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COMMISSION DIRECTIVE 2001/50/EC

of 3 July 2001

amending Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs

(Text with EEA relevance)

(OJ L 190, 12.7.2001, p. 14)

Corrected by:

► C1 Corrigendum, OJ L 217, 11.8.2001, p. 18 (2001/50/EC)

▼B**COMMISSION DIRECTIVE 2001/50/EC****of 3 July 2001****amending Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption⁽¹⁾, as amended by Directive 94/34/EC of the European Parliament and of the Council⁽²⁾ and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee for Food,

Whereas:

- (1) ►**C1** Directive 94/36/EC of the European Parliament and of the Council ◀ of 30 June 1994 on colours for use in foodstuffs⁽³⁾ lists those substances which may be used as colours in foodstuffs.
- (2) ►**C1** Commission Directive 95/45/EC ◀ of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs⁽⁴⁾, as amended by Directive 1999/75/EC⁽⁵⁾, sets out the purity criteria for the colours mentioned in Directive 94/36/EC.
- (3) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/45/EC for mixed carotenes (E160a(i)) and beta-carotene (E160a(ii)).
- (4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (5) It is consequently necessary to adapt Directive 95/45/EC.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In part B of the Annex to Directive 95/45/EC, the text concerning mixed carotenes (E160a(i)) and beta-carotene (E160a(ii)) is replaced by the text of the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 30 June 2002. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 237, 10.9.1994, p. 13.

⁽⁴⁾ OJ L 226, 22.9.1995, p. 1.

⁽⁵⁾ OJ L 206, 5.8.1999, p. 19.

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Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

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ANNEX

‘E 160 a (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 β -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 (*), 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 vegetables oils: not less than 0,2 % in edible fats

$E_{1\%}^{1\text{cm}}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Identification

A. Spectrometry

Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 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

Dichloromethane

Not more than 10 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

2. Algal carotenes

Synonyms

CI food orange 5

Definition

Mixed carotenes may also be produced from natural strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. β -carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29

The main colouring principle consists of carotenoids of which β -carotene accounts for the major part. α -carotene, lutein, zeaxanthin and β -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

▼**B**

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 20 % $E^{1\%}_{1\text{cm}} \geq 2\,500$ at approximately by 440 nm to 457 nm in cyclohexane

Identification

A. Spectrometry	Maximum in cyclohexane at 448 nm to 457 nm and 474 nm to 486 nm
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Purity

Natural tocopherols in edible oil	Not more than 0,3 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 160 a (ii) BETA-CAROTENE**1. Beta-carotene**

Synonyms CI food orange 5

Definition These specifications apply predominantly to all trans isomer of β -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	β -carotene, β,β -carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as β -carotene) $E^{1\%}_{1\text{cm}} \geq 2\,500$ at approximately by 440 nm to 457 nm in cyclohexane

Description Red to brownish-red crystals or crystalline powder

Identification

A. Spectrometry	Maximum in cyclohexane at 453 nm to 456 nm
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Purity

Sulphated ash	Not more than 0,2 %
Subsidiary colouring matters	Carotenoids other than β -carotene: not more than 3,0 % of total colouring matters
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 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 β -carotene is extracted from the biomass with ethyl acetate and crystallised. The crystallised product consists mainly of trans β -carotene. Because of the natural process approximately 3 % of the product consists of mixed carotenoids, which is specific for the product

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Class	Carotenoid
Colour Index No	40800
Einecs	230-636-6
Chemical names	β -carotene, β,β -carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as β -carotene) $E^{1\%}_{1\text{cm}}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Description

Red to brownish-red crystals or crystalline powder

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
Sulphated ash	Not more than 0,2 %	
Subsidiary colouring matters	Carotenoids other than β -carotene: not more than 3,0 % of total colouring matters	
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 5 mg/kg	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 1 mg/kg	
Aflatoxin B1	Absent	
Mycotoxins:		
T2	} Absent	
Ochratoxin		
Zearalenone		
Microbiology:		
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	

(*) Benzene not more than 0,05 % v/v.