

COUNCIL DIRECTIVE

of 4 May 1976

amending for the second time Directive 65/66/EEC laying down specific criteria of purity for the preservatives authorized for use in foodstuffs intended for human consumption

(76/463/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption⁽¹⁾, as last amended by Directive 76/462/EEC⁽²⁾, and in particular Article 8 thereof,

Having regard to the proposal from the Commission,

Whereas Directive 65/66/EEC⁽³⁾, as amended by Directive 67/428/EEC⁽⁴⁾, laid down specific criteria of purity for the preservatives listed in the Annex to Directive 64/54/EEC; whereas that Annex was supplemented by Directive 71/160/EEC which added

calcium sulphite to the list of authorized preservatives, by the Act of Accession which added methyl p-hydroxybenzoate and calcium bisulphite, by Directive 74/62/EEC which added formic acid, sodium formate, calcium formate and hexamethylenetetramine, by Directive 74/394/EEC which added thiabendazole and Directive 76/462/EEC which added the sodium derivative of methyl p-hydroxybenzoate, potassium nitrite and potassium propionate;

Whereas it is necessary to lay down specific criteria of purity for the eleven preservatives mentioned above,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 65/66/EEC shall be amended as follows:

1. The following specifications shall be inserted between Nos E 217 and E 220:

E 218 p-hydroxybenzoate

Appearance:	White, almost odourless, crystalline powder
Melting range:	125 to 128 °C
Content:	Not less than 99.0 % expressed as C ₈ H ₈ O ₃ after drying for two hours at 80 °C
Sulphated ash:	Not more than 0.05 %
Free acidity:	Not more than 0.7 % expressed as p-hydroxybenzoic acid
Salicylic acid:	Not more than 0.1 %
Loss on drying:	Not more than 0.5 % after drying for two hours at 80 °C

E 219 Sodium derivative of methyl p-hydroxybenzoate

Appearance:	White hygroscopic powder
Melting range of methyl ester:	The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl p-hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 to 128 °C.

⁽¹⁾ OJ No 12, 27. 1. 1964, p. 161/64.

⁽²⁾ See page 31 of this Official Journal.

⁽³⁾ OJ No 22, 9. 2. 1965, p. 373/65.

⁽⁴⁾ OJ No 148, 11. 7. 1967, p. 10.

Content :	Not less than 99.5 % of $C_8H_7O_3Na$ calculated on the dry matter
Moisture :	Not more than 5.0 % (Karl-Fischer)
Sulphated ash :	40.0 to 44.5 % calculated on the dry matter
pH (0.1 % solution in carbon dioxide-free water) :	Not less than 9.7 and not more than 10.3
Salicylic acid :	Not more than 0.1 %

2. The following specifications shall be inserted between Nos E 225 and E 230 :

E 226 Calcium sulphite

Appearance :	White crystals or white crystalline powder
Content :	Not less than 95 % of $CaSO_3 \cdot 2H_2O$ and not less than 39 % of SO_2
Sulphates :	Not more than 0.1 %, expressed as SO_4
Chlorides :	Not more than 0.05 % expressed as Cl
Iron :	Not more than 0.005 %
Selenium :	Not more than 10 mg/kg of the SO_2 content

E 227 Calcium hydrogen sulphite

Appearance :	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide
Content :	6 to 8 % (w/v) of sulphur dioxide and 2.5 to 3.5 % (w/v) of calcium oxide corresponding to 10 to 14 % (w/v) of calcium bisulphite $[Ca(HSO_3)_2]$
Iron :	Not more than 30 mg/kg
Selenium :	Not more than 10 mg/kg of the SO_2 content

3. The following specifications shall be inserted between Nos E 232 and E 250

E 233 2-(4-thiazolyl) benzimidazole (thiabendazole)

Appearance :	White, or almost white, odourless powder
Melting range :	296 to 303 °C
Content :	98 to 101 % $C_{10}H_7N_3S$ calculated on the anhydrous product
Sulphated ash :	Not more than 0.2 %
Moisture :	Not more than 0.5 % (Karl-Fischer)
UV Absorption (0.0005 % w/v in 0.1 N HCl) :	$E_{1\text{ cm}}^{1\%}$ at $302 \pm 2\text{ nm}$ = 1 230 approximately $E_{1\text{ cm}}^{1\%}$ at $258 \pm 2\text{ nm}$ = 200 approximately $E_{1\text{ cm}}^{1\%}$ at $243 \pm 2\text{ nm}$ = 620 approximately Ratio of $\frac{\text{absorption at } 241 \text{ to } 245\text{ nm}}{\text{absorption at } 300 \text{ to } 304\text{ nm}}$ = 0.47 to 0.53 Ratio of $\frac{\text{absorption at } 256 \text{ to } 260\text{ nm}}{\text{absorption at } 300 \text{ to } 304\text{ nm}}$ = 0.14 to 0.18
Selenium :	10 mg/kg

