

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) Council Directive 94/36/EC of the European Parliament and of Council of 30 June 1994 on colours for use in foodstuffs ⁽³⁾ lists those substances which may be used as colours in foodstuffs.
- (2) Commission Directive 94/45/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.

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.

Done at Brussels, 3 July 2001.

For the Commission

David BYRNE

Member of the Commission

⁽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.

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

$E_{1\text{ cm}}^{1\%}$ 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 |
| 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 % $E_{1\text{ cm}}^{1\%}$ 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 |
|-----------------|---|

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) $E_{1\text{ cm}}^{1\%}$ 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 |
|-----------------|--|

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

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)

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

Red to brownish-red crystals or crystalline powder

Description

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

Ochratoxin

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

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