

Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011

(Extract from Pages 665, 706, 707 and 709)

Table 12

Salts, spices, soups, salads and protein products						
Food category System	Food Category Name	Food Additive	INS No	Recommended Maximum Level	Note	
	salt, iron fortified salt, iodized salt)*	FERROCYANIDE S		10 mg/kg	24, 107	
		Magnesium carbonate	504(i)	20 g/kg		
		Magnesium oxide	530	GMP		
		Magnesium silicate, synthetic	553(i)	20 g/kg		
		PHOSPHATES		8,800 mg/kg	33	
		POLYSORBATES		10 mg/kg		
		Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	470(i)	20 g/kg	71	
		Silicon dioxide amorphous	551	GMP		
		52[Sodium aluminosilicate]	554	1,000 mg/kg	6,254	
		ETHYLENE DIAMINE TETRA ACETATES (EDTA)		50 mg/kg		
		Adipic acid	355	250 mg/kg		
		*Only the following additives permitted in double fortified salt				
		Hydroxy propyl methyl cellulose	464	GMP		
		Titanium dioxide	171	GMP		
12.1.2	Salt substitutes	Diacetyl tartaric and fatty acid esters of glycerol	472e	16,000 mg/kg		
		FERROCYANIDE S		20 mg/kg	24	
		PHOSPHATES		4,400 mg/kg		
		Calcium lactate	327	GMP		
		Citric acid	330	GMP		
		Fumaric acid	297	GMP		
		Lactic acid, L-, D-	270	GMP		

Note No.	Notes to the Food Additives mentioned in the Table 1 to 15.
1	As adipic acid.
2	On the dry ingredient, dry weight, dry mix or concentrate basis.
3	For use in surface treatment only.
4	For use in decoration, stamping, marking or branding the product only.
5	Excluding products conforming to the standard for jams, jellies and marmalades
6	As aluminium.
7	For use in coffee substitutes only.
8	As bixin.
9	Except for use in ready-to-drink coffee products at 10,000 mg/kg.
10	As ascorbyl stearate.
11	On the flour basis.
12	As a result of carryover from flavouring substances.
13	As benzoic acid.
14	For use in 706hydrolysed protein liquid formula only.
15	On the fat or oil basis.
16	For use in glaze, coatings or decorations for fruit, vegetables, meat or fish only.
18	As added level; residue not detected in ready-to-eat food.

19	For use in cocoa fat only.
20	Singly or in combination with other stabilizers, thickeners and/or gums.
21	As anhydrous calcium disodium ethylenediaminetetraacetate.
22	For use in smoked fish products only.
23	As iron.
24	As anhydrous sodium ferrocyanide.
25	For use at GMP in full fat soy flour only.
26	As steviol equivalents.
27	As para-hydroxybenzoic acid.
28	Except for use in wheat flour conforming to the standard for wheat flour at 2,000 mg/kg.
29	For non-standardized food only.
30	As residual NO ₃ ion.
31	On the mash used basis.
32	As residual NO ₂ ion.
33	As phosphorus.
34	On the anhydrous basis.
35	For use in cloudy juices only.
36	On the residual level basis.
37	For non-standardized food and food conforming to the standard for quick frozen blocks of fish fillets, minced fish flesh and mixtures of fillets and minced fish flesh.
38	On the creaming mixture basis.
39	For use in products containing butter or other fats and oils only.
40	Pentasodium triphosphate (INS 451(i)) only, to enhance the effectiveness of benzoates and sorbates.
41	For use in breading or batter coatings only.
42	As sorbic acid.
43	As tin.
44	As residual SO ₂ .
45	As tartaric acid.
46	As thiodipropionic acid.
47	On the dry egg yolk weight basis.
48	For use in olives only.
49	For use on citrus fruits only.
50	For use in fish roe only.
51	For use in herbs only.
52	Excluding chocolate milk.
53	For use in coatings only.
54	For use in cocktail cherries and candied cherries only.
55	Within the limits for sodium, calcium, and potassium specified in the standard for infant formula and formula for special dietary purposes intended for infants: singly or in combination with other sodium, calcium, and/or potassium salts.

