Safety of mineral salt containing potassium and magnesium as a novel food pursuant to Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA)

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SCIENTIFIC OPINION

Safety of mineral salt containing potassium and magnesium as a novel food pursuant to Regulation (EU) 2015/2283

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on a mineral salt, containing potassium and magnesium, as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF is a mineral salt that consists mainly of magnesium potassium trichloride hexahydrate. The information provided on the composition is sufficient for characterising the NF and does not raise safety concerns. The production process is sufficiently described and does not raise safety concerns. The NF is intended to be added to meat, sausages and dishes based on pasta, rice and other cereals. Taking into account the composition of the NF and the proposed use and use levels, the Panel considers that the consumption of the NF is not nutritionally disadvantageous. Regarding the presence of bromide in the NF, the Panel notes that the combined daily intake of bromide from the NF and the background diet does not exceed the tolerable daily intake of bromide of 0.4 mg/kg body weight (bw) per day. Based on its physicochemical characteristics and solubility data, the NF is expected to be dissociated in the gastrointestinal tract. Taking into account the composition and the nature of the NF, the Panel considers that no toxicological studies with the NF are required. The Panel concludes that the NF (i.e. a mineral salt containing potassium and magnesium) is safe under the proposed conditions of use.

KEYWORDS

magnesium, mineral salt, novel food, potassium, safety

CONTENTS

1 | INTRODUCTION

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

On 21 December 2018, the company BK Guilini GmbH (member of the ICL group) submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283[1] to authorise placing on the market a mineral salt containing potassium and magnesium as a Novel Food (NF). The applicant requests to authorise the use of a mineral salt containing potassium and magnesium in a number of foods. The target population is adults and elderly people. The applicant has not requested data protection under Article 26 of Regulation (EU) 2015/2283.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority (EFSA) to provide a scientific opinion on the safety of a mineral salt containing potassium and magnesium as a NF.

2 | DATA AND METHODOLOGIES

2.1 | Data

The safety assessment of this NF is based on data supplied in the application and information submitted by the applicant following EFSA's requests for supplementary information.

During the assessment, the Panel identified additional data which were not included in the application.

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in Commission Implementing Regulation (EU) 2017/2469.[2]

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all available (proprietary, confidential and published) scientific data (including both data in favour and not in favour) that are pertinent to the safety of the NF.

During the assessment, the applicant requested data protection in accordance with Article 26 of Regulation (EU) 2015/2283 for information on the production process and composition. The data requested by the applicant to be protected are listed in Appendix A.

2.2 | Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3 | ASSESSMENT

3.1 | Introduction

The NF which is the subject of this application is a mineral salt, which mainly consists of magnesium potassium trichloride hexahydrate. The NF falls under the category of 'food consisting of, isolated from or produced from material of mineral origin' (Art. 3 (2) (a) (iii)). The NF is produced by a multi-step crystallisation process of seawater from the Dead Sea by solar evaporation. The NF is intended to be added to meat, sausages, pasta-based dishes, rice-based dishes and other cereal based-dishes.

3.2 | Identity of the NF

The NF is a natural mixture of mineral salts, which mainly consists of magnesium potassium trichloride hexahydrate (CAS No. 1318-27-0; chemical formula: $KMgCl_3{\cdot}6H_2O$ or $KCl.MgCl_2{\cdot}6H_2O$; molecular weight: 277.85; synonyms: carnallite, magnesium potassium trichloride hydrate).

In order to characterise the saline structure of the NF, infrared spectra were performed on three batches of the NF. X-ray diffraction spectroscopy was applied to six batches of the NF to determine the composition of the crystals of the NF. These

[1]Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 concerning novel foods. OJ L 327, 11.12.2015, pp. 1–22.

[2]Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

analyses showed that magnesium potassium trichloride hexahydrate ($KMgCl_3.6H_2O$) amounted to 80%–93% in the batches tested. The other salts identified in these batches were magnesium chloride hexahydrate ($MgCl_2.6H_2O$) (3%–16%), sodium chloride (NaCl) (2%–5%) and magnesium chloride ($MgCl_2$), which was detected only in one batch (1%).

3.3 | Production process

The NF is produced by solar evaporation of water exclusively originating from the Dead Sea in Israel through a series of evaporation ponds. The process is based on precipitation of minerals, dredging the minerals by large, auger-style dredges, and processing them into the final product. The NF is produced in a discontinuous process about four to six times a year, each process lasting about 5 days.

Dead Sea brines are pumped into the first of a series of so-called 'salt ponds', where solar evaporation results in the precipitation of NaCl. Subsequently, the resulting brine is pumped into a series of ponds called 'carnallite ponds'. In these ponds, the solution is further concentrated via solar evaporation, and carnallite crystallises and precipitates. Carnallite is mechanically 'harvested' from the bottom of the ponds and transferred to the food grade salt plant where the damp crystals are sieved. The final material is stored in silos and packed in polyethylene (PE) bags.

