight was determined at GD 0, 6, 8, 10 and 14. On GD 14, caesarean section was carried out. There was no evidence for maternal or developmental toxicity up to the highest dose tested.

Rabbits

Groups of 11–23 Dutch belted inseminated rabbits (pregnant n = 10–15/group) received on GD 6–18 sodium aluminium silicate via gavage at dose levels of 0, 16, 74.3, 345 or 1,600 mg/kg bw per day (water solution) (FDRL, 1973, Documentation provided to EFSA No 5). Two does of the 345 mg/kg group died (GD 11 and GD 19), whereas no deaths were recorded in the other groups. Two does of the 345 mg/kg group and one of the 1,600 mg/kg group aborted. The study was terminated by caesarean section on GD 29. No treatment-related effects on the number of corpora lutea, live litters, implantation sites, resorptions, live or dead fetuses or on the fetal weights were detected. Examination of all the fetuses did not reveal a treatment-related increase in abnormalities. The number of neonatal deaths was increased in all test groups. However, it should be noted that the number of does with live litters was low (10, 10, 12, 9 or 13 in the 0, 16, 74.3, 345 or 1,600 mg/kg bw per day groups, respectively) and therefore not reliable for hazard assessment.

Overall, prenatal developmental toxicity studies with sodium aluminium silicate in mice, rats, hamsters and rabbits were available with administration of sodium aluminium silicate from implantation until the end of organogenesis (FDRL, 1973, Documentation provided to EFSA No 5). No treatment-related maternal and developmental effects were observed at the highest dose level of 1,600 mg/kg bw per day in rats and hamsters. In the study in mice, a high number of unexplained non-pregnant females were observed and the number of pregnant rabbits at term was insufficient for a reliable hazard assessment. Reporting of the prenatal developmental studies was limited.

3.4.3. Toxicological data on potassium aluminium silicate

No biological and toxicological data after oral administration of potassium aluminium silicate were submitted or available from the literature.

4. Potassium aluminium silicate-based pearlescent pigments

According to the interested business operators, potassium aluminium silicate is only used for the manufacturing process of a group of 'pearl pigments' (Documentation provided to EFSA No 2 and 3). Pearlescent pigments are prepared by precipitation of an inorganic metal oxide/hydroxide onto platelet-shaped substrates followed by calcination. These substrates may consist of natural or synthetic mica, glass flakes, silica flakes, alumina flakes or other platelets (Documentation provided to EFSA No 2). The components of the 'potassium aluminium silicate-based pearlescent pigments' – potassium aluminium silicate, titanium dioxide or iron oxides – are bound to each other by strong physical forces and cannot be separated from each other by standard methods. Potassium aluminium silicate (E 555) in a single, pure form is not used as a food additive (Documentation provided to EFSA No 3).

According to Regulation (EC) No 231/2012, platelet forms of rutile titanium dioxide (E 171) are produced using mica that has to be removed later during the manufacturing process, and therefore, the description of pearlescent pigments, based on potassium aluminium silicate coated with titanium dioxide, is not covered by the definition of titanium dioxide (E 171) as a food additive.

JECFA (2013) established specifications for 'potassium aluminium silicate-based pearlescent pigments' under the INS number 176. These pigments are described as potassium aluminium silicate (mica) coated with titanium dioxide or iron oxides or both (JECFA, 2013).

Potassium aluminium silicate (E 555) is only authorised in the EU as a carrier for the food additives titanium dioxide (E 171) and iron oxides (E 172) according to Annex III of Regulation (EC) No 1333/2008.

The interested business operators indicated that 'the specific pearl effect of these pigments is generated by the difference of the refractive indices of the combined ingredients with their specific pearlescent effect being created at their interfaces. The thickness of titanium dioxide and/or iron oxide

coating can be modified resulting in different colour shades. These colours shades depend on the thickness of the applied layer of the colorant and are not created or influenced by the mica'. The presence of mica determines the physical form or shape of the final pearlescent pigment effect and contributes the necessary interface. The interested business operators stated that 'without mica, a pearlescent effect is absent. The colour of the pearlescent effect could not be achieved without titanium dioxide or iron oxide' (Documentation provided to EFSA No 3).

The description of the technological role of mica in 'potassium aluminium silicate-based pearlescent pigments' does not meet the definition of 'carrier'¹⁵ according to Regulation (EC) No 1333/2008. The Panel therefore considered that 'potassium aluminium silicate-based pearlescent pigments' is a new entity, not listed in the Regulation (EC) No 1333/2008 and not previously evaluated in the EU. Therefore, 'potassium aluminium silicate-based pearlescent pigments' should be considered as a new food additive.