92	Excluding tomato-based sauces.
93	Excluding natural wine produced from <i>Vitis vinifera</i> grapes.
94	For use in loganiza (fresh, uncured sausage) only.
95	For use in surimi and fish roe products only.
96	On the dried weight basis of the high intensity sweetener.
97	On the final cocoa and chocolate product basis.
98	For use in dust control only.
99	For use in fish fillets and minced fish only.
100	For use in crystalline products and sugar toppings only.
101	When used in combination with other emulsifiers, total combined use level not to exceed 15,000 mg/kg as specified in the standard for chocolate and chocolate products.
102	For use in fat emulsions for baking purposes only.
103	Except for use in special white wines at 400 mg/kg.
104	Except for use in bread and yeast-leavened bakery products: maximum 5,000 mg/kg residue.
105	Except for use in dried gourd strips at 5,000 mg/kg.
106	Except for use in Dijon mustard at 500 mg/kg.
107	Except for use of sodium ferrocyanide (INS 535) and potassium ferrocyanide (INS 536) in foodgrade dendridic salt at 29 mg/kg as anhydrous sodium ferrocyanide.
108	For use on coffee beans only.
109	Use level reported as 25 lbs/1,000 gal x (0.45 kg/lb) x (1 gal/3.75 L) x (1 L/kg) x (10E6 mg/kg) = 3,000 mg/kg
110	For use in frozen French fried potatoes only.
111	Except for use in dried glucose syrup used in the manufacture of sugar confectionery at 150 mg/kg and glucose syrup used in the manufacture of sugar confectionery at 400 mg/kg.
112	For use in grated cheese only.
113	As acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68).
114	Excluding cocoa powder.
115	For use in pineapple juice only.
116	For use in doughs only.
117	Except for use in fresh, uncured sausage at 1,000 mg/kg.
118	Except for use in fresh, cured sausage at 1,000 mg/kg.
119	As aspartame equivalents (the reported maximum level can be converted to an aspartame acesulfame salt basis by dividing by 0.64). Combined use of aspartame-acesulfame salt with individual aspartame or acesulfame potassium should not exceed the individual maximum levels for aspartame or acesulfame potassium (the

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as Food Additives

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Re-evaluation of sodium ferrocyanide (E 535), potassium ferrocyanide (E 536) and calcium ferrocyanide (E 538) as food additives

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Abstract

The Panel on Food Additives and Nutrient Sources added to Food (ANS) provided a scientific opinion re-evaluating the safety of sodium ferrocyanide (E 535), potassium ferrocyanide (E 536), and evaluating the safety of calcium ferrocyanide (E 538) as food additives. The Panel considered that adequate exposure and toxicity data were available. Ferrocyanides (E 535–538) are solely authorised in two food categories as salt substitutes. To assess the dietary exposure to ferrocyanides (E 535–538) from their use as food additives, the exposure was calculated based on regulatory maximum level exposure assessment scenario (maximum permitted level (MPL)) and the refined exposure assessment scenario. Dietary exposure to ferrocyanides was calculated based on mean and high levels consumption of salts in both the regulatory maximum level and the refined scenario. In the MPL scenario, the exposure to ferrocyanides (E 535–538) from their use as a food additive was up to 0.009 mg/kg body weight (bw) per day in children and adolescents. In the refined estimated exposure scenario, the exposure was up to 0.003 mg/kg bw per day in children and adolescents. Absorption of ferrocyanides is low and there is no accumulation in human. There is no concern with respect to genotoxicity and carcinogenicity. Reproductive studies were not available, but a no observed adverse effect level (NOAEL) of 1,000 mg sodium ferrocyanide/kg bw per day (highest dose tested) was identified from a prenatal developmental toxicity study. The kidney appeared to be the target organ for ferrocyanides toxicity and 4.4 mg sodium ferrocyanide/kg bw per day was identified as the NOAEL for the renal effects in a chronic (2-year) study in rats. Assuming that the toxicity of this compound is due to the ferrocyanide ion only, the Panel established a group acceptable daily intake (ADI) for sodium, potassium and calcium ferrocyanide of 0.03 mg/kg bw per day expressed as ferrocyanide ion. The Panel concluded that ferrocyanides (E 535–538) are of no safety concern at the current authorised use and use levels.