According to the information provided, the NF is produced in line with good manufacturing practice and hazard analysis critical control points principles.

The Panel considers that the production process is sufficiently described and does not raise safety concerns.

3.4 | Compositional data

The NF mainly consists of magnesium potassium trichloride hexahydrate. In order to confirm that the manufacturing process is reproducible and adequate to produce the NF on a commercial scale, the applicant provided analytical information for up to six batches of the NF (Tables 1 and 2). The applicant also tested up to six batches of the NF for several metals and other elements, which may be present in the seawater of the Dead Sea (Table 3). Upon EFSA's request for additional information, the applicant investigated the possible formation of bromate (BrO_3^-) in the NF which may be formed by reaction of bromide and ozone. The analysis provided by the applicant showed that bromate was below the limit of quantification (LOQ < 1 mg/kg) in all three analysed batches of the NF.

The batches were also tested for pesticides, polycyclic aromatic hydrocarbons, dioxins and dioxin-like polychlorinated biphenyls, which were all found to be below LOQs.

The applicant provided information on the accreditation of the laboratories which conducted the analyses presented in this application.

TABLE 1 Batch to batch analysis of the NF.

Parameter	Batch 1	Batch 2	Batch 3	Batch 7	Batch 8	Batch 9	Method of analysis
Potassium (g/100 g)	11.3	11.5	11.7	11.8	12.1	12.5	Batches 1, 2, 3: ICP-OES (according to DIN EN ISO 11885:2009–09) Batches 7, 8, 9: ICP-MS (according to DIN EN ISO 17294-2)
Magnesium (g/100 g)	8.0	8.2	8.5	9.2[b]	9.2[b]	8.9	
Calcium (g/100 g)	0.068	0.070	0.076	0.110	0.116	0.064	
Sodium (g/100 g)	2.00	1.76	2.09	2.37	1.91	2.25	
Chloride (g/100 g)	41.3	41.3	40.2	(–)	(–)	(–)	§ 64 LFGB L 17.00–6: 1988–12 (potentiometric titration)
Bromine (total) (g/100 g)	0.43	0.42	0.42	0.416[c] 0.381[d]	0.415[c] 0.418[d]	0.431[c] 0.397[d]	Batches 1, 2, 3: ICP-MS Batches 7, 8, 9[c,d]
Bromide (Br^-) (g/100 g)	(–)	(–)	(–)	0.40	0.35	0.39	Ion-chromatography (according to DIN EN ISO 10304-1:2009–07)
Total water at 180°C (water of crystallisation plus moisture) (g/100 g)	36.2[e]	36.3[e]	36.4[e]	(–)	(–)	(–)	Gravimetric method
Carnallite (g/100 g)	94.13	94.94	91.73	(–)	(–)	(–)	Calculated[a]

Note: (–) not tested or not calculated.

Abbreviations: DIN, Deutsches Institut für Normung (German Institute for Standardization); EN, Europäische Norm (European Standard); ICP-MS, Inductively Coupled Plasma Mass Spectrometry; ICP-OES, Inductively Coupled Plasma Optical Emission Spectrometry; ISO, International Organization for Standardization; LFGB, Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (German Food, Articles of Daily Use and Feed Code).

[a]Carnallite calculated from ion analysis and gravimetry only = 100 – (%NaCl + %$CaCl_2$ + SO_4^{2-} + Br^- + %insoluble).

[b]This value exceeds the limit listed in the specifications (Table 4).

[c]Results obtained with X-ray (according to DIN 51418-2).

[d]Results obtained with ICP-MS (according to DIN EN ISO 17294-2).

[e]Total water at 180°C was measured in three other batches.

TABLE 2 Physicochemical and microbiological parameters of the NF.

	Batch 1	Batch 2	Batch 3	Method of analysis
Appearance and smell	**White dry granules without a specific smell**			
Moisture (g/100 g)	1.5	3.2	0.8	64 LFGB L 17.00–1: 1982–05
Ash (g/100 g)	60.5	60.2	58.7	64 LFGB L 17.00–3: 1982–05
Ash, HCl-insoluble (g/100 g)	1.7	2.3	2.2	64 LFGB L 53.00–4: 1996–02
Insoluble parts (cold water) (g/100 g)	< 1.0	< 1.0	< 1.0	HH-MA-M 10–004: 2016–10
Insoluble parts (boiling water) (g/100 g)	0.25	0.35	0.33	ISO 2479: 1972–12
Acid insoluble parts (g/100 g)	< 0.05	< 0.05	< 0.05	ISO 2479: 1972–12
Water activity (aw-value) (25°C)	0.024 ± 0.001[a]	0.026 ± 0.001[a]	0.027 ± 0.001[a]	ISO 18787
Relative density	1.662	1.665	1.666	2011–0335202-04D
Melting point, onset°C	151.9	152.7	151.9	2011–0353502-03D – Ph.Eur. 9.5
Protein, N x F: 6.25 (g/100 g)	< 0.1	< 0.1	< 0.1	§ 64 LFGB L 17.00–15: 2013–08
Total organic carbon (%)	< 0.10	< 0.10	< 0.10	ISO 10694: 1995–03
Extractable organic halides (mg/kg)	< 1.0	< 1.0	< 1.0	DIN 38409–8 (H8): 1984–09
Total Plate Count (CFU/g)	< 10	< 10	< 10	DIN EN ISO 4833-1: 2013–12
Coliforms (CFU/g)	< 10	< 10	< 10	ISO 4832: 2006–02
E. coli (in 1 gram)	Not detected	Not detected	Not detected	Ph. Eur. 2.6.13: 2010–04
Staphylococci. coag. positive (CFU/g)	< 10	< 10	< 10	DIN EN ISO 6888-1: 2003–12
Salmonella (in 25 gram)	Not detected	Not detected	Not detected	64 LFGB L 00.00–20: 2008–12
Halotolerant bacteria (CFU/g)	< 100	< 100	< 100	MB Bd. VI 7.22.2, 7. Erg. 2010

