



31 March 2006

**ISDI COMMENTS ON
Draft Revised Standard for Infant Formula and Formula for Special Medical Purposes
Intended for Infants**

SECTION B: Formula for Special Medical Purposes Intended for Infants

ALINORM 05/29/26 § 129 & section B of Appendix IV
At step 5

Answer to Circular letter CL 2005/53 - NFSDU

General comment:

ISDI would like to propose the cross references in the Section B to be removed and replaced by the entire text.

Rationale:

It would simplify the reading of the document and reduce risks of confusion/errors where the practical aspects of the Standard will be implemented, and will impact on consumers i.e. the labelling information.

Proposed text	ISDI comments and justification
1. Scope 1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk <u>or infant formula</u> in meeting the special nutritional requirements deriving from the disorder, disease or medical condition for whose dietary management the product has been formulated.	ISDI supports the proposed wording.
1.4 The application of this section of the Standard should take into account, <u>as far as appropriate for the products to which this section applies and the special needs of the infants for whom they are intended,</u> the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).	ISDI supports the proposed wording.

<p>2. DESCRIPTION</p> <p>2.1 Product definition</p> <p>2.1.1 Formula for Special Medical Purposes Intended for Infants <u>means a substitute for human milk or infant formula</u> that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.</p>	<p>ISDI supports the proposed wording.</p>
<p>3.1 Essential Composition</p> <p>3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of <u>animal, plant and/or synthetic origin</u> suitable for human consumption. All ingredients and food additives shall be gluten-free.</p>	<p>ISDI supports the proposed wording.</p> <p>However, ISDI would like to remind that Essential Composition in Section A is not final yet and therefore adjustments may need to be done in the future.</p>
<p>3.1.2 The composition of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles and Their use should have been demonstrated by scientific evidence, to be safe, and beneficial in meeting the nutritional requirements of infants for whom they are intended.</p>	<p><u>Delete</u> part of the second sentence</p> <p><u>Rationale:</u> it is redundant.</p>
<p>4. Food Additives</p> <p>see Section A 4.</p> <p>The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (to be filled in).</p>	<p>ISDI detailed comments have been previously provided to the delegation of Switzerland in charge of the revision of this section.</p> <p><u>Rationale:</u> see annex</p>
<p>9.5 Information for Use</p> <p>see section A 9.5</p> <p>[Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation.</p> <p>All products should be used according to instructions for use. Products in powder form and concentrated liquids should be prepared with safe and previously boiled water before feeding. Ready for consumption liquid formula may be used directly according to instructions for use.</p>	<p><u>Reword</u> and change the order of the sentence.</p> <p><u>Rationale:</u> adds clarity and powdered formula are the most commonly used type of formula around the world.</p>
<p>9.6 Additional Labelling Requirements</p> <p>9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labelled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, and 4.5.1 and 4.5.5 of CODEX STAN 180-1991.</p>	<p><u>Delete</u> the cross reference to section 4.5.5.</p> <p><u>Add</u> “and”</p> <p><u>Rationale:</u> it is redundant with section 4.5.3. which section 9.6.3. refers to.</p>

ANNEXComments on Food Additives for FSMPs
(Section 4. Food Additives)

These comments are based on CX/NFSDU 05/27/6-ADD.1 the Proposed List of Food Additives for the Codex Draft Revised Standard For Infant Formula and Formulas for Special Medical Purposes Intended for Infants Prepared By the Swiss Electronic Working Group and ALN 06/29/26.

We support the additives proposed by the Swiss Electronic Working Group for Section A and the additional additives the Working Group as proposed for Section B, with the following comments:

Part 1: Additives listed in Appendix IV(A) where ISDI requests a different level for FSMPs (Section B) that the one proposed in Section A.

	INS NO.		Maximum level in 100 mL of the “ready for consumption” product	Technological Justification
4.1	<i>Thickening Agents</i>			
4.1.2	410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula REQUESTED at 0.5 g /100ml	Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon. This can be obtained only by minimum concentrations from 0.4g/100ml.

