

**COMMISSION DIRECTIVE 2003/95/EC
of 27 October 2003**

**amending Directive 96/77/EC laying down specific purity criteria on food additives other than
colours and sweeteners**

(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 on Food,

Whereas:

- (1) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽³⁾, as last amended by Directive 2001/5/EC ⁽⁴⁾, lays down a list of substances which may be used as additives other than colours and sweeteners in foodstuffs.
- (2) Commission Directive 96/77/EC ⁽⁵⁾, as last amended by Directive 2002/82/EC ⁽⁶⁾, sets out the purity criteria for the additives mentioned in Directive 95/2/EC.
- (3) The Scientific Committee on Food concluded in its opinion of 6 May 2002 that the presence of ethylene oxide should be brought below the detection limit. Consequently, the relevant criterion of the existing purity criteria set out in Directive 96/77/EC needs to be adapted.
- (4) It is necessary to adapt to technical progress the existing purity criteria for E 251 sodium nitrate and E 459 beta-cyclodextrin.
- (5) 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).
- (6) Directive 96/77/EC should therefore be amended accordingly.
- (7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 96/77/EC is amended as set out in 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 by 1 November 2004 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

Products put on the market or labelled before 1 November 2004 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 27 October 2003.

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 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 55, 24.2.2001, p. 59.

⁽⁵⁾ OJ L 339, 30.12.1996, p. 1.

⁽⁶⁾ OJ L 292, 28.10.2002, p. 1.

ANNEX

The Annex to Directive 96/77/EC is amended as follows:

1. The text concerning E 251 sodium nitrate is replaced by the following:

E 251 SODIUM NITRATE**1. SOLID SODIUM NITRATE****Synonyms**

Chile saltpetre
Cubic or soda nitre

Definition

Chemical name

Sodium nitrate

EINECS

231-554-3

Chemical formula

NaNO₃

Molecular weight

85,00

Assay

Content not less than 99 % after drying

Description

White crystalline, slightly hygroscopic powder

Identification

A. Positive tests for nitrate and for sodium

B. pH of a 5 % solution

Not less than 5,5 and not more than 8,3

Purity

Loss on drying

Not more than 2 % after drying at 105 °C for four hours

Nitrites

Not more than 30 mg/kg expressed as NaNO₂

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 251 SODIUM NITRATE**2. LIQUID SODIUM NITRATE****Definition**

Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoichiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled.

Chemical name

Sodium nitrate

EINECS

231-554-3

Chemical formula

NaNO₃

Molecular weight

85,00

Assay

Content between 33,5 % and 40,0 % of NaNO₃

Description

Clear colourless liquid

Identification

A. Positive tests for nitrate and for sodium

B. pH

Not less than 1,5 and not more than 3,5

Purity

Free nitric acid

Not more than 0,01 %

Nitrites

Not more than 10 mg/kg expressed as NaNO₂

Arsenic

Not more than 1 mg/kg

Lead

Not more than 1 mg/kg

Mercury

Not more than 0,3 mg/kg

This specification refers to a 35 % aqueous solution.

2. The text concerning E 431 Polyoxyethylene (40) stearate, E 432 Polyoxyethylene sorbitan monolaurate (Polysorbate 20), E 433 Polyoxyethylene sorbitan monooleate (Polysorbate 80), E 434 Polyoxyethylene sorbitan monopalmitate (Polysorbate 40), E 435 Polyoxyethylene sorbitan monostearate (Polysorbate 60) and E 436 Polyoxyethylene sorbitan tristearate (Polysorbate 65) is replaced by the following:

'E 431 POLYOXYETHYLENE (40) STEARATE

Synonyms

Polyoxyl (40) stearate

Definition

polyoxyethylene (40) monostearate

A mixture of the mono- and diesters of edible commercial stearic acid and mixed polyoxyethylene diols (having an average polymer length of about 40 oxyethylene units) together with free polyol

Assay

Content not less than 97,5 % on the anhydrous basis

Description

Cream-coloured flakes or waxy solid at 25 °C with a faint odour

Identification

A. Solubility

Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil

B. Congealing range

39 °C — 44 °C

C. Infrared absorption spectrum

Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water

Not more than 3 % (Karl Fischer method)