Abbreviations: CFU, colony forming units; DIN, Deutsches Institut für Normung; DIN EN ISO, Deutsches Institut für Normung, Europäische Norm, International Organization for Standardization; F, factor; HH, Headspace Analysis; LFGB, Lebensmittel-Bedarfsgegenstände- und Futtermittelgesetzbuch (German Food, Articles of Daily Use and Feed Code); MA, Mass Spectrometry Analysis; N, nitrogen; Ph. Eur., Pharmacopoeia Europaea (European Pharmacopoeia).

[a]Water activity was measured in three other batches.

TABLE 3 Batch-to batch analyses for metals and other elements in the NF.

Parameter	Batch 1	Batch 2	Batch 3	Batch 7	Batch 8	Batch 9	Method of analysis
Aluminium (mg/kg)	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	DIN EN15763, mod., ICP-MS: 2010–04
Ammonium (% w/w)	< 0.02	< 0.02	< 0.02	(–)	(–)	(–)	2011–0589701-00D (ion selective electrode)
Antimony (mg/kg)	< 0.050	< 0.050	< 0.050	(–)	(–)	(–)	DIN EN 15763, mod., ICP-MS: 2010–04
Arsenic (mg/kg)	< 0.040	< 0.040	< 0.040	(–)	(–)	(–)	DIN EN ISO 15763, ICP-MS: 2010–04
Barium (mg/kg)	0.22	0.22	0.26	0.27	0.24	0.15	DIN EN 15763, mod., ICP-MS: 2010–04
Bismuth (mg/kg)	< 0.50	< 0.50	< 0.50	(–)	(–)	(–)	DIN EN ISO 17294-2 (E29), ICP-MS:2017–01
Boron (mg/kg)	< 10	< 10	< 10	(–)	(–)	(–)	DIN EN ISO 11885, ICP-OES: 2009–09
Bromate (mg/kg)	(–)	(–)	(–)	< 1	< 1	< 1	DIN EN ISO ion chromatography 10,304–1: 2009–07
Cadmium (mg/kg)	< 0.010	< 0.010	< 0.010	(–)	(–)	(–)	DIN EN 15763, ICP-MS: 2010–04
Carbonate (wt.-%)	0.039	0.036	0.040	(–)	(–)	(–)	Calculated from solids (carbon, inorganic)
Chlorate (mg/kg)	0.15	0.16	0.17	(–)	(–)	(–)	HH-MA-M 02–151, LC–MS/MS: 2018–03
Chromium (mg/kg)	< 0.080	< 0.080	< 0.080	(–)	(–)	(–)	DIN EN 15763, mod., ICP-MS: 2010–04
Cobalt (mg/kg)	< 0.050	< 0.050	< 0.050	(–)	(–)	(–)	DIN EN 15763, mod., ICP-MS: 2010–04
Copper (mg/kg)	0.046	0.060	< 0.040	0.03	0.03	0.10	DIN EN 15763, mod., ICP-MS: 2010–04
Fluoride (mg/kg)	< 5	< 5	< 5	< 40*	< 40*	< 40*	Batches 1,2, 3: selective electrode DIN EN ISO 16279: 2012–09 Batches 7, 8, 9: ion chromatography DIN EN ISO 10304-1: 2009–07
Iodine (mg/kg)	< 0.1	< 0.1	< 0.1	(–)	(–)	(–)	DIN EN 15111: 2007–06 ICP/MS
Iron (mg/kg)	2.1	2.0	1.8	3.6	3.4	2.5	DIN EN ISO 11885, ICP-OES: 2009–09
Lead (mg/kg)	< 0.020	< 0.020	< 0.020	(–)	(–)	(–)	DIN EN 15763, ICP-MS: 2010–04

TABLE 3 (Continued)