Interested business operators stated that 'potassium aluminium silicate-based pearlescent pigments' (e.g. potassium aluminium silicate coated with titanium dioxide) used on a food product is labelled as E 171 or titanium dioxide. Therefore, it is not possible to differentiate from the labelling if pure titanium dioxide pigment for whitening purposes or a titanium dioxide containing pearlescent colour for decoration is used in a food product (Documentation provided to EFSA No 3).

Information on the manufacturing process of 'potassium aluminium silicate-based pearlescent pigments' from raw mica indicate that after calcination, grinding and sorting according to particle size, it is transformed to purified mica. Inorganic oxides/hydroxides (from titanium (IV), iron (II), iron (III) or mixed iron (II/III)) are precipitated onto this platelet-shaped substrate. For certain products, more than one layer of oxides/hydroxides can be applied. These layers may be separated by silica layers or may follow directly on each other. The coated product is dried and then again subjected to calcination (500–900°C).

Several analytical reports of the analysis of the particle size of different 'potassium aluminium silicate-based pearlescent pigments' by laser diffraction (LD), transmission electron microscopy (TEM), scanning electron microscopy (SEM) or 3D laser scanning microscopy were submitted and the analysis was focused on the measurement of the flake of potassium aluminium silicate (particle size usually more than 5 µm). However, no information on the particle size of the inorganic oxide(s) – titanium dioxide or iron oxide – coated has been provided (Documentation provided to EFSA No 2 and 3). The Panel noted that analyses of samples named as 'additive mixture of E 171 with E 555' has shown that the material consists of mica platelets coated with titanium dioxide particles with a median particle size in the nano range (20–30 nm) (Otmar et al., 2019; Verleysen et al., 2020). These data indicate that if some detachment of inorganic oxides from the mica substrate occurs, this could result in exposure to nano particles of the inorganic oxides.

5. Discussion

No information on the physicochemical characterisation of sodium aluminium silicate when used as a food additive E 554 has been submitted. Only developmental toxicity studies with sodium aluminium silicate in mice, rats, hamsters and rabbits were available. No treatment-related maternal and developmental effects were observed. The reporting of the prenatal developmental studies was too limited to allow the use of data for hazard assessment.

No information on the physicochemical characterisation of potassium aluminium silicate when used as a food additive E 555 has been submitted and no toxicological data were available.

Only use levels for sodium aluminium silicate (E 554) in food supplement (FC 17) were available. The exposure to E 554 based on the reported use levels could be up to 2.9 mg/kg bw per day at the mean level and 3.9 mg/kg bw per day at the high intake level (P95), both in children. In this assessment, it was assumed that all food supplements consumed contained sodium aluminium silicate (E 554) at the highest reported use level.

Considering that, based on the maximum amount of Al₂O₃ in E 554 as stated in the EU specifications (Table 1), sodium aluminium silicate (E 554) contains up to 7.8% aluminium, the maximum exposure to aluminium from the use of E 554 could be up to 1.58 mg/kg bw per week at the mean and up to 2.13 mg/kg bw per week at the P95 for children. This alone would exceed the TWI of 1 mg/kg bw per week for dietary aluminium from all sources established by EFSA (EFSA, 2008).

¹⁵ Carriers' are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use.

Based on the data provided by interested business operators, the Panel considered that E 555 is not being used as a carrier but as an inseparable component of 'potassium aluminium silicate-based pearlescent pigments'. According to the Mintel GNPD, E 555 was labelled on 151 products, of which 146 were also labelled with iron oxide (E 172) or titanium dioxide (E 171).

Based on the current authorisation for E 555 as a carrier for titanium dioxide (E 171) and iron oxides and hydroxides (E 172) with a maximum level of '90% relative to the pigment' (Annex III of Regulation 1333/2008), the Panel calculated the theoretical regulatory maximum exposure to E 555 from this authorised use (see Appendices C and E). Considering that potassium aluminium silicate (E 555) contains 20.4% aluminium (based on the molecular mass), the maximum exposure to aluminium from potassium aluminium silicate (E 555) as carrier for E 171 could be up to 388 mg/kg bw per week and the maximum exposure to aluminium from potassium aluminium silicate (E 555) as carrier for E 172 could be up to 297 mg/kg bw per week. The Panel noted that this single use at the maximum permitted level could theoretically far exceed the TWI for dietary aluminium from all sources established by EFSA (2008) (see Appendix D). The assumption that E 555 is always used as a carrier for E 171 and E 172 results in an overestimation of exposure to aluminium. However, even if it were used only in 50% of the cases as carrier and even if only the mean intake of E 171 or E 172 of the non-brand-loyal scenario were considered, an exceedance of the TWI could be possible. The Panel emphasises that these are theoretical calculations and data would be needed in order to perform a realistic exposure assessment.

