

L.N. 113 of 2002

**DRUGS AND DRINKING WATER ACT  
(Cap. 231)**

**Casein and Caseinates Regulations, 2002**

IN exercise of the powers conferred by article 12 of the Food, Drugs and Drinking Water Act, the Minister of Health, on the advice of the Malta Standards Authority, has made the following regulations:

**1.** The title of these regulations is the Casein and Caseinates Regulations, 2002 and they shall come into force on the 1st July, 2002. Citation and  
Commencement

**2.1** These regulations shall apply to lactoproteins, as defined in the Schedules, which are intended for human consumption and mixtures thereof. Scope and  
Applicability.

**3.1** In these regulations, unless the context otherwise requires, the following definitions shall apply: Definitions.

*Casein:*

the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk by precipitation:

- by the addition of acid, or
- by microbial acidification, or
- by using rennet, or
- by using other milk-coagulating enzymes, without prejudice to the possibility of prior use of ion exchange processes and concentration processes.

*Skimmed milk:*

the milk of one or more cows to which nothing has been added and of which only the fat content has been reduced.

*Caseinates:*

products obtained by drying caseins treated with neutralising agents.

**4.1** The products defined in the Schedules to these regulations may be marketed only if they conform to the definitions and rules laid down in these regulations and the Schedules thereto. Marketing of  
Lactoproteins.

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4.2 Products which do not satisfy the criteria laid down in the Schedules must be named and labelled in such a way that the buyer is not misled as to their nature, quality or use.

Reserved Names

4.3 The names referred to in the Schedules shall be reserved for the products defined and must be used commercially to designate those products.

Labelling of  
Lactoproteins.

5.1 Without prejudice to the provisions of the Labelling, Presentation and Advertising of Foodstuffs Regulations and without prejudice to other provisions which may be adopted concerning the labelling of foodstuffs not intended for the ultimate consumer, the only mandatory particulars to be marked in indelible characters in a clearly visible and easily legible manner on the packages, containers or labels of the products defined in the Schedules shall be as follows:

5.1.1 the name reserved for the products in accordance with regulation 4.3 with, in the case of caseinates, an indication of the cation or cations;

5.1.2 in the case of products marketed as mixtures,

- the words ‘mixture of ....’ followed by the names of the different products which make up the mixture, in decreasing order of weight,
- an indication of the cation or cations in the case of caseinate or caseinates,
- the protein content in the case of mixtures containing caseinates;

5.1.3 the net quantity expressed in kilograms or grams;

5.1.4 the name or business name and the address of the manufacturer or packager or of a seller established in Malta or within the European Community;

5.1.5 in the case of products imported from outside the European Community, the name of the country of origin;

5.1.6 the date of manufacture or some marking by which the batch can be identified.

5.2 The marketing of edible caseins and caseinates is prohibited if the particulars referred to in paragraphs 5.1.1, 5.1.2, 5.1.5 and 5.1.6 do not appear in at least one of the following languages - Maltese, English or Italian – unless the information is provided by other means.

5.3 The particulars specified in paragraphs 5.1.2, third indent, 5.1.3, 5.1.4 and 5.1.5 need appear only on an accompanying document. For transport in bulk, this derogation shall also apply to the particulars specified in paragraphs 5.1.2, second indent, and 5.1.6.

**6.1** Without prejudice to other provisions which may be adopted in the field of health and hygiene in connection with the basic materials referred to in the First and Second Schedules, such products must be subjected to heat treatment which will render the phosphatase negative. Heat Treatment.

7.1.1 Where, as a result of new information or of a reassessment of existing information, the Superintendent of Public Health finds there is detailed evidence that the use in the products defined in the First and Second Schedules of these Regulations of one of the substances referred to therein or the maximum quantity of such substance that may be used constitutes a danger to human health, even though it complies with the provisions of these regulations, he may, after consulting with the Directorate responsible for foodstuffs within the Malta Standards Authority, suspend or restrict application of the provisions in question. Safeguard Clause.

**8.1** The analyses necessary for verification of the criteria set out in these regulations shall be carried out in accordance with First Commission Directive 85/503/EEC<sup>1</sup>. Methods of Analysis.

