

A.L. 487 ta' l-2004

**ATT DWAR IS-SIGURTÀ FL-IKEL
 (KAP. 449)**

**Regolamenti ta' l-2004 li jemendaw ir-Regolamenti dwar Kuluri
 għall-Użu fi Hwejjeġ ta' l-Ikel**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 10 ta' l-Att dwar is-Sigurtà fl-Ikel, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità għamel ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2004 li jemendaw ir-Regolamenti dwar Kuluri għall-Użu fi Hwejjeġ ta' l-Ikel, u għandhom jinqraw u jinftieħmu bhala haġa wahda mar-Regolamenti ta' l-1995 dwar Kuluri għall-Użu fi Hwejjeġ ta' l-Ikel, (A.L. 107 ta' l-1995) hawn iktar 'il quddiem imsejhin "ir-regolamenti prinċipali". Titolu u dhul fis-sehh.
2. Dawn ir-regolamenti jimplimentaw il-provvedimenti tad-Direttiva tal-Kummissjoni 2004/47/EC ta' l-16 ta' April 2004. Skop.
3. Dawn ir-regolamenti jidhlu fis-sehh fl-1 ta' April 2005, iżda prodotti fis-suq f'dik id-data jew li ġew ittikkettjati qabel dik id-data li ma jikkonformawx ma' dawn ir-regolamenti, iżda li jikkonformaw mar-Regolamenti ta' l-1995 dwar Kuluri (Użu fl-Ikel), kif emendati, jistgħu jinbiegħu sakemm jkunu eżawriti l-ħażniet. Data tad-dhul.
4. F'Parti B tas-Sitt Skeda, il-kapitolu li jirrigwarda E 160a (i) Karoteni Mhallta u E 160a (ii) beta-karotene għandu jinbidel bit-test tal-Iskeda ta' dawn ir-regolamenti. Jemenda is-Sitt Skeda tar-regolamenti prinċipali.

SKEDA

‘ E 160a (i) karoteni mhallta

1. KAROTENI MILL-PJANTI

Sinonimi	CI Food Orange 5
Definizzjoni	<p>Karoteni mhallta mehudin permezz ta' estrazzjoni b'solventi ta' varjetajiet naturali ta' pjanti li jittieklu, karrotti, żjut veġetali, ħaxix, alfalfa (<i>lucerne</i>) u ħurrieq.</p> <p>Il-prinċipju ewlieni li jagħti l-kulur jikkonsisti f'karotenojdi li minnhom il-β-karotene tikkonstitwixi l-akbar parti. α, γ-karotene u kuluri oħra jistgħu jkunu preżenti. Minbarra l-kuluri, din is-sustanza jista' jkollha fiha żjut, xahmijiet u xemgħat li jinstabu b'mod naturali fil-materjal oriġinali.</p> <p>Dawn is-solventi li ġejjin biss jistgħu jintużaw fl-estraxxjoni: aċeton, <i>methyl ethyl ketone</i>, metanol, etanol, propan-2-ol, ħexan (¹), dikolorometan u diossidu tal-karbonju.</p>
Klassi	Karotenojdi
Numru tal-Indiċi tal-Kulur	75130
EINECS	230-636-6
Formula kimika	β-karotene: C ₄₀ H ₅₆
Piż molekulari	β-karotene: 536.88
Eżami	<p>Kontenut ta' karoteni (ikkalkulat bħala β-karotene) mhux anqas minn 5 %. Għal prodotti meħuda permezz ta' estraxxjoni minn żjut veġetali: mhux anqas minn 0.2 % fi żjut li jittieklu</p> <p>$E_{1cm}^{1\%}$ 2500 fi ca 440 nm – 457 nm fi ċikloħexan</p>
Identifikazzjoni	
Spektrometrija	Massimu fi ċikloħexan fi 440 nm – 457 nm u 470 nm – 486 nm
Purità	
Reżidwi ta' solventi	Aċeton

¹ Benzene mhux aktar minn 0.05 % v/v.