Parameter	Batch 1	Batch 2	Batch 3	Batch 7	Batch 8	Batch 9	Method of analysis
Lithium (mg/kg)	1.0	1.1	0.77	1.0	0.95	0.65	DIN EN ISO 11885, ICP-OES: 2009–09
Manganese (mg/kg)	2.1	2.1	2.8	2.5	1.9	1.9	DIN EN ISO 11885, ICP-OES: 2009–09
Mercury (mg/kg)	< 0.010	< 0.010	< 0.010	(–)	(–)	(–)	DIN EN 15763, ICP-MS: 2010–04
Nickel (mg/kg)	< 0.040	< 0.040	< 0.040	(–)	(–)	(–)	DIN EN 15763, mod., ICP-MS: 2010–04
Nitrate (mg/kg)	< 100	< 100	< 100	< 400	< 400	< 400	Batches 1,2, 3: 2011–0572501-99D (ion chromatography) Batches 7, 8, 9: DIN EN ISO 10304-1: 2009–07
Nitrite (mg/kg)	< 100*	< 100*	< 100*	< 10	< 10	< 10	Batches 1,2, 3: 2011–0572501-99D (ion chromatography) Batches 7, 8, 9: DIN EN ISO 10304-1: 2009–07
Perchlorate (mg/kg)	< 0.050	< 0.050	< 0.050	(–)	(–)	(–)	HH-MA-M 02–151, LC–MS/MS: 2018–03
Phosphate (mg/kg)	< 100	< 100	< 100	(–)	(–)	(–)	2011–0572501-99D (ion chromatography)
Phosphorus (total) (mg/kg)	< 5.0	< 5.0	< 5.0	(–)	(–)	(–)	DIN EN ISO 11885, ICP-OES: 2009–09
Selenium (mg/kg)	< 0.10	< 0.10	< 0.10	(–)	(–)	(–)	DIN EN 15763, mod., ICP-MS: 2010–04
Silicon (mg/kg)	(–)	(–)	(–)	< 10	< 10	< 10	DIN EN ISO 17294-2, ICP-MS: 01/2017
Silver (mg/kg)	< 0.050	< 0.050	< 0.050	(–)	(–)	(–)	DIN EN 15763, mod., ICP-MS: 2010–04
Strontium (mg/kg)	14	14	20	21	19	12	DIN EN ISO 11885, ICP-OES: 2009–09
Sulfate (mg/kg)	100	100	100	< 400	< 400	< 400	Batches 1, 2, 3: ion chromatography (according to 2011–0572501-99D) Batches 7, 8, 9: ion chromatography (according to DIN EN ISO 10304-1: 2009–07)
Sulfur (mg/kg)	51	< 50.0	54.9	< 1000	< 1000	< 1000	Batches 1, 2 and 3: ICP-MS Batches 7, 8, 9: DIN EN ISO 11885, ICP-OES: 2009–09
Tin (mg/kg)	< 0.040	< 0.040	< 0.040	(–)	(–)	(–)	DIN EN 15763, ICP-MS: 2010–04
Zinc (mg/kg)	< 0.50	0.54	0.58	(–)	(–)	(–)	DIN EN 15763, ICP-MS: 2010–04

Note: (–) not analysed.

Abbreviations: DIN EN, Deutsches Institut für Normung, Europäische Norm; DIN EN ISO, Deutsches Institut für Normung, Europäische Norm, International Organization for Standardization; HH, Headspace Analysis; ICP-MS, Inductively Coupled Plasma Mass Spectrometry; ICP-OES, Inductively Coupled Plasma Optical Emission Spectrometry; ISO, International Organization for Standardization; LC–MS/MS, Liquid Chromatography Tandem Mass Spectrometry; MA, Mass Spectrometry Analysis; Ph. Eur., Pharmacopoeia Europaea (European Pharmacopoeia); w/w, weight per weight.

*Value above the proposed limit in the specifications.

Sieve analyses of three batches of the NF resulted in 55%–60% of the particles sized 180–450 µm with only less than 0.5% of the particles with a particle size below 180 µm. A laser diffraction analysis indicated that the particle size distribution ranged from 52.33 to 1184 µm with a mean value of 556.4 µm.

During the assessment, the applicant was requested to perform solubility tests in accordance with the EFSA Guidance on the technical requirements to establish the presence of small particles, including nanoparticles (EFSA Scientific Committee, 2021). Considering the high solubility of the NF (≥ 33.3 g/L), there are no concerns regarding the presence of particles in the nanoscale range.

The Panel considers that the information provided on the composition of the NF is sufficient and does not raise safety concerns.

3.4.1 | Stability

The applicant proposed a shelf-life of 60 months for the NF, to be stored in a dry covered area at humidity below 75%. The NF is packed in PE bags to prevent absorption of water.

The water activity of the NF is lower than the water activity of KCl and NaCl.

Taking into account the nature of the NF, the Panel considers that no undesirable degradation products are expected to occur under the proposed storage conditions.

3.5 | Specifications

The specifications of the NF are presented in Table 4.

