
A.L. 374 ta' l-2011

**ATT DWAR IS-SIGURTA TA' L-IKEL
(KAP. 449)**

**Regolamenti ta' l-2011 li jemendaw ir-Regolamenti dwar
Kuluri għall-Użu fi Hwejjeg ta' l-Ikel**

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

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2011 li jemendaw ir-Regolamenti dwar Kuluri għall-Użu fi Hwejjeg ta' l-Ikel, u għandhom jinqraw u jinfthiemu haġa waħda mar-Regolamenti ta' l-1995 dwar Kuluri għall-Użu fi Hwejjeg ta' l-Ikel, hawn izjed 'il quddiem imsejha "ir-regolamenti prinċipali".

Titolu u bidu fis-sehħ.

A.L. 107 ta' l-1995.

(2) Dawn ir-regolamenti għandhom jitqiesu li daħlu fis-sehħ fil-1 ta' Settembru 2011.

2. Regolamenti 3 jimplementa il-provvedimenti tad-Direttiva tal-Kummissjoni 2011/3/UE tas-17 ta' Jannar 2011 li temenda d-Direttiva tal-Kummissjoni 2008/128/KE li tippreskrivi l-kriterji speċifiċi tal-purità ta' sustanzi ta' taħlil (kuluri)għall-użu fl-oġġetti tal-ikel.

Skop.

3. It-Taqsimha 2 tas-Sitt Skeda, li tinsab mar-regolamenti prinċipali, għandha tiġi emendata kif ġej:-

Jemenda is-Sitt Skeda li tinsab mar-regolamenti prinċipali.

(a) Għall-entrata dwar E 160, għandu jidhol dan li ġej:-

“E 160 D LIKOPEN	
(i) Likopen sintetiku	
Sinonimi	Likopen mis-sintezi kimika
Definizzjoni	Il-likopen sintetiku huwa taħlita ta' iżoremi geometriċi tal-likopen u magħmul bil-kondensazzjoni Wittig tal-intermedjarji sintetiċi użati ġeneralment fil-produzzjoni ta' karotenojdi oħrajn li huma użati fl-ikel. Likopen sintetiku hu magħmul l-aktar minn likopen-kollu-trans flimkien ma' 5-cis-lycopene u kwantitajiet żgħar ta' iżomeri oħra. Il-preparazzjonijiet tal-likopen kummerċjali li huma intizi għall-użu fl-ikel huma formulati bħala sospensjonijiet fiż-żjut tal-ikel jew trab idrodispersibbli jew trab li jinħall fl-ilma.
Numru Indiċi tal-Kulur	75125
EINECS	207-949-1
Isem kimiku	Ψ,Ψ-karoten, likopen-kollu-trans, (kollu-E)-likopen, (kollu-E)-2,6,10,14,19,23,27,31-oktametil-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriakontatridekaene
Formula kimika	C ₄₀ H ₅₆
Piż molekulari	536,85
Analizi	Mhux anqas mis-96 % tal-likopeni totali (mhux anqas minn 70 % tal-likopen-kollu-trans) E 1 cm 1 % f'465 - 475 nm f'eżan (għal 100 % likopen-kollu-trans pur) huwa 3 450
Deskrizzjoni	Trab abjad kristallin
Identifikazzjoni	
Spettrufotometrija	Soluzzjoni f'eżan turi assorbiment massimu ta' madwar 470 nm.
Test għall-karotenojdi	Il-kulur tas-soluzzjoni tal-kampjun faċeton jisparixxi wara żidiet suċċessivi ta' 5 % soluzzjoni tan-nitrit tas-sodju u l-aċidu tal-kubrit 1N
Solubbiltà	Mhux solubbli fl-ilma, solubbli liberament fil-kloroform
Karatteristiċi ta' 1 % soluzzjoni fil- kloroform	Ĉara u għandha kulur aħmar-orangjo intensiv
Purità	
Telf fit-tnixxif	Mhux aktar minn 0,5% (40 °C, 4 h f'20