	<i>Methyl ethyl ketone</i>	
	Metanol	Mhux aktar minn 50 mg/kg, waħedhom jew flimkien
	Propan-2-ol	
	Hexan	
	Etanol	
	Diklorometan	Mhux aktar minn 10 mg/kg
Ċomb	Mhux aktar minn 5 mg/kg	

2. KAROTENI MILL-ALGA

Definizzjoni	<p>Karoteni mħallta jistgħu wkoll jittieħdu mill-alga <i>Dunaliella salina</i>, mkabbra ġewwa għadajjar kbar tal-ilma mielaħ li jinsabu ġewwa Whyalla, fl-Awstralja tan-Nofsinhar. Il-Beta-karotene tiġi estratta permezz ta' żejt essenzjali. Il-preparat huwa sospensjoni ta' 20 – 30 % f'žejt li jittiekel. Il-proporzjon ta' izomeri trans-cis huwa bejn 50/50 sa 71/29.</p> <p>Il-prinċipju attiv li jagħti l-kulur jikkonsisti f'karotenojdi li minnhom il-beta-karotene tikkostitwixxi l-akbar parti. Jistgħu wkoll ikunu prezenti l-alfa-karotene, il-luteina, żeaksantina u beta-kriptoksantina. Minbarra sustanzi li jagħtu l-kulur, din is-sustanza jista' jkollha zjut, xaħmijiet u xemgħat li jinstabu naturalment fil-materjal oriġinali.</p>
Klassi	Karotenojdi
Numru ta' Indici tal-Kulur	75130
Formula kimika	Beta-karotene: C ₄₀ H ₅₆
Piż molekulari	Beta-karotene: 536.88
Eżami	<p>Kontenut ta' karoteni (ikkalkulat bħala β-karotene) mhux inqas minn 20 %.</p> <p>$E_{1cm}^{1\%}$ 2500 f'bejn wieħed u ieħor 440 nm – 457 nm fiċ-ċiklohexan</p>
Identifikazzjoni	
A. Spektrometrija	Massimu fiċ-ċiklohexan fi 448 nm – 457 nm u 474 nm – 486 nm
Purità	
Tokoferoli naturali f'žejt li jittiekel	Mhux aktar minn 0.3 %
Ċomb	Mhux anqas minn 5 mg/kg

E 160 a (ii) Beta-karotene

1. Beta-karotene

Sinonimi	CI Food Orange 5
Definizzjoni	Dawn l-ispeċifikazzjonijiet japplikaw l-aktar għall-izomeri trans kollha ta' beta-karotene flimkien ma' ammonti żgħir ta' karotenojdi oħra. Preparazzjonijiet dilwiti u stabilizzati jista' jkollhom proporzjonijiet differenti ta' trans-cis.
Klassi	Karotenojdi
Nru ta' l-indiċi tal-kulur	40800
EINECS	230-636-6
Ismijiet kimiċi	Beta-karotene, beta,beta-karotene
Formula kimika	$C_{40}H_{56}$
Piż molekulari	536.88
Eżami	Total mhux anqas minn 96 % ta' materjal kulurit (espress bħala beta-karotene) $E_{1cm}^{1\%}$ 2500 f'bejn wieħed u ieħor 440 nm – 457 nm fiċ-ċiklohexan
Deskrizzjoni	Kristalli jew trab kristallin aħmar sa aħmar fil-kannella
Identifikazzjoni	
A. Spettrometrija	Massimu fiċ-ċiklohexan fi 453 sa 456 nm
Purità	
Rmied sulfat	Mhux aktar minn 0.2 %
Materjal kulurit sussidjarju	Karotenojdi minbarra l-beta-karotene: mhux aktar minn 3.0 % tal-materjal kulurit totali
Ĉomb	Mhux aktar minn 2 mg/kg

