

SUBSIDIARY LEGISLATION 231.48**DIETARY FOODS FOR SPECIAL MEDICAL
PURPOSES REGULATIONS**

1st January, 2002

Legal Notice 309 of 2001.

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| <p>1. The title of these regulations is the Dietary Foods for Special Medical Purposes Regulations.</p> | Title. |
| <p>2. These regulations lay down compositional and labelling requirements for dietary foods for special medical purposes as defined in regulation 3.1 and presented as such.</p> | Scope and applicability. |
| <p>3.1 In these regulations, unless the context otherwise requires, the following definitions shall apply:</p> <ul style="list-style-type: none">(a) "infants" means children under the age of twelve months;(b) "dietary foods for special medical purposes" means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two. | Definitions. |
| <p>3.2 Dietary foods for special medical purposes are classified in the following three categories:</p> <ul style="list-style-type: none">(a) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;(b) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;(c) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of | |

nourishment.

3.3 The foods referred to in regulation 3.2(b) and (c) may also be used as a partial replacement or as a supplement to the patient's diet.

Marketing of dietary foods for special medical purposes.

4.1 Dietary foods for special medical purposes may be marketed only if they comply with the rules laid down in these regulations.

Formulation of dietary foods for special medical purposes.

5.1 The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.

5.2 Dietary foods for special medical purposes must comply with the compositional criteria specified in the Schedule.

Labelling of dietary foods for special medical purposes.

6.1 The name under which dietary foods for special medical purposes are sold shall be respectively:

- in Maltese:

"Ikel intiż għal skopijiet mediċi speċjali"

- in English:

"Food(s) for special medical purposes"

- in Italian:

"Alimento dietetico destinato a fini mediċi speciali".

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6.2 The labelling shall bear, in addition to the particulars provided for in the Labelling, Presentation and Advertising of Foodstuffs Regulations, the following mandatory particulars:

- (a) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;
- (b) the average quantity of each mineral substance and each vitamin mentioned in the Schedule present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;
- (c) selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components the declaration of which would be

necessary for the appropriate intended use of the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

- (d) information on the osmolality or the osmolarity of the product where appropriate;
- (e) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

6.3 The labelling shall in addition bear the following mandatory particulars, preceded by the words "important notice" or their equivalent:

- (a) a statement that the product must be used under medical supervision;
- (b) a statement whether the product is suitable for use as the sole source of nourishment;
- (c) a statement that the product is intended for a specific age group, as appropriate;
- (d) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

6.3.1 The particulars mentioned in regulation 6.3(a) and (d) and in regulation 6.4(d) shall be given in at least the Maltese or English language.

6.4 The labelling shall also include:

- (a) the statement "For the dietary management of" where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;
- (b) where appropriate a statement concerning adequate precautions and contra-indications;
- (c) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;
- (d) where appropriate a warning that the product is not for parenteral use.

6.5 The labelling shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

7.1 When a dietary food for special medical purposes is placed on the market, the manufacturer or the importer shall notify the Superintendent of Public Health by forwarding a model of the label

Notification procedure.

used for the product.

SCHEDULE

Essential Composition of Foods for Special Medical Purposes

The specifications refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Products referred to in regulation 3.2(a) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1.
2. Products referred to in regulation 3.2(b) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
3. Maximum levels of vitamins and mineral substances present in products referred to in regulation 3.2(c) intended specifically for infants shall not exceed those specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
4. Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the provisions relating to other nutrients applicable to infant formulae and follow-on formulae, as the case may be, laid down in the Infant Formulae and Follow-on Formulae Regulations.
5. Products referred to in regulation 3.2(a), other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2.
6. Products referred to in regulation 3.2(b) other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2 without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
7. Maximum levels of vitamins and mineral substances present in products referred to in regulation 3.2(c) other than those intended specifically for infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

TABLE 1

Values for vitamins, mineral and trace elements in nutritionally complete foods intended for use by infants

Vitamins:				
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A ($\mu\text{g RE}$)	14	43	60	180
Vitamin D (μg)	0.25	0.75	1	3
Vitamin K (μg)	1	5	4	20
Vitamin C (mg)	1.9	6	8	25
Thiamin (mg)	0.01	0.075	0.04	0.3
Riboflavin (mg)	0.014	0.1	0.06	0.45
Vitamin B6 (mg)	0.009	0.075	0.035	0.3
Niacin (mg NE)	0.2	0.75	0.8	3
Folic acid (μg)	1	6	4	25
Vitamin B12 (μg)	0.025	0.12	0.1	0.5
Pantothenic acid (mg)	0.07	0.5	0.3	2
Biotin (μg)	0.4	5	1.5	20
Vitamin E (mg α - TE)	0.5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	0.75	0.5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kcal	3

Minerals:				
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Chloride (mg)	12	29	50	125
Potassium (mg)	15	35	60	145
Calcium (mg)	12	60	50	250
Phosphorus (mg) ¹	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg)	0.12	0.5	0.5	2
Zinc (mg)	0.12	0.6	0.5	2.4
Copper (μg)	4.8	29	20	120
Iodine (μg)	1.2	8.4	5	35
Selenium (μg)	0.25	0.7	1	3

Minerals:				
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Manganese (mg)	0.012	0.05	0.05	0.2
Chromium (µg)	-	2.5	-	10
Molybdenum (µg)	-	2.5	-	10
Fluoride (mg)	-	0.05	-	0.2
1 The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.				

TABLE 2

Values for vitamins, minerals and trace elements in nutritionally complete foods other than those intended for use by infants

Vitamins:				
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)	8.4	43	35	180
Vitamin D (µg)	0.12	0.65/0.75 ²	0.5	2.5/3 ²
Vitamin K (µg)	0.85	5	3.5	20
Vitamin C (mg)	0.54	5.25	2.25	22
Thiamin (mg)	0.015	0.12	0.06	0.5
Riboflavin (mg)	0.02	0.12	0.08	0.5
Vitamin B6 (mg)	0.02	0.12	0.08	0.5
Niacin (mg NE)	0.22	0.75	0.9	3
Folic acid (µg)	2.5	12.5	10	50
Vitamin B12 (µg)	0.017	0.17	0.07	0.7
Pantothenic acid (mg)	0.035	0.35	0.15	1.5
Biotin (µg)	0.18	1.8	0.75	7.5
Vitamin E (mg α - TE)	0.5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	0.75	0.5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kcal	3
2 For products intended for children of 1 to 10 years of age.				

Minerals:				
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	7.2	42	30	175
Chloride (mg)	7.2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8.4/12 ²	42/60 ²	35/50 ²	175/250 ²
Phosphorus (mg) ³	7.2	19	30	80
Magnesium (mg)	1.8	6	7.5	25
Iron (mg)	0.12	0.5	0.5	2
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (µg)	15	125	60	500
Iodine (µg)	1.55	8.4	6.5	35
Selenium (µg)	0.6	2.5	2.5	10
Manganese (mg)	0.012	0.12	0.05	0.5
Chromium (µg)	0.3	3.6	1.25	15
Molybdenum (µg)	0.72	4.3	3.5	18
Fluoride (mg)	-	0.05	-	0.2
3 The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.				