No information on the physicochemical characterisation of sodium aluminium silicate and potassium aluminium silicate when used as food additives has been submitted and only very limited toxicological data were available for sodium aluminium silicate. Therefore, a risk assessment could not be performed for these food additives.

According to the interested business operators, potassium aluminium silicate is only used for the manufacturing of a group of 'pearl pigments' (Documentation provided to EFSA No 2 and 3). The Panel noted that potassium aluminium silicate in 'potassium aluminium silicate-based pearlescent pigments' does not meet the definition of a carrier according to Regulation (EC) 1333/2008 and 'potassium aluminium silicate-based pearlescent pigments' are not listed in Regulation (EC) 1333/2008. Therefore 'potassium aluminium silicate-based pearlescent pigments' have not been considered in the current evaluation.

6. Conclusions

Considering that only very limited toxicological data and insufficient information on the physicochemical characterisation of both food additives were available, the Panel concluded that the safety of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) could not be assessed.

According to the interested business operators, potassium aluminium silicate is only used for the manufacturing of a group of 'potassium aluminium silicate-based pearlescent pigments'. The Panel concluded that potassium aluminium silicate in 'potassium aluminium silicate-based pearlescent pigments' does not meet the definition of a carrier according to Regulation (EC) 1333/2008 and 'potassium aluminium silicate-based pearlescent pigments' are not listed in Regulation (EC) 1333/2008. The Panel also concluded that 'potassium aluminium silicate-based pearlescent pigments' should be evaluated as a new food additive.

7. Recommendations

The Panel recommended that:

- data in line with the current Guidance document on evaluation of food additives (EFSA ANS Panel, 2012) is required for E 554 and E 555 to perform the risk assessment of these food additives and evaluate the potential exceedance of the TWI for aluminium resulting from the use of both food additives.

Documentation provided to EFSA

- 1) Association of the European Self-Medication Industry (AESGP), 2017. Data on use levels of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) in foods in response to the EFSA call for food additives usage level and/or concentration data in food

- and beverages intended for human consumption (2017). Submitted to EFSA on 31 January 2017. Further clarifications submitted between October 2019 and February 2020.
- 2) Data submitted in response to the EFSA call for scientific data on sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) authorised food additives in the EU (2018). Submitted by Merck on 2 October 2019.
 - 3) Data submitted in response to the EFSA call for scientific data on sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) authorised food additives in the EU (2018). Submitted by Zucceroo GmbH on 8 October 2019.
 - 4) Personal communication to EFSA from CEFIC following the EFA call for data (2018) to inform that their Sector Groups have no interest in supporting the use of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) in food, December 2018.
 - 5) FDRL (Food and Drug Research:Laboratories), 1973. Teratologic Evaluation of FDA 71-45 (Sodium Silicoaluminate). Report No. FDABF-GRAS-129. Submitted by the FDA, July 2017.
 - 6) Food Supplements Europe (FSE), 2017. Data on use levels of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2017). Submitted to EFSA on 1 February 2017. Further clarifications submitted between October 2019 and March 2020.

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Abbreviations

AESGP	Association of the European Self-Medication Industry
ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
CONTAM	EFSA Panel on Contaminants
EINECS	European Inventory of Existing Commercial Chemical Substances
FAF	EFSA Panel on Food Additives and Flavourings
FDA	Food and Drug Administration
FDRL	Food and Drug Research Laboratories
FSE	Food Supplements Europe
GD	gestation day

GNPD	Global New Products Database
IARC	International Agency for Research on Cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LD	laser diffraction
NOAEL	no observed adverse effect level
MPL	maximum permitted level
OECD	Organisation for Economic Co-operation and Development
PTWI	provisional tolerable weekly intake
SEM	scanning electron microscopy
SCF	Scientific Committee on Food
TEM	transmission electron microscopy
TWI	tolerable weekly intake

Appendix A – Summary of reported use levels (mg/kg or mg/L as appropriate) of sodium aluminium silicate (E 554) and potassium aluminium silicate-based pearlescent pigments provided by industry

Table A.1: Sodium aluminium silicate (E 554)

Food category number	Food category name	E-number	MPL	Number of samples	Mean of typical usage levels	Minimum of typical usage levels	Maximum of typical usage levels	Maximum usage level	Comments, restrictions	Provided by
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	E 554	15,000	12	4,633	3,000	8,000	–		FSE

MPL: maximum permitted level; FSE: Food Supplements Europe.