	mm Hg)
Apo-12 ³ -likopenuż	Mhux aktar minn 0,15 %
Ossidu tal-fosfin tat-trifenil	Mhux aktar minn 0,01 %
Residwi tas-solvent	Metanol mhux aktar minn 200 mg/kg Eżan, Propan-2-ol: Mhux aktar minn 10 mg/kg kull wieħed. Diklorometan: Mhux aktar minn 10 mg/kg (fi preparazzjonijiet kummerċjali biss)
Ċomb	Mhux aktar minn 1 mg/kg
(ii) Mit-tadam aħmar	
Sinonimi	Isfar Naturali 27
Definizzjoni	Il-likopen jinkiseb permezz ta' estrazzjoni ta' solventi tat-tadam aħmar (Lycopersicon esculentum L.) bit-tneħħija sussegwenti tas-solvent. Dan is-solvent biss jista' jintuża: dijossidu karboniku, aċetat etiliku, aċeton, propan-2-ol, metanol, etanol, eżan. Il-prinċipju ewlieni tal-kulur tat-tadam huwa l-likopen, jista' jkun hemm ammonti żgħar ta' pigmenti karotenojdi oħra. Barra il-pigmenti tal-kulur, il-prodott jista' jkollu żejt, xaħmijiet, xama' u komponenti tat-toġhma li jseħħu b'mod naturali fit-tadam.
Numru Indiċi tal-Kulur	75125
EINECS	207-949-1
Isem kimiku	Ψ,Ψ-karoten, likopen-kollu-trans, (kollu-E)-likopen, (kollu-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriakontatridekaene
Formula kimika	C ₄₀ H ₅₆
Piż molekulari	536,85
Analizi	E _{1 cm} 1 % f'465 - 475 nm f'eżan (għal 100 % likopen-kollu-trans pur) huwa 3 450. Il-kontenut mhux anqas minn 5 % tal-materja tal-kulur totali
Deskrizzjoni	Likwidu viskuż aħmar skur
Identifikazzjoni	
Spettrufotometrija	Massimu f'eżan f'ca 472 nm
Purità	
Residwi tas-solvent	Propan-2-ol Eżan Aċeton Etanol Metanol Aċetat etiliku Mhux aktar minn 50 mg/kg, waħdu jew f'taħlita
Irmied issulfat	Mhux aktar minn 1 %

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Merkurju	Mhux aktar minn 1 mg/kg
Kadmju	Mhux aktar minn 1 mg/kg
Arseniku	Mhux aktar minn 3 mg/kg
Ċomb	Mhux aktar minn 2 mg/kg
(iii) minn <i>Blakeslea trispora</i>	
Sinonimi	Isfar Naturali 27
Definizzjoni	Likopen minn <i>Blakeslea trispora</i> huwa estratt mill-bijomassa fungali u ppurifikat bil-kristallizzazzjoni u l-filtrazzjoni. Dan magħmul l-aktar minn likopen-kollu-trans. Fih ukoll kwantitajiet żgħar ta' karotenojdi oħra. l-isopropanol u l-aċetat tal-isobutil huma l-uniċi solventi użati fil-manifattura. Il-preparazzjonijiet tal-likopen kummerċjali li huma intiżi għall-użu fl-ikel huma formulati bħala sospensjonijiet fiż-żjut tal-ikel jew trab idrodispersibbli jew trab li jinħall fl-ilma.
Numru Indiċi tal-Kulur	75125
EINECS	207-949-1
Isem kimiku	Ψ,Ψ-karoten, likopen-kollu-trans, (kollu-E)-likopen, (kollu-E)-2,6,10,14,19,23,27,31-oktametil-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriakontatridekaene
Formula kimika	C ₄₀ H ₅₆
Piż molekulari	536,85
Deskrizzjoni	Trab abjad kristallin
Identifikazzjoni	
Spettrufotometrija	Soluzzjoni f'eżan turi assorbiment massimu ta' madwar 470 nm.
Test għall-karotenojdi	Il-kulur tas-soluzzjoni tal-kampjun f'aċeton jisparixxi wara żidiet suċċessivi ta' 5 % soluzzjoni tan-nitrit tas-sodju u l-aċidu tal-kubrit 1N
Solubbiltà	Mhux solubbli fl-ilma, solubbli liberament fil-kloroform
Karatteristiċi ta' 1 % soluzzjoni fil- kloroform	Ċara u għandha kulur aħmar-orangjo intensiv

Purità	
Telf fit-tnixxif	Mhux aktar minn 0,5 % (40 °C, 4 h f'20 mm Hg)
Karotenojdi oħra	Mhux aktar minn 5 %
Residwi tas-solvent	Propan-2-ol: Mhux aktar minn 0,1 % Aċetat tal-isobutil: Mhux aktar minn 1,0 % Diklorometan: Mhux aktar minn 10 mg/kg (fi preparazzjonijiet kummerċjali biss)
Irmied issulfat	Mhux aktar minn 0,3 %
Ĉomb	Mhux aktar minn 1 mg/kg ² .

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L.N. 374 of 2011

**FOOD SAFETY ACT
(CAP. 449)**

Use of Colours in Foodstuffs (Amendment) Regulations, 2011

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

Citation and commencement.