The Panel considers that the information provided on the specifications of the NF is sufficient and does not raise safety concerns.

TABLE 4 Specifications of the NF.

Description of the NF, Mineral salt containing potassium and magnesium. White, off-white crystalline, fine granular, slightly hygroscopic product with a characteristic saline taste. Exclusively originating from water of the Dead Sea, Israel, produced by fractional precipitation.	
Synonyms	Potassium magnesium chloride hydrate
Identity	Positive by X-ray diffraction
Parameter	**Specification (unit)**
Melting point (range)	149.6–160.2°C
Solubility	
pH 1.94; 4.13 and 6.80	Freely soluble
pH 8.06	Slightly soluble
Insoluble parts	≤ 0.3% (w/w)
Water at 180°C (water of crystallisation plus moisture)	32%–40%
Main constituents	
Chloride	40%–42% (w/w)
Potassium	11.0%–13.6% (w/w)
Magnesium	7.9%–8.9% (w/w)
Calcium	≤ 0.2% (w/w)
Sodium	≤ 2.75% (w/w)
Heavy metals	
Arsenic	< 0.1 mg/kg
Cadmium	< 0.1 mg/kg
Mercury	< 0.05 mg/kg
Lead	< 0.1 mg/kg
Trace elements	
Bromide (Br^-)	≤ 0.40% (w/w)
Strontium	≤ 25 mg/kg
Manganese	≤ 3.0 mg/kg
Iron	≤ 4.0 mg/kg
Copper	≤ 0.5 mg/kg
Boron	≤ 10 mg/kg
Aluminium	≤ 1.0 mg/kg
Total phosphorous	≤ 5 mg/kg
Sulfate	< 500 mg/kg
Nitrite	< 10 mg/kg
Nitrate	< 400 mg/kg
Chlorate	< 0.2 mg/kg
Bromate	< 1 mg/kg
Fluoride	≤ 5 mg/kg
Iodine	< 0.1 mg/kg
Microbiological parameters	
Total plate count	< 100 CFU/g
E. coli	Not detected in 1 g
Salmonella	Not detected in 25 g
Salt-tolerant microorganisms	< 100 CFU/g
Sum parameters	
TOC	< 0.10% (w/w)

Abbreviations: CFU, colony forming units; TOC, total organic carbon; w/w, weight per weight.

3.6 | History of use of the NF

In 2012, a GRAS (generally recognised as safe) status of the NF was granted by the FDA (GRN n. 403[3]).

3.7 | Proposed uses and use levels and anticipated intake

3.7.1 | Target population

The target population proposed by the applicant is adults (individuals aged 18 years and above). However, as the NF is intended to be used as an ingredient in standard foods, it cannot be excluded that the NF would be also consumed by other groups of the population. Therefore, the safety data and the exposure assessment shall cover all population groups (Article 5(6) of Commission Implementing Regulation (EU) 2017/2469).

3.7.2 | Proposed uses and use levels

During the assessment, EFSA requested the applicant to revise the initially proposed uses and use levels of the NF taking into account the recently established tolerable daily intake (TDI) of bromide (see Section 3.7.4). Table 5 presents the new intended uses proposed by the applicant with the maximum use levels.

The applicant clarified that the NF is intended to partially replace salt, and it is to be sold exclusively to food manufacturers and not to final consumers.

TABLE 5 Food categories (defined using the FoodEx2[a] hierarchy) and maximum use levels of the NF.

FoodEx2 codes	FoodEx2 level	Food category	Maximum use level of the NF
A022R	L3	Raw cured (or seasoned) meat	1050 mg/100 g
A023G	L3	Cooked cured (or seasoned) meat	700 mg/100 g
A040M	L3	Pastas and rice (or other cereal)-based dishes	600 mg/100 g
A0EYP	L3	Preserved or partly preserved sausage	1050 mg/100 g

[a]EFSA food classification system https://www.efsa.europa.eu/en/data/data-standardisation.

3.7.3 | Anticipated daily intake of the NF

The applicant performed an intake assessment of the anticipated daily intake of the NF, which was confirmed by EFSA, based on the applicant's proposed uses and maximum use levels (Table 5), using the EFSA Dietary Exposure (DietEx) Tool[4] which is based on individual data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011).

The lowest and highest mean and 95th percentile anticipated daily intakes of the NF for each population group, among the EU dietary surveys, are presented in Tables 6 and 7 (expressed as mg/kg bw per day and mg/day, respectively).

The estimated daily intake of the NF for each population group from each EU dietary survey is available in the Excel file annexed to this scientific opinion (under supporting information).

TABLE 6 Ranges (lowest and highest) among EU dietary surveys of the estimated daily intake of the NF (mg/kg bw per day) as an ingredient in the intended food categories at the maximum proposed use levels.

	Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)	
Population groups (age)	Lowest[a]	Highest[a]	Lowest[b]	Highest[b]
Infants (up to 11 months)	0.01	8.69	0.00	44.72
Young children (12–35 months)[c]	1.80	21.19	9.84	67.04
Other children (3–9 years)	4.26	20.77	14.30	59.14
Adolescents (10–17 years)	2.24	13.63	7.40	36.77
Adults (18 years and above)[d]	0.62	10.23	3.09	31.28

Abbreviations: bw, body weight; P95, 95th percentile.

[a]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 16 July 2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 16 July 2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[c]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[d]Includes population groups of elderly, very elderly, pregnant women and lactating women.

[3]https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=403&sort=GRN_No&order=DESC&startrow=1&type=basic&search=403.

[4]https://www.efsa.europa.eu/it/science/tools-and-resources/dietex.

TABLE 7 Ranges (lowest and highest) among EU dietary surveys of the estimated daily intake of the NF (mg/day) as an ingredient in the intended food categories at the maximum proposed use levels.

	Mean intake (mg/day)		P95 intake (mg/day)	
Population groups (age)	**Lowest[a]**	**Highest[a]**	**Lowest[b]**	**Highest[b]**
Infants (up to 11 months)	0.13	66.89	0.00	399.00
Young children (12–35 months)[c]	21.49	261.75	118.13	866.25
Other children (3–9 years)	100.51	515.56	336.00	1320.63
Adolescents (10–17 years)	124.72	676.96	386.61	1785.00
Adults (18 years and above)[d]	51.09	799.25	262.50	2464.87

Abbreviation: P95, 95th percentile.

[a]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 16 July 2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 16 July 2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[c]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[d]Includes population groups of elderly, very elderly, pregnant women and lactating women.

3.7.4 | Estimate of exposure to undesirable substances

Considering the maximum amounts of lithium and barium observed in the NF and the maximum limits of strontium and chlorate set in the specifications of the NF and the intended use of the NF, the Panel considers that the contribution of these substances to the background diet is small and of no concern.

The exposure to bromide and bromate from the NF has been addressed in the following subsections.

Bromide

The EFSA Scientific Committee conducted an assessment to establish toxicological reference values for bromide.[5] On 20 November 2024, during the open plenary of the EFSA Scientific Committee, the opinion on bromide was discussed and adopted (EFSA Scientific Committee, 2025). The adopted opinion sets a TDI for bromide of 0.4 mg/kg bw per day. Based on this recently established TDI and considering an exposure to bromide from the background diet of 0.1 mg/kg bw per day, as indicated in the opinion on bromide, the applicant was requested to revise the intended uses and use levels of the NF, which are presented in Table 5.

Based on the highest 95th percentile anticipated daily intake of the NF (67.04 mg/kg bw per day), which occurred in the population group of young children, and the maximum level of bromide proposed in the specifications (0.4%), the highest 95th percentile exposure to bromide from the NF was estimated to be 0.27 mg/kg bw per day.

The Panel notes that the highest 95th percentile exposure to bromide from the NF (0.27 mg/kg bw per day) in combination with the chronic exposure to bromide from the diet (0.1 mg/kg bw per day) does not exceed the TDI of bromide of 0.4 mg/kg bw per day.

Bromate

Considering the production process, which occurs via solar irradiation of ponds covering large areas, the Panel requested the applicant to investigate the possible presence of bromate (BrO_3-) in the NF which could be formed by reaction of bromide (Br-) and ozone (O_3). Bromate was below the LOQ (LOQ: 1 mg/kg) in all three batches of the NF tested (Table 3).

In a worst-case scenario in which bromate from the NF would be present in amounts close to the LOQ of 1 mg/kg, the exposure to bromate from the NF would range from 0.031 to 0.067 μg/kg bw per day.

Considering the TDI reported by WHO, (2005 – publication retrieved by EFSA) (1 μg/kg bw per day), the Panel considers that the potential presence of bromate in the NF does not raise safety concerns.

3.8 | Absorption, distribution, metabolism and excretion (ADME)

Based on its physicochemical characteristics and solubility data, the NF is expected to dissociate in the gastrointestinal tract. Taking into account the nature of the NF, ADME information on the main constituents of the NF (i.e. chloride, potassium, magnesium) as well as bromide are described in this section.

[5]https://open.efsa.europa.eu/questions/EFSA-Q-2022-00329.

Chloride

As reported in the EFSA opinion on dietary reference values (DRV) for chloride (EFSA NDA Panel, 2019), in healthy people, chloride is efficiently absorbed in the gut. Following absorption, chloride anions are freely transported in the blood, where their concentration is maintained within a narrow range. Renal excretion of chloride is coupled to that of sodium and potassium.

Potassium

As reported in the EFSA opinion on DRV for potassium (EFSA NDA Panel, 2016), about 90% of dietary potassium is absorbed, mainly in the small intestine. Body potassium content is regulated by the balance between dietary intake and renal excretion.