2. Beta-karotene minn *Blakeslea trispora*

Sinonimi	CI Food Orange 5
Definizzjoni	Mehud bi proċess ta' fermentazzjoni billi tintuża kultura mħallta taż-żewġ tipi sesswali (+) u (-) tal-varjetajiet naturali tal-moffa <i>Blakeslea trispora</i> . Il-beta-karotene hija estratta mill-massa bioloġika bl-aċetat tal-etil, jew bl-aċetat tal-iżobutil segwit bl-alkoħol iżopropil, u kristallizzat. Minħabba l-proċess naturali, madwar 3 % tal-prodott jikkonsisti f'karotenojdi mħallta, li huwa speċifiku għall-prodott.
Klassi	Karotenojdi
Numru tal-indiċi tal-kulur	40800
EINECS	230-636-6
Ismijiet kimiċi	Beta-karotene, beta,beta-karotene
Formula kimika	$C_{40}H_{56}$
Piż molekulari	536.88
Eżami	Total mhux anqas minn 96 % ta' materjal kulurit (espress bħala beta-karotene) $E_{1cm}^{1\%}$ 2500 f'bejn wieħed u ieħor 440 nm – 457 nm fiċ-ċiklohexan
Deskrizzjoni	Kristalli jew trab kristallin aħmar, aħmar fil-kannella jew vjola fil-vjola skur (il-kulur ivarja skond is-solvent ta' l-estrazzjoni wżat u l-kondizzjonijiet tal-kristallizzazzjoni)
Identifikazzjoni	
A. Spettrometrija	Massimu fiċ-ċiklohexan fi 453 nm sa 456 nm
Purità	
Reżidwi ta' solventi	Aċetat ta' l-etil Mhux aktar minn 0.8 % Etanol waħedhom jew flimkien Aċetat ta' l-iżobutil: Mhux aktar minn 1.0 % Alkoħol iżopropil: Mhux aktar minn 0.1 %
Rmied sulfat	Mhux aktar minn 0.2 %
Materjal kulurit sussidjarju	Karotenojdi minbarra beta-karotene: mhux aktar minn 3.0 % tal-materjal kulurit totali

Comb	Mhux aktar minn 2 mg/kg
<i>Mikotossini:</i>	
Aflatossina B1	Assenti
Trikotećene (T2)	Assenti
Okratossina	Assenti
Żearalenone	Assenti
<i>Mikrobiologija:</i>	
Mofof	Mhux aktar minn 100/g
Hmira	Mhux aktar minn 100/g
<i>Salmonella</i>	Assenti f' 25 g
<i>Escherichia coli</i>	Assenti f' 5 g'

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:

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”.

Citation and
commencement
L.N. 107 of 1995

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

Scope.

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.

Commencement
date.

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:-

Amends the Sixth
Schedule to the
principal
regulations.

“ E 160a (i) mixed carotenes

1. PLANT CAROTENES

Synonyms	CI Food Orange 5							
Definition	<p>Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.</p> <p>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.</p> <p>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.</p>							
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	<p>Content of carotenes (calculated as β-carotene) is not less than 5 %.</p> <p>For products obtained by extraction of vegetable oils: not less than 0.2 % in edible fats</p> <p>$E_{1cm}^{1\%}$ 2500 at ca 440 nm – 457 nm in cyclohexane</p>							
Identification								
A. Spectrometry	Maximum in cyclohexane at 440 nm – 457 nm and 470 nm – 486 nm							
Purity								
Solvent residues	<table border="1"> <tr> <td>Acetone</td> <td rowspan="6">Not more than 50 mg/kg, singly or in combination</td> </tr> <tr> <td>Methyl ethyl ketone</td> </tr> <tr> <td>Methanol</td> </tr> <tr> <td>Propan-2-ol</td> </tr> <tr> <td>Hexane</td> </tr> <tr> <td>Ethanol</td> </tr> </table>	Acetone	Not more than 50 mg/kg, singly or in combination	Methyl ethyl ketone	Methanol	Propan-2-ol	Hexane	Ethanol
Acetone	Not more than 50 mg/kg, singly or in combination							
Methyl ethyl ketone								
Methanol								
Propan-2-ol								
Hexane								
Ethanol								

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 <i>Dunaliella salina</i> , 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 <i>Blakeslea trispora</i> . 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	<table border="1"> <tr> <td>Ethyl acetate</td> <td rowspan="2">Not more than 0.8 % singly or in combination</td> </tr> <tr> <td>Ethanol</td> </tr> <tr> <td>Isobutyl acetate</td> <td>Not more than 1.0 %</td> </tr> <tr> <td>Isopropyl alcohol</td> <td>Not more than 0.1 %</td> </tr> </table>	Ethyl acetate	Not more than 0.8 % singly or in combination	Ethanol	Isobutyl acetate	Not more than 1.0 %	Isopropyl alcohol	Not more than 0.1 %
Ethyl acetate	Not more than 0.8 % singly or in combination							
Ethanol								
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							

B 7900

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