L.N. 107 of 1995.

1. (1) The title of these regulations is the Use of Colours in Foodstuffs (Amendment) Regulations, 2011, and they shall be read and construed as one with the Use of Colours in Foodstuffs Regulations, 1995, hereinafter referred to as “the principal regulations”.

(2) These regulations shall be deemed to have come into force on the 1st September 2011.

Scope.

2. Regulation 3 implements the provisions of Commission Directive 2011/3/EU of 17 January 2011, amending Directive 2008/128/EC, laying down specific purity criteria on colours for use in foodstuffs.

Amends the Sixth Schedule to the principal regulations.

3. Part II of the Sixth Schedule to the principal regulations, shall be amended as follows:

(a) For the entry on E 160, there shall be substituted the following:

“E 160 D LYCOPENE	
(i) <i>synthetic lycopene</i>	
Synonyms	Lycopene from chemical synthesis
Definition	Synthetic lycopene is a mixture of geometric isomeres of lycopenes and is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists predominantly of all-trans-lycopene together with 5-cis-lycopene and minor quantities of other isomers. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.
Colour Index No	75125
EINECS	207-949-1
Chemical name	Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19, 23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	C ₄₀ H ₅₆
Molecular weight	536,85
Assay	Not less than 96 % total lycopenes (not less than 70 % all-translycopene) E _{1 cm} ^{1%} at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450
Description	Red crystalline powder
Identification	
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Test for carotenoids	The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid
Solubility	Insoluble in water, freely soluble in chloroform
Properties of 1 % solution in chloroform	Is clear and has intensive red-orange colour

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Purity	
Loss on drying	Not more than 0,5 % (40 °C, 4 h at 20 mm Hg)
Apo-12'-lycopenal	Not more than 0,15 %
Triphenyl phosphine oxide	Not more than 0,01 %
Solvent residues	Methanol not more than 200 mg/kg, Hexane, Propan-2-ol: Not more than 10 mg/kg each. Dichloromethane: Not more than 10 mg/kg (in commercial preparations only)
Lead	Not more than 1 mg/kg
<i>(ii) from red tomatoes</i>	
Synonyms	Natural Yellow 27
Definition	Lycopene is obtained by solvent extraction of red tomatoes (<i>Lycopersicon esculentum</i> L.) with subsequent removal of the solvent. Only the following solvent may be used: carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol, hexane. The major colouring principle of tomatoes is lycopene, minor amounts of other carotenoid pigments may be present. Besides the colour pigments the product may contain oil, fats, waxes and flavour components naturally occurring in tomatoes.
Colour Index No	75125
EINECS	207-949-1
Chemical name	Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19, 23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	C ₄₀ H ₅₆
Molecular weight	536,85
Assay	E _{1 cm} ^{1%} at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450. Content not less than 5 % total colouring matters
Description	Dark red viscous liquid
Identification	
Spectrophotometry	Maximum in hexane at ca 472 nm

Purity	
Solvent residues	Propane-2-ol Hexane Acetone Ethanol Methanol Ethylacetate Not more than 50 mg/kg, singly or in combination
Sulphated ash	Not more than 1 %
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
(iii) from <i>Blakeslea trispora</i>	
Synonyms	Natural Yellow 27
Definition	Lycopene from <i>Blakeslea trispora</i> is extracted from the fungal biomass and purified by crystallisation and filtration. It consists predominantly of all-trans-lycopene. It also contains minor quantities of other carotenoids. Isopropanol and isobutyl acetate are the only solvents used in the manufacture. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water- dispersible or water-soluble powder.
Colour Index No	75125
EINECS	207-949-1
Chemical name	Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19, 23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	C ₄₀ H ₅₆
Molecular weight	536,85
Assay	Not less than 95 % total lycopenes and not less than 90 % all-translycopene of all colouring matters E _{1 cm 1 %} at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450

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Description	Red crystalline powder
Identification	
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Test of carotenoids	The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid
Solubility	Insoluble in water, freely soluble in chloroform
Properties of 1 % solution in chloroform	Is clear and has intensive red-orange colour
Purity	
Loss on drying	Not more than 0,5 % (40 °C, 4 h at 20 mm Hg)
Other carotenoids	Not more than 5 %
Solvent residues	Propan-2-ol: Not more than 0,1 % Isobutyl acetate: Not more than 1,0 % Dichloromethane: Not more than 10 mg/kg (in commercial preparations only)
Sulphated ash	Not more than 0,3 %
Lead	Not more than 1 mg/kg”.