Table A.2: Potassium aluminium silicate-based pearlescent pigments

Food category number	Food category name	E-number	MPL	Number of samples	Mean of typical usage levels	Minimum of typical usage levels	Maximum of typical usage levels	Maximum usage level	Comments, restrictions	Provided by
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	Both interested parties clarified that the reported use levels refer to potassium aluminium silicate-based pearlescent pigments and not to E 555 which is not used as such		5	1,788	100	3,628	2,351	Potassium aluminium silicate is part of the pearlescent pigments preparation and are not added as such to the products	FSE
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms			13	4,504	100	5,714	6,286	All carriers, typical usage level = 90% relative to the pigment	AESGP

MPL: maximum permitted level; FSE: Food Supplements Europe; AESGP: Association of the European Self-Medication Industry.

Appendix B – Number and percentage of food products labelled with sodium aluminium silicate (E 554) or potassium aluminium silicate (E 555) out of the total number of food products present in the Mintel GNPD per food subcategory between 2015 and 2020

Table B.1: Food products labelled with potassium aluminium silicate (E 555)

Mintel subcategory ^(a)	Total number of products	Products labelled with potassium aluminium silicate (E 555)	
		Number	%
Frozen Desserts	1,261	11	0.9
Vitamins & Dietary Supplements	10,973	35	0.3
Baking Ingredients & Mixes	9,481	30	0.3
Non-Individually Wrapped Chocolate Pieces	6,242	17	0.3
Sucrose	1,214	2	0.2
Liquorice	701	1	0.1
Cakes, Pastries & Sweet Goods	14,328	19	0.1
Seasonal Chocolate	8,598	10	0.1
Water Based Ice Lollies, Pops & Sorbets	1,075	1	0.1
Snack Mixes	2,203	2	0.1
Other Sugar Confectionery	1,300	1	0.1
Pastilles, Gums, Jellies & Chews	4,436	3	0.1
Dairy Based Ice Cream & Frozen Yogurt	7,340	4	0.1
Meal Replacements & Other Drinks	3,705	2	0.1
Potato Snacks	5,844	3	0.1
Toffees, Caramels & Nougat	2,065	1	0.0
Chilled Desserts	5,560	2	0.0
Sweet Biscuits/Cookies	19,203	4	0.0
Seasonings	9,477	1	0.0
Tea	9,709	1	0.0
Coffee	10,045	1	0.0
Total sample^(b)	134,760	151	0.1

GNPD: Global New Products Database.

(a): According to the Mintel GNPD food categorisation.

(b): In total, around 0.1% of the foods available on the Mintel GNPD were labelled with E 555 between January 2015 and April 2020.

Table B.2: Food products labelled with sodium aluminium silicate (E 554)

Mintel sub-category ^(a)	Total number of products	Products labelled with sodium aluminium silicate (E 554)	
		Number	%
Instant Noodles	1,101	9	0.8
Rice Snacks	595	2	0.3
Malt & Other Hot Beverages	1,061	2	0.2
Snack Mixes	2,203	2	0.1
Frozen Desserts	1,261	1	0.1
Meat Pastes & Pates	2,680	2	0.1
Dry Soup	1,445	1	0.1
Vitamins & Dietary Supplements	10,973	5	0.0
Meal Replacements & Other Drinks	3,705	1	0.0

Mintel sub-category ^(a)	Total number of products	Products labelled with sodium aluminium silicate (E 554)	
		Number	%
Hors d'oeuvres/Canapes	3,875	1	0.0
Coffee	10,045	2	0.0
Poultry Products	8,717	1	0.0
Tea	9,709	1	0.0
Meat Products	20,909	1	0.0
Total sample^(b)	78,279	31	0.04

GNPD: Global New Products Database.

(a): According to the Mintel GNPD food categorisation.