**9.1** Caseins and caseinates falling within the scope of these regulations shall be sampled in accordance with First Commission Directive 86/424/EEC<sup>2</sup>. Sampling Procedures.

<sup>1</sup> OJ L 308/12, 20.11.1985

<sup>2</sup> OJ L 243/29, 28.8.1986

**FIRST SCHEDULE****Edible Caseins****I. NAMES AND DEFINITIONS**

(a) 'edible acid casein' means edible casein obtained by precipitation using the technological adjuvants and bacterial cultures listed in Section II(d) which comply with the standards laid down in Section II.

(b) 'edible rennet casein' means edible casein obtained by precipitation using the technological adjuvants listed in Section III(d) which comply with the standards laid down in Section III.

**II. STANDARDS APPLICABLE TO 'EDIBLE ACID CASEIN'****(a) Essential factors of composition**

1.	Maximum moisture content	10.0 % by weight
2.	Minimum milk protein content calculated on the dried extract of which minimum casein content	90 % by weight 95 % by weight
3.	Maximum milk fat content calculated on the dried extract	2.25 % by weight
4.	Maximum titratable acidity, expressed in ml of decinormal sodium hydroxide solution per g	0.27
5.	Maximum ash content (P <sub>2</sub> O <sub>5</sub> included)	2.5 % by weight
6.	Maximum anhydrous lactose content	1 % by weight
7.	Maximum sediment content (burnt particles)	22.5 mg in 25 g

**(b) Contaminants**

	Maximum lead content	1 mg/kg
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**(c) Impurities**

	Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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**(d) Harmless technological adjuvants and bacterial cultures suitable for human consumption**

(i)	- lactic acid (E 270) - hydrochloric acid - sulphuric acid - citric acid (E 330) - acetic acid (E 260) - orthophosphoric acid	
(ii)	- whey - bacterial cultures producing lactic acid	

(e) **Organoleptic characteristics**

1.	Odour	No foreign odours
2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.

## III. STANDARDS APPLICABLE TO 'EDIBLE RENNET CASEIN'

1.	Maximum moisture content	10.0 % by weight
2.	Minimum milk protein content calculated on the dried extract	84 % by weight
	of which minimum casein content	95 % by weight
3.	Maximum milk fat content calculated on the dried extract	2 % by weight
4.	Maximum ash content (P <sub>2</sub> O <sub>5</sub> included)	7.50 % by weight
5.	Maximum anhydrous lactose content	1 % by weight
6.	Maximum sediment content (burnt particles)	22.5 mg in 25 g

(b) **Contaminants**

	Maximum lead content	1 mg/kg
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(c) **Impurities**

	Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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(d) **Harmless technological adjuvants suitable for human consumption**

	- rennet - other milk-coagulating enzymes	
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(e) **Organoleptic characteristics**

1.	Odour	No foreign odours
2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.

## SECOND SCHEDULE

## Edible Caseinates

## I. DENOMINATIONS AND DEFINITIONS

*'edible caseinates'* means caseinates obtained from edible caseins using neutralising agents of edible quality listed under Section II(d) and complying with the standards set out in Section II.

## II. STANDARDS APPLICABLE TO EDIBLE CASEINATES

1.	Maximum moisture content	8 % by weight
2.	Minimum content of milk protein casein, calculated on the dried extract	88 % by weight
3.	Maximum milk fat content calculated on the dried extract	2 % by weight
4.	Maximum anhydrous lactose content	1 % by weight
5.	pH value	6.0 to 8.0
6.	Maximum sediment content (burnt particles)	5 mg in 25 g

## (b) Contaminants

	Maximum lead content	1 mg/kg
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## (c) Impurities

	Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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(d) Technological adjuvants of edible quality  
(optional neutralising and buffering agents)

	hydroxides carbonates phosphates citrates	of	sodium potassium calcium ammonium magnesium
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## (e) Characteristics

1.	Odour	Very slight foreign flavours and odours
2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.
3.	Solubility	Almost entirely soluble in distilled water, except for the calcium caseinate