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the production of wine only small residues are found, and only small technological levels are needed as anticaking agent in salt. Therefore, the Committee has no objection, on toxicological grounds, to the continued use for these purposes'. The Panel noted that in the SCF (1991) evaluation, calcium ferrocyanide was not explicitly mentioned.

The Panel noted that the ADI of 0.025 mg/kg bw per day for sodium and potassium ferrocyanide has been calculated as sodium ferrocyanide while the maximum permitted level is expressed as anhydrous potassium ferrocyanide.

Sodium, potassium and calcium ferrocyanide were evaluated by JECFA in 1969, 1973 and 1974 (JECFA, 1970a, 1974a, 1975). A temporary acceptance of 0–0.00125 mg/kg bw per day was established in 1969 based on a dietary level of 0.05% sodium ferrocyanide (calculated by JECFA to be equivalent to 25 mg/kg bw per day) not causing toxicological effects in a subchronic rat study (Unpublished study by Oser (1959), as cited by JECFA (1975)). The Panel noted that a large uncertainty factor of 20,000 (25 mg/kg bw divided by 0.00125 mg/kg bw) was used. There is no explanation in the toxicological monograph (JECFA, 1970a) or the technical report (JECFA, 1970b) why this unusually high uncertainty factor was used. In 1973, a temporary ADI of 0–0.025 mg/kg bw per day was established on the basis of the data also available for the previous evaluation in 1969 (JECFA, 1970a). However, metabolic studies in man and if necessary a long-term study in one species were required (JECFA, 1974a,b). In 1974, the temporary ADI of 0–0.025 mg/kg per bw (calculated as sodium ferrocyanide) was confirmed and the request for metabolic studies waived due to the notion that such data would only provide limited additional information and require the use of unwanted high levels of radioactive materials in human subjects. A larger uncertainty factor (1,000) than the generally one employed was used to compensate for the absence of a long-term feeding study (JECFA, 1974c).

Potassium and sodium ferrocyanide were evaluated by the UK Committees on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in 1994 (COT, 1994a). The Committee set a group ADI for ferrocyanides of 0–0.05 mg/kg bw per day based on a NOAEL (the lowest dose tested) in a long-term rat study of 50 mg/kg and an uncertainty factor of 100.

The Scientific Committee for Animal Nutrition (SCAN) evaluated the safety for the target animals, the users, the workers, the consumers and the environment of sodium and potassium ferrocyanide used as anticaking agents (European Commission, 2001). It was concluded that sodium and potassium ferrocyanide in salt for feed use (20, 80 and 100 mg/kg in salt for man, poultry and livestock, respectively) is acceptable in regard to the safety for target animals and human consumers.

Sodium, potassium and calcium ferrocyanide were evaluated by a working group established by the Nordic Council of Ministers in 2000 (TemaNord, 2002). Sodium, potassium and calcium ferrocyanide were not considered to cause a safety problem due to the very small quantities consumed. It was noted that without long-term or reproductive studies a full toxicological evaluation would not be possible.

2. Data and methodologies

Data

The Panel on Food Additives and Nutrient Sources added to Food (ANS) was not provided with a newly submitted dossier. EFSA launched public call for data⁶ and, if relevant, contacted other risk assessment bodies to collect relevant information from interested parties.

The Panel based its assessment on information submitted to EFSA following the public call for data, information from previous evaluations and additional available literature up to the last Working Group (WG) meeting.⁷ 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.

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database⁸) was used to estimate the dietary exposure.

The Mintel's Global New Products Database (GNPD) is an online resource listing food products and compulsory ingredient information that should be included in labelling. This database was used to verify the use of sodium ferrocyanide (E 535), potassium ferrocyanide (E 536) and calcium ferrocyanide (E 538) in food products.

⁶ Call for Call for technical and toxicological data on miscellaneous food additives to be re-evaluated under the Regulation (EU) No 257/2010. Published: 11 August 2017. Available from: <https://www.efsa.europa.eu/en/consultations/call/170811> Available online: <http://www.efsa.europa.eu/en/food-consumption/comprehensive-database>

⁷ 11–12 May 2018.

⁸ Available online: <http://www.efsa.europa.eu/en/food-consumption/comprehensive-database>