

APPLICATION FOR THE APPROVAL OF IRON MILK PROTEINATE AS A NOVEL FOOD INGREDIENT IN THE EUROPEAN UNION

Pursuant to

***Regulation (EU) 2015/2283 of the European
Parliament and of the Council of 25 November
2015 on Novel Foods***

Non-Confidential Summary of the Technical Dossier

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Summary

The subject matter of this application is iron milk proteinate, a complex of ferric iron (Fe³⁺) bound to sodium caseinate in the presence of orthophosphate. Iron milk proteinate is a dark-red-to-orange powder that is highly soluble in water. The individual components of iron milk proteinate have a long history of consumption in the human diet. Dietary iron is available from meat, fish, cereals, beans, nuts, egg yolks, dark green vegetables, potatoes, and fortified food products. Iron milk proteinate has an iron loading of at least 2% (w/w). Phosphorus is naturally present in many different foods high in protein such as milk and milk products, meat, poultry, fish, grain products, and legumes. Casein and caseinates (including sodium and calcium salts) have an extensive history of safe consumption as they are naturally occurring proteins in milk.

Iron milk proteinate is manufactured by dissolving ferric iron salts in a food-grade sodium caseinate solution in the presence of orthophosphate. The pH of the solution is maintained at near neutral to ensure that the proteins do not precipitate from solution. The solution is stirred and pasteurized, and then concentrated. The final solution may be spray dried into a powder.

Iron milk proteinate is intended for use by the general population as a bioavailable source of dietary iron in various food and beverage products, and is intended as a direct replacement of other iron fortificants currently on the European Union (EU) marketplace. The intended uses of iron milk proteinate will be fully substitutional to existing iron fortificants on the EU marketplace. Iron milk proteinate is intended to provide iron at levels of 30% of the nutrient reference value in adults, equivalent to 14 mg/day or 4.2 mg iron/serving. The food products to which iron milk proteinate is added are intended for consumption by all age groups over 4 years of age, including those consuming diets based on Foods for Special Medical Purposes (FSMPs). The food-uses and use levels of iron milk proteinate were matched closely with the FoodEx2 food categorisation system developed by EFSA and are presented in Table 1 below.

Table 1 Food Categories and Use Levels used for the Intake Assessment of Iron from Iron Milk Proteinate Based on the FoodEx2 Classification System

Specified Food Category	FoodEx2 Group Name	FoodEx2 Code	FoodEx2 Level	Proposed Use Level of Iron from IMP (mg/serving) ^a	Serving Size (g) ^b , as consumed	Reconstitution Factor ^c	Maximum Proposed Use Level of Iron from IMP (mg/100 g), as consumed ^d
Powdered Milk and Milk Beverages	Milk and dairy powders	A02PH	L3	4.2	200	9	19
Sports Beverages	Isotonic and sport drinks	A03GB	L4	4.2	250 to 500	-	1.7
	Carbohydrate-electrolyte solutions for sports people	A03RZ	L4	4.2	250 to 500	-	1.7
Powdered Chocolate and Malt Beverages	Cocoa beverage-preparation, powder	A03HH	L4	4.2	260	10	16
	Malt coffee ingredient	A03GT	L4	4.2	260	13 ^e	21
Fortified Cereal Bars	Cereal Bars ^f	A00EY	L3	4.2	30 to 60 ^g	-	14
	Carbohydrate-rich energy food products	A03RY	L4	4.2	30 to 68 ^g	-	14

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	for sports people						
Instant Noodles	Asian-style noodles other than glass noodles	A007R	L5	4.2	280	-	1.5
Bouillon Cubes/Powders	Stock cubes or granulate (bouillon base)	A043F	L3	4.2	220	50	95
Meal replacement for weight control [as bars or beverages (milk-based and non-milk-based)]	Single meal replacement for weight reduction	A03RV	L4	4.2	178 ^h (275 to 330 mL for beverages; 26 to 60 g for bars ^g)	-	2.4

“-” = not applicable; IMP = iron milk proteinate.

^a IMP is intended to be added as an ingredient to foods and beverages at a level providing 4.2 mg iron/serving.

^b Serving sizes were obtained from the United Kingdom Food Standards Agency Food Portion Sizes (FSA, 2002).

^c Dilution factors for powders were obtained from EFSA (2018): <https://zenodo.org/record/1256085#.XJgSgOSQxFo>. These were used to determine the use level of iron from IMP for reconstituted food and beverage products, as consumed.

^d Use levels applied in the intake assessment.

^e According to the FSA (2002), 20 g of Horlicks malted food drink is used for 1 mug (260 mL).

^f Surrogate for fortified cereal bars.

^g Portion sizes were based on similar products available on the UK market.

^h It was confirmed by the European Food Safety Authority that this food code captures various types of meal replacements. For this reason, the serving size used to determine the use level of IMP on a mg/100 g basis was based on the average serving size between bars (minimum 26 g) and beverages (maximum 330 mL), as these are the types of meal replacements intended to contain IMP.

In addition to the above, iron milk proteinate is proposed for use in specialised food categories, for which a maximum daily intake is proposed (*i.e.*, food supplements, total diet replacement for weight reduction and FSMPs) as presented in Table 2. The use in food supplements and total replacements is equivalent to 14 mg/day, while the level for use in FSMPs will be in accordance with the particular nutritional requirements of the persons for whom the products are intended.

Table 2 Proposed Uses of Iron from Iron Milk Proteinate in Specialised Food Categories in the EU

Specific Proposed Food-Use	Maximum Levels
Total diet replacement for weight control as defined under Regulation (EU) No 609/2013 ^a , excluding foods for infants and young children	4.7 mg/meal ^b
Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ^c , excluding food supplements for infants and young children	14 mg/day
Foods for Special Medical Purposes, as Defined in Regulation (EU) No 609/2013 ^a , excluding those for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended

EC = European Commission; EU = European Union.

Table 2 Proposed Uses of Iron from Iron Milk Proteinate in Specialised Food Categories in the EU

Specific Proposed Food-Use	Maximum Levels
<p>^a Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L 181, 29.6.2013, p. 35-56.</p>	
<p>^b Calculation (14 mg per day/3 meals)</p>	
<p>^c Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183 12.7.2002, p. 51.</p>	

The available data indicate that iron milk proteinate share similar bioaccessibility and bioavailability as ferrous sulphate, and therefore, it is expected to be handled in a similar manner as other inorganic iron sources. The iron-peptide complex is soluble and facilitates transport to the apical membrane, where it is transported into the enterocyte. Once inside the enterocyte, the iron from iron milk proteinate is dissociated, added to the intracellular iron pool, and is expected to be processed similar to other iron compounds. The components of the novel food ingredient are all normal constituents of the human diet with a history of safe consumption; thus consumption of iron milk proteinate would not introduce a novel substance that would pose any safety concerns and is supported by the existing safety conclusions for each component. The resulting intakes of iron from the proposed food uses of iron milk proteinate are below the respective established upper limits, indicating that no safety concerns are to be expected.

The totality of the presented data highlights the safety and suitability of iron milk proteinate for its proposed food uses.