	472e	Diacetyltartaric and fatty acid of esters of glycerol		REQUESTED at GMP	Retains homogeneity of liquid products and liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB, works better in combination with additive 322 and 471. Has a GRAS status in the US
	308	Gamma-tocopherol		REQUESTED at 1 mg in all types of infant formula singly or in combination	Alone or in combination to stabilise preparations containing fats and vitamins. Synergistic effect with additives 304 and 305. They are used as natural antioxidants and are much more effective in preventing oxidation of vulnerable fatty acids than alpha tocopherol.
	309	Delta-tocopherol			

Part 2: Additives not listed in Appendix IV(A) that ISDI requests for FSMPs (Section B) in addition to those proposed in Section A.

	INS no.			Maximum level in 1kg or 1l of the product	<i>Technological Justification</i>
	<i>Thickening agents</i>				
	401	Sodium alginate		<p style="text-align: center;">1g/l</p> <p>From four months onwards in special food products with adapted composition, required for metabolic disorders and for general tube feeding</p>	Used in some liquid formula containing fibre. When used in combination with additive 412, 401, 410, 415, the hydrocolloids in the mix prevent the separation of fibre in the liquid feed. It is important during the sterilisation process that the room temperature viscosity of the product is reduced otherwise the sterilisation effect will be impaired. At the same time, the same viscosity and gelling effect must be thermoreversible in order to hold the fibres together during feeding. Single hydrocolloids do not have the necessary effect and there are no other protein free additives available for this type of application.

	410	Carob bean gum (Locust bean gum)		10 g/l From birth onwards in products for reduction of gastro-oesophageal reflux	Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon.
	412	Guar gum		10 g/l From birth onwards in products in liquid formulae containing hydrolysed proteins, peptides or amino-acids.	Minimises and delays physical separation of the product, fat separation and fat globule coalescence. Guar gum is an excellent water binder, it does not form gel, which is an advantage in liquid products, it is cold water soluble and will not modify the thickening effect obtained by carrageenan.
	415	Xanthan gum		1.2 g/l From birth onwards for use in products based on amino acids or peptides for use with patients who have problems with impairment of the gastro-intestinal tract, protein mal-absorption or inborn errors of metabolism.	Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.
	440	Pectins		10 g/l From birth onwards in products used in case of gastro-intestinal disorders.	Used a gelling agent in place of gelatine. Particularly efficient in presence of fruits and in acidic preparations. Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.
	466	Sodium carboxymethyl cellulose		10 g/l or kg From birth onwards in products for the dietary management of metabolic disorders.	Better thickening, gel formation, solvation and a less "sandy" product is obtained with additive 466 compared to pectine. It disperses easily in water forming colloidal solutions; it can therefore be used as a suspending agent, an emulsifying agent and in the preparation of gels. Furthermore, it improves dispersion of other agents. Its technological functions are hardly influenced by temperature and metal salts have little effect on its viscosity.

	472c	Citric and fatty acid esters of glycerol		7.5 g/kg for formulae sold as powder 9 g/l for formulae sold as liquid	Has an HLB value of 10-12, is one of the most effective emulsifiers of oil in water emulsions. Produces a stable, milky white emulsion, giving the final product (usually products with superior stability, taste and organoleptic properties. Positive opinion on such usage has been expressed by the European Scientific Committee for Food in June 1997 and September 2002)
	1450	Starch sodium octenyl succinate		20 g/l From birth onwards	Viscosity and stability properties that native starch tend to lose when processed
	<i>Emulsifier</i>				
	471	Mono- and diglycerides of fatty acids		5 g/l From birth onwards in specialised diets, particularly those devoid of proteins	Natural stabiliser that retains homogeneity of liquid products and liquid reconstituted powder. Because it has an intermediate hydrophilic/lipophilic balance (HLB) value, it is suitable for emulsifying products containing fats which require intermediate HLB emulsifiers. It is a robust substance in that it can withstand harsh processing conditions, such as spray drying and UHT processing. This property has been beneficial for the development of ready-to-feed UHT liquid products providing complete nutrition. It is also used extensively for emulsifying fat and carbohydrate components. Its resistance to ionic interactions make it suitable for use in products containing mineral and trace elements such as nutritionally complete products.