Magnesium

As reported in the EFSA opinion on DRV for magnesium (EFSA NDA Panel, 2015), the absorption percentage is generally considered to be 40%–50%, but figures from 10% to 70% have also been reported depending on the intake, type of magnesium salt and food matrix. The kidneys play a major role in magnesium homeostasis and maintenance of serum concentration.

Bromide

Bromide is readily absorbed passively from the gut in humans by the paracellular pathway (EMEA, 1997). Plasma bromide concentration initially rises rapidly and reaches a plateau after 3 weeks. The plateau concentrations of bromide in serum, kidney and brain are directly proportional to the dietary concentrations. Excretion of bromide is mainly via the kidneys. The plasma half-life is 3 days in rats and 10–12 days in humans. In rats fed a chloride-deficient diet, the clearance of bromide is reduced and the plasma half-life is extended to 25 days (Rauws, 1983).

3.9 | Nutritional information

The NF is intended to be added to foods at maximum use levels as indicated in Table 5. The NF is meant to partially replace salt (NaCl).

Based on the anticipated daily intake of the NF (Table 7) and the maximum limits proposed in the specifications (Table 4), the highest 95th percentile anticipated daily intakes of chloride, potassium, magnesium, sodium, iron, calcium and manganese were estimated (Table 8).

TABLE 8 Highest 95th percentile anticipated intakes of minerals based on their maximum limits proposed in the specifications and the highest P95th anticipated daily intake of the NF (mg or μg per day).

Highest 95th percentile anticipated daily intakes							
Population groups (age)	Chloride mg/day	Potassium mg/day	Magnesium mg/day	Sodium mg/day	Iron μg/day	Calcium mg/day	Manganese mg/day
Infants (up to 11 months)	167.6	54.3	35.5	11.0	1.60	0.8	0.0012
Young children (12–35 months)	363.8	117.8	77.1	23.8	3.47	1.7	0.0026
Other children (3–9 years)	554.7	179.6	117.5	36.3	5.28	2.6	0.0040
Adolescents (10–17 years)	749.7	242.8	158.9	49.1	7.14	3.6	0.0054
Adults (18 years and above)	1035.2	335.2	219.4	67.8	9.86	4.9	0.0074

Sodium, iron, calcium and manganese

The Panel considers that the contribution of sodium, iron, calcium and manganese from the NF to the diet is not nutritionally relevant, particularly considering that the NF is expected to substitute salt (NaCl) in the proposed foods.

Chloride

Among the different population groups, the highest 95th percentile anticipated daily intakes of chloride from the NF range from 167.6 mg/day (infants) to 1035.2 mg/day (adults) (Table 8).

Safe and adequate intakes for chloride were established by EFSA (EFSA NDA Panel, 2019): from 1.7 g/day for children aged 1–3 years; 3.1 g/day for adolescents and adults (individuals aged 11 years and above; including pregnant and lactating women).

Chloride-based food additives are authorised in the EU. In 2019, at the end of the re-evaluation of these food additives (EFSA FAF Panel, 2019), the FAF Panel concluded that the exposure to chloride from hydrochloric acid and its potassium, calcium and magnesium salts as food additives does not raise a safety concern.

Considering that the NF is expected to substitute salt (NaCl) in the proposed foods and the fact that its chloride content is approximately 40%, as opposed to the content in salt (60%), the Panel considers that the use of the NF will not result in increased chloride intake.

Potassium

Among the different population groups, the highest 95th percentile anticipated daily intakes of potassium from the NF range from 54.3 mg/day (infants) to 335.2 mg/day (adults; Table 8). This represents limited additional intakes as compared to observed potassium intakes in EU populations (EFSA NDA Panel, 2016). No tolerable upper intake level (UL) for potassium has been set by EFSA due to insufficient data (EFSA, 2005; EFSA NDA Panel, 2016).

Based on the above information, the Panel considers that the additional intake of potassium from the NF does not represent a safety concern for the general population.

Magnesium

Among the different population groups, the highest 95th percentile anticipated daily intakes of magnesium from the NF range from 35.5 mg/day (infants) to 219.4 mg/day (adults; Table 8). This represents lower additional intakes as compared to observed magnesium intakes in EU populations (NDA Panel, 2015). The UL for magnesium applying only to readily dissociable Mg salts in food supplements, in water or added to foods, amounts to 250 mg/day and was established for adults including pregnant and lactating women, and children from 4 years of age and older. Owing to a lack of data, a UL could not be established for children aged 1–3 years (EFSA NDA Panel, 2015).

Based on the above information, the Panel considers that the additional intake of magnesium from the NF does not represent a safety concern for the general population.

Overall considerations

Taking into account the composition of the NF and the proposed uses and use levels, the Panel considers that the consumption of the NF is not nutritionally disadvantageous.

3.10 | Toxicological information

No toxicological studies with the NF were provided. Based on its physicochemical characteristics and solubility data, the NF is expected to dissociate in the gastrointestinal tract. Taking into account the composition and the nature of the NF, the Panel considers that no toxicological studies with the NF are required.