(b): In total, around 0.04% of the foods available on the Mintel GNPD were labelled with E 554 between January 2015 and April 2020.

Appendix C – Regulatory maximum exposure to potassium aluminium silicate (E 555) used as carrier for E 171 based on the provisions of Regulation (EC) No 1333/2008

Titanium dioxide (E 171) can be used at *quantum satis* in many food categories according to Annex II to Regulation (EC) No 1333/2008. The refined exposure estimates for titanium dioxide (E 171) performed by EFSA (EFSA ANS Panel, 2016) are summarised for all age groups in Table C.1. Children had the highest exposure to E 171. Therefore, the Panel calculated the regulatory maximum exposure to potassium aluminium silicate (E 555) resulting from its use as a carrier for titanium dioxide (E 171) based on the exposure of children to E 171 (EFSA ANS Panel, 2016).

Table C.1: Exposure to E 171 for all age groups (min–max across dietary surveys) and for children (min–max across dietary surveys) (EFSA ANS Panel, 2016)

Scenario		Range for all age groups (mg/kg bw per day)	Children (mg/kg bw per day)
Brand-loyal scenario	Mean	0.4–8.8	1.5–8.8
	95th percentile	1.1–30.2	4.1–30.2
Non-brand-loyal scenario	Mean	0.2–5.5	0.9–5.5
	95th percentile	0.5–14.8	2.4–14.8

bw: body weight.

Scenario A

If potassium aluminium silicate (E 555) is used as a carrier for E 171 at the maximum level of 90% (relative to the pigment) in all cases in which E 171 is used as a food additive and assuming that the resulting mixture contains 90% E 555 and 10% E 171, the regulatory maximum exposure would be 9-fold higher for E 555 than for E 171 (Table C.2).

Table C.2: Regulatory maximum exposure to E 555 for children from its use as carrier for E 171 assuming that the pigment contains 90% E 555 and 10% E 171 (min – max across dietary surveys) (*scenario A*)

Scenario		Exposure to E 555 (mg/kg bw per day)
Brand-loyal scenario	Mean	13.5–79.2
	95th percentile	36.9–271.8
Non-brand-loyal scenario	Mean	8.1–49.5
	95th percentile	21.6–133.2

bw: body weight.

Scenario B

If potassium aluminium silicate (E 555) were used as a carrier for E 171 at the maximum level of 90% (relative to the pigment) in all cases in which E 171 is used as a food additive and assuming the resulting mixture contains 90 g E 555 and 100 g E 171, the regulatory maximum exposure to E 555 would be 90% of the exposure estimated for E 171 (Table C.3).

Table C.3: Regulatory maximum exposure to E 555 for children from its use as carrier for E 171 assuming that the pigment contains 90 grams E 555 and 100 g E 171 (min – max across dietary surveys) (*scenario B*)

Scenario		Exposure to E 555 (mg/kg bw per day)
Brand-loyal scenario	Mean	1.35–7.92
	95th percentile	3.69–27.18
Non-brand-loyal scenario	Mean	0.81–4.95
	95th percentile	2.16–13.32

bw: body weight.

Appendix D – Regulatory maximum exposure to aluminium from the use of potassium aluminium silicate (E 555) as a carrier for E 171 based on the provisions of Regulation (EC) No 1333/2008

Regulatory maximum exposure to aluminium from the use of potassium aluminium silicate (E 555) as a carrier for E 171 was calculated for children (for which the exposure to E 171 was higher than for other age groups) considering the food additive contains 20.4% aluminium (based on the molecular mass). The exposure was calculated for both scenarios and results are given in Table D.1.

Table D.1: Regulatory maximum exposure to aluminium for children from the use of E 555 as carrier for E 171 (min–max across dietary surveys) (*Scenario A and B*)

		Exposure to aluminium	
		mg/kg bw per day	mg/kg bw per week
Scenario A			
Brand-loyal scenario	Mean	2.7–16.1	19.3–113.1
	95th percentile	7.5–55.4	52.7–388.1
Non-brand-loyal scenario	Mean	1.6–10.1	11.6–70.7
	95th percentile	4.4–27.2	30.8–190.2
Scenario B			
Brand-loyal scenario	Mean	0.2–1.6	1.9–11.3
	95th percentile	0.7–5.5	5.3–38.8
Non-brand-loyal scenario	Mean	0.2–1.0	1.2–7.1
	95th percentile	0.4–2.7	3.1–19.0

bw: body weight.