Acid value

Not more than 1

Saponification value

Not less than 25 and not more than 35

Hydroxyl value

Not less than 27 and not more than 40

1,4-dioxane

Not more than 5 mg/kg

Ethylene oxide

Not more than 0,2 mg/kg

Ethylene glycols (mono- and di-)

Not more than 0,25 %

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 432 POLYOXYETHYLENE SORBITAN MONOLAUROATE (POLYSORBATE 20)

Synonyms

Polysorbate 20

Polyoxyethylene (20) sorbitan monolaurate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay

Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis

Description

A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

Identification

A. Solubility

Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether

B. Infrared absorption spectrum

Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 40 and not more than 50
Hydroxyl value	Not less than 96 and not more than 108
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
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 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)**Synonyms**

Polysorbate 80
Polyoxyethylene (20) sorbitan monooleate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay

Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis

Description

A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

Identification

- | | |
|---------------------------------|--|
| A. Solubility | Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 65 and not more than 80
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
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 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)

Synonyms	Polysorbate 40 Polyoxyethylene (20) sorbitan monopalmitate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 41 and not more than 52
Hydroxyl value	Not less than 90 and not more than 107
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
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 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)

Synonyms	Polysorbate 60 Polyoxyethylene (20) sorbitan monostearate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 81 and not more than 96
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
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 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)**Synonyms**

Polysorbate 65
Polyoxyethylene (20) sorbitan tristearate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay

Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis

Description

A tan-coloured, waxy solid at 25 °C with a faint characteristic odour

Identification

A. Solubility	Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol
B. Congealing range	29 — 33 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 88 and not more than 98
Hydroxyl value	Not less than 40 and not more than 60
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
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

3. The text concerning E 459 beta-cyclodextrin is replaced by the following:

'E 459 BETA-CYCLODEXTRIN

Definition

Chemical name

EINECS

Chemical formula

Molecular weight

Assay

Description

Identification

A. Solubility

B. Specific rotation

Purity

Water

Other cyclodextrins

Residual solvents (toluene and trichloroethylene)

Sulphated ash

Arsenic

Lead

Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α -1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cyclodextran transferase (CGTase) obtained from *Bacillus circulans*, *Paenibacillus macerans* or recombinant *Bacillus licheniformis* strain SJ1608 on partially hydrolysed starch.

Cycloheptaamylose

231-493-2

$(C_6H_{10}O_5)_7$

1135

Content not less than 98,0 % of $(C_6H_{10}O_5)_7$ on an anhydrous basis

Virtually odourless white or almost white crystalline solid

Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol

$[\alpha]_D^{25}$: +160 ° to +164 ° (1 % solution)

Not more than 14 % (Karl Fischer method)

Not more than 2 % on an anhydrous basis

Not more than 1 mg/kg for each solvent

Not more than 0,1 %

Not more than 1 mg/kg

Not more than 1 mg/kg

4. The text concerning Polyethylene glycol 6000 is replaced by the following:

'POLYETHYLENE GLYCOL 6000

Synonyms

Definition

Chemical formula

Molecular weight

Assay

Description

Identification

A. Solubility

B. Melting range

Purity

Viscosity

Hydroxyl value

Sulphated ash

Ethylene oxide

Arsenic

Lead

PEG 6000

Macrogol 6000

Polyethylene glycol 6000 is a mixture of polymers with the general formula $H-(OCH_2-CH_2)_n-OH$ corresponding to an average relative molecular mass of approximately 6 000

$(C_2H_4O)_n \cdot H_2O$ (n = number of ethylene oxide units corresponding to a molecular weight of 6 000, about 140)

5 600 — 7 000

Not less than 90,0 % and not more than 110,0 %

A white or almost white solid with a waxy or paraffin-like appearance

Very soluble in water and in methylene chloride. Practically insoluble in alcohol, in ether and in fatty and mineral oils

Between 55 °C and 61 °C

Between 0,220 and 0,275 kgm⁻¹s⁻¹ at 20 °C

Between 16 and 22

Not more than 0,2 %

Not more than 0,2 mg/kg

Not more than 3 mg/kg

Not more than 5 mg/kg