3.10.1 | Human data

No human studies with the NF were provided.

3.11 | Allergenicity

Considering the mineral origin of the NF, the Panel considers that the NF is unlikely to trigger allergic reactions.

4 | DISCUSSION

The NF, which is the subject of this application, is a mineral salt that consists mainly of magnesium potassium trichloride hexahydrate. The information provided on the composition is sufficient for characterising the NF and does not raise safety concerns. The production process is sufficiently described and does not raise safety concerns.

The NF is intended to be added to meat, sausages, pasta-based dishes, rice-based dishes and other cereal based-dishes.

Taking into account the composition of the NF and the proposed uses and use levels, the Panel considers that the consumption of the NF is not nutritionally disadvantageous.

Regarding the presence of bromide in the NF, the Panel notes that the combined daily intake of bromide from the NF and the background diet does not exceed the TDI of bromide of 0.4 mg/kg bw per day recently established by the EFSA Scientific Committee.

Based on its physicochemical characteristics and solubility data, the NF is expected to dissociate in the gastrointestinal tract. Taking into account the composition and the nature of the NF, the Panel considers that no toxicological studies with the NF are required.

5 | CONCLUSIONS

The Panel concludes that the NF (a mineral salt containing potassium and magnesium) is safe under the proposed conditions of use.

5.1 | Protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283

The Panel could not have reached the conclusion on the safety of the NF under the proposed conditions of use without the data claimed as proprietary by the applicant as listed in Appendix A.

6 | STEPS TAKEN BY EFSA

1. On 11/09/2019 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of a mineral salt containing potassium and magnesium. Ref. Ares(2019)5357024–22/08/2019.
2. On 11/09/2019, a valid application on a mineral salt containing potassium and magnesium, which was submitted by BK Guilini GmbH, member of ICL Group (Germany), was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2018/0798) and the scientific evaluation procedure was initiated.
3. On 20/12/2019, 11/12/2020, 17/10/2022 and 13/09/2024, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4. On 25/09/2020, 14/10/2022, 24/07/2024 and 26/11/2024 additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
5. During its meeting on 17/12/2024, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of a mineral salt containing potassium and magnesium as a NF pursuant to Regulation (EU) 2015/2283.

ABBREVIATIONS

AI	adequate intakes
ADME	absorption, distribution, metabolism and excretion
bw	body weight
CAS	chemical abstract service
CFU	colony forming units
DietEx	EFSA Dietary Exposure
EMEA	European Agency for the Evaluation of Medicinal Products
DRV	dietary reference values
FDA	Food and Drug Administration
GRAS	generally recognised as safe
LOQ	limit of quantification
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PE	polyethylene
TDI	tolerable daily intake
UL	tolerable upper intake level

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2019-00230

AMENDMENT

Minor editorial changes in the Identity, Tables 1 and 3 were implemented that do not affect the contents or outcome of this scientific output. To avoid confusion, the original version of the output has been removed from the EFSA journal, but it is available on request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

List of elements of the dossier for which data protection was requested by the applicant

NF section	Elements of the application dossier for which a request for data protection was filed by the applicant	File considered as pertinent for the NDA panel to reach the conclusion on the safety (Yes/No)
Production process	Confidential Salona® Process Flowchart (part 1 and 2) (Annex AI)	Yes
	Confidential Specification EF brine (Annex A2)	Yes
	Manufacturing licence (Annex B4)	Yes
	Salona® Process Flow chart non confidential – AI blacked out (part 1 and 2) (Annex B6)	Yes
	Salona® HACCP study 22.08.18 (Annex B8)	Yes
	Salona® RM HACCP study 3.10.18 (Annex B8)	Yes
	Salona® Impurity Profile 2014Y, 2015Y, 2016Y, 2017Y) (Annexes B9, B10, B 11, B12)	Yes
Compositional data	Certificates of analysis (Annexes C2, C3, C4, C7, C8, C9, C10, C11, C12, C13, C15, C17, C18, C19, C25, C25.1, C25.2, C28)	Yes
	Full study report LAUS_Statement Water Solubility_OECD 105 resp. EU A.6 (Annex S13)	Yes
	Full study report CURRENTA_X-Ray Diffraction_Melting Range (Annex S14)	Yes
	Full study report ICL FS_LEMGO_SALONA® in Raw Dry Sausage and its EN translation (Annex S2 and S3)	Yes
	Full study report ICL-1159 Salona® Analytical_en (Annex si)	Yes
	Full study report LAUS_Solubilty_OECD_105_b4, b5, b6 (Annexes S4, S5 and S6)	Yes
	Full study report LAUS_combined water content b4, b5, b6 (Annexes S7, S8 and S9)	Yes
	Full study report LAUS water activity_b4, b5, b6 (Annexes S10, S11, S12)	Yes

ANNEX A

Dietary exposure estimates to the Novel Food

Information provided in the Annex above is available under 'Supporting Information'.