E 236 Formic acid

Appearance :	; colourless, highly corrosive liquid with a characteristic pungent odour
Content :	less than 98.0 % of CH_2O_2
Acetic acid :	more than 0.5 %

Sulphates :	Not more than 40 mg/kg, expressed as SO ₄
Sulphites :	Dilute 25 ml of formic acid with 25 ml of water. Add 0.1 ml of 0.1 N iodine solution. The solution should retain a distinct yellow colour
Chlorides :	Not more than 50 mg/kg, expressed as Cl
Specific gravity :	1.216 to 1.220 (20/20 °C)
Non-volatile matter :	Not more than 0.05 %
Aldehydes :	A slightly alkaline 5 % solution, on heating must not give off a sharp or burnt smell
Formaldehyde :	Not more than 0.1 % of the formic acid content, determined using chromotropic acid
Oxalic acid :	Not more than 0.5 % of the formic acid content determined as calcium oxalate, expressed as oxalic acid

E 237 Sodium formate

Appearance :	White crystalline powder
Content :	Not less than 98 % NaCHO ₂ after drying for two hours at 105 °C
Volatile matter :	Not more than 2 % by drying for two hours at 105 °C
Degree of acidity or alkalinity :	Neutralization of 1 g of sodium formate in the presence of phenolphthalein must not require more than 0.5 ml of 0.1 N HCl or 0.1 N NaOH
Aldehydes :	A 5 % solution on heating must not give off a sharp or burnt smell
Formaldehyde :	Not more than 0.1 % of the sodium formate content, determined using chromotropic acid
Oxalic acid :	Not more than 0.5 % of the sodium formate content, determined as calcium oxalate, expressed as oxalic acid

E 238 Calcium formate

Appearance :	White crystalline powder
Content :	Not less than 98 % CaC ₂ H ₂ O ₄ after drying for two hours at 105 °C
Volatile matter :	Not more than 2 % after drying for two hours at 105 °C
Water-insoluble matter :	Not more than 0.5 %
Degree of acidity or alkalinity :	Neutralization of 1 g of calcium formate in the presence of phenolphthalein must not require more than 0.5 ml of 0.1 N HCl or 0.1 N NaOH
Aldehydes :	A 5 % solution on heating must not give off a sharp or burnt smell
Formaldehyde :	Not more than 0.1 % of the calcium formate content, determined using chromotropic acid
Oxalic acid :	Not more than 0.3 % of the calcium formate content, determined as calcium oxalate, expressed as oxalic acid

E 239 Hexamethylenetetramine

Appearance :	Colourless, or white, crystalline powder
Content :	Not less than 99 % C ₆ H ₁₂ N ₄
Loss on drying :	Not more than 0.5 % after drying at 105 °C in vacuum over phosphorus pentoxide for two hours
Sublimation point :	Sublimes at about 260 °C
Sulphated ash :	Not more than 0.05 %
Sulphates :	Not more than 0.005 %, expressed as SO ₄
Chlorides :	Not more than 0.005 % expressed as Cl

E 249 Potassium nitrite

Appearance :	White, or slightly yellow, deliquescent granules
Content :	Not less than 95 % after drying for four hours over silica gel
pH (5 % solution in carbon dioxide-free and ammonia-free water) :	Not less than 6.0 and not more than 9.0

4. The following specifications shall be inserted between Nos E 282 and E 290

E 283 Potassium propionate

Appearance :	White crystalline powder
Content :	Not less than 99 % after drying for two hours at 105 °C
Volatile substances :	Not more than 4 % after drying for two hours at 105 °C
Water-insoluble substances :	Not more than 0.3 %
Readily oxidizable substances :	No trace
Iron :	Not more than 30 mg/kg

Article 2

Member States shall make any amendments to their laws necessary to comply with this Directive within one year of its notification and shall forthwith inform the Commission thereof. The laws thus amended shall be brought into force not later than two years after such notification.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 4 May 1976.

For the Council

The President

G. THORN