Appendix E – Regulatory maximum exposure to potassium aluminium silicate (E 555) used as carrier for E 172 based on the provisions of Regulation (EC) No 1333/2008

Iron oxides and hydroxides (E 172) can be used at *quantum satis* in many food categories according to Annex II to Regulation (EC) No 1333/2008. The refined exposure estimates for iron oxides and hydroxides (E 172) performed by EFSA (EFSA ANS Panel, 2015) are summarised for all age groups in Table E.1. Toddlers had the highest exposure to E 172. Therefore, the Panel calculated the regulatory maximum exposure to potassium aluminium silicate (E 555) resulting from its use as a carrier for iron oxides and hydroxides (E 172) based on the exposure of toddlers to E 172 (EFSA ANS Panel, 2015).

Table E.1: Exposure to E 172 for all age groups (min–max across dietary surveys) and for toddlers (min–max across dietary surveys) (EFSA ANS Panel, 2015)

Scenario		Range for all age groups (mg/kg bw per day)	Toddlers (mg/kg bw per day)
Brand-loyal scenario	Mean	0.1–8.9	0.4–8.9
	95th percentile	0.2–23.1	1.6–23.1
Non-brand-loyal scenario	Mean	0.03–3.7	0.2–3.7
	95th percentile	0.1–9.5	0.7–9.5

bw: body weight.

Scenario A

If potassium aluminium silicate (E 555) is used as a carrier for E 172 at the maximum level of 90% (relative to the pigment) in all cases in which E 172 is used as a food additive and assuming that the resulting mixture contains 90% E 555 and 10% E 172, the regulatory maximum exposure would be 9-fold higher for E 555 than for E 172 (Table E.2).

Table E.2: Regulatory maximum exposure to E 555 for toddlers from its use as carrier for E 172 assuming that the pigment contains 90% E 555 and 10% E 172 (min–max across dietary surveys) (*scenario A*)

Scenario		Exposure to E 555 (mg/kg bw per day)
Brand-loyal scenario	Mean	3.6–80.1
	95th percentile	14.4–207.9
Non-brand-loyal scenario	Mean	1.8–33.3
	95th percentile	6.3–85.5

bw: body weight.

Scenario B

If potassium aluminium silicate (E 555) were used as a carrier for E 172 at the maximum level of 90% (relative to the pigment) in all cases in which E 172 is used as a food additive and assuming the resulting mixture contains 90 g E 555 and 100 g E 172, the regulatory maximum exposure to E 555 would be 90% of the exposure estimated for E 172 (Table E.3).

Table E.3: Regulatory maximum exposure to E 555 for toddlers from its use as carrier for E 172 assuming that the pigment contains 90 grams E 555 and 100 g E 172 (min–max across dietary surveys) (*scenario B*)

Scenario		Exposure to E 555 (mg/kg bw per day)
Brand-loyal scenario	Mean	0.36–8.01
	95th percentile	1.44–20.79
Non-brand-loyal scenario	Mean	0.18–3.33
	95th percentile	0.63–8.55

bw: body weight.

Appendix F – Regulatory maximum exposure to aluminium from the use of potassium aluminium silicate (E 555) as a carrier for E 172 based on the provisions of Regulation (EC) No 1333/2008

Regulatory maximum exposure to aluminium from the use of potassium aluminium silicate (E 555) as a carrier for E 172 was calculated for toddlers (for which the exposure to E 172 was higher than for other age groups) considering the food additive contains 20.4% aluminium (based on the molecular mass). The exposure was calculated for both scenarios and results are given in Table F.1.

Table F.1: Regulatory maximum exposure to aluminium for toddlers from the use of E 555 as carrier for E 172 (min–max across dietary surveys) (*Scenario A and B*)

		Exposure to aluminium	
		mg/kg bw per day	mg/kg bw per week
Scenario A			
Brand-loyal scenario	Mean	0.7–16.3	5.1–114.4
	95th percentile	2.9–42.4	20.6–296.9
Non-brand-loyal scenario	Mean	0.4–6.8	2.6–47.6
	95th percentile	1.3–17.4	9.0–122.1
Scenario B			
Brand-loyal scenario	Mean	0.1–1.6	0.5–11.4
	95th percentile	0.3–4.2	2.1–29.7
Non-brand-loyal scenario	Mean	0.0–0.7	0.3–4.8
	95th percentile	0.1–1.7	0.9–12.2

bw: body weight.