L.N. 487 of 2004

FOOD SAFETY ACT
(CAP. 449)

Colours (Use in Foodstuffs) (Amendment) Regulations, 2004

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:

Citation and commencement L.N. 107 of 1995

1. The title of these regulations is the Colours (Use in Foodstuffs) (Amendment) Regulations, 2004, and they shall be read and construed as one with the Colours (Use in Foodstuffs) Regulations, 1995, hereinafter referred to as "the principal regulations".

Scope.

2. These regulations implement the provisions of Commission Directive 2004/47/EC of the 16th April, 2004.

Commencement date.

3. These regulations shall enter into force on the 1st April, 2005, provided that products on the market at the date or labelled before that date which do not comply with these regulations, but which comply with the Colours (Use in Foodstuffs) Regulations, 1995, may be marketed until stocks are exhausted.

Amends the Sixth Schedule to the principal regulations.

4. In part B of the Sixth Schedule to the principal regulations, for the chapter concerning E 160a (i) Mixed Carotenes and E 160 a (ii) beta-carotene there shall be substituted the following:-

" **E 160a (i) mixed carotenes**

1. PLANT CAROTENES

Synonyms	CI Food Orange 5
Definition	Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. α, γ-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material. Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane ([1]), dichloromethane and carbon dioxide.
Class	Carotenoid
Colour Index No	75130
EINECS	230-636-6
Chemical formula	β-Carotene: $C_{40}H_{56}$
Molecular weight	β-Carotene: 536.88
Assay	Content of carotenes (calculated as β-carotene) is not less than 5 %. For products obtained by extraction of vegetable oils: not less than 0.2 % in edible fats $E_{1cm}^{1\%}$ 2500 at ca 440 nm – 457 nm in cyclohexane
Identification	
A. Spectrometry	Maximum in cyclohexane at 440 nm – 457 nm and 470 nm – 486 nm
Purity	
Solvent residues	Acetone Methyl ethyl ketone Methanol Propan-2-ol Hexane Ethanol — Not more than 50 mg/kg, singly or in combination

[1] Benzene not more than 0.05 % v/v.

	Dichloromethane — Not more than 10 mg/kg
Lead	Not more than 5 mg/kg

2. ALGAL CAROTENES

Synonyms	CI Food Orange 5
Definition	Mixed carotenes may also be produced from the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. Beta-carotene is extracted using an essential oil. The preparation is a 20-30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 – 71/29. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.
Class	Carotenoid
Colour Index No	75130
Chemical formula	Beta-carotene: $C_{40}H_{56}$
Molecular weight	Beta-carotene: 536.88
Assay	Content of carotenes (calculated as β-carotene) is not less than 20 %. $E_{1cm}^{1\%}$ 2500 at approximately 440 nm – 457 nm in cyclohexane
Identification	
A. Spectrometry	Maximum in cyclohexane at 448 nm – 457 nm and 474 nm – 486 nm
Purity	
Natural tocopherols in edible oil	Not more than 0.3 %
Lead	Not more than 5 mg/kg

E 160 a (iii) Beta-Carotene

1. Beta-carotene

Synonyms	CI Food Orange 5
Definition	These specifications apply predominantly to all trans isomers of beta carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios.
Class	Carotenoid
Colour index No	40800
EINECS	230-636-6
Chemical names	Beta-carotene, beta,beta-carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536.88
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene) $E_{1cm}^{1\%}$ 2500 at approximately 440 nm – 457 nm in cyclohexane
Description	Red to brownish-red crystals or crystalline powder
Identification	
A. Spectrometry	Maximum in cyclohexane at 453 to 456 nm
Purity	
Sulfated ash	Not more than 0.2 %
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3.0 % of total colouring matters
Lead	Not more than 2 mg/kg

2. Beta-carotene from *Blakeslea trispora*

Synonyms	CI Food Orange 5	
Definition	Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (-) of natural strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate, or isobutyl acetate followed by isopropyl alcohol, and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process, approximately 3 % of the product consists of mixed carotenoids, which is specific for the product.	
Class	Carotenoid	
Colour index No	40800	
EINECS	230-636-6	
Chemical names	Beta-carotene, beta,beta-carotene	
Chemical formula	$C_{40}H_{56}$	
Molecular weight	536.88	
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene) $E_{1cm}^{1\%}$ 2500 at approximately 440 nm – 457 nm in cyclohexane	
Description	Red, brownish-red or purple-violet or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation)	
Identification		
A. Spectrometry	Maximum in cyclohexane at 453 nm to 456 nm	
Purity		
Solvent residues	Ethyl acetate Ethanol	Not more than 0.8 % singly or in combination
	Isobutyl acetate	Not more than 1.0 %
	Isopropyl alcohol	Not more than 0.1 %
Sulfated ash	Not more than 0.2 %	
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3.0 % of total colouring matters	

Lead	Not more than 2 mg/kg
Mycotoxins:	
Aflatoxin B1	Absent
Trichothecene (T2)	Absent
Ochratoxin	Absent
Zearalenone	Absent
Microbiology:	
Moulds	Not more than 100/g
Yeasts	Not more than 100/g
Salmonella	Absent in 25 g
Escherichia coli	Absent in 5 g".

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) Valletta - *Published by the Department of Information - (doi.gov.mt) - Valletta*
Mitbugħ fl-Istamperija tal-Gvern - *Printed at the Government Printing Press*

Prezz 24¢ - *Price 24c*