ANNEX

The Annex to Directive 95/31/EC is amended and corrected as follows:

1. The following text concerning E 968 erythritol is inserted after E 967 xylitol:

E 968 ERYTHRITOL	
Synonyms	Meso-erythritol, tetrahydroxybutane, erythrite
Definition	Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as *Moniliella pollinis* or *Trichosporonoides megachilensis*, followed by purification and drying
Chemical name	1,2,3,4-Butanetetrol
Einecs	205-737-3
Chemical formula	$C_4H_{10}O_4$
Molecular weight	122,12
Assay	Not less than 99 % after drying
Description	White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose.
Identification	
A. Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.
B. Melting range	119-123 °C
Purity	
Loss on drying	Not more than 0,2 % (70 °C, six hours, in a vacuum desiccator)
Sulphated ash	Not more than 0,1 %
Reducing substances	Not more than 0,3 % expressed as D-glucose
Ribitol and glycerol	Not more than 0,1 %
Lead	Not more than 0,5 mg/kg

2. The text concerning E 954 saccharin and its Na, K and Ca salts is replaced by the following:

E 954 SACCHARIN AND ITS Na, K AND Ca SALTS
(I) SACCHARIN
Definition

Chemical name	3-Oxo-2,3-dihydrobenzo(d)isothiazol-1,1-dioxide
Einecs	201-321-0
Chemical formula	$C_7H_5NO_3S$
Relative molecular mass	183,18
Assay	Not less than 99 % and not more than 101 % of $C_7H_5NO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint, aromatic odour, having a sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
Identification	
Solubility	Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 1 % (105 °C, two hours)
Melting range	226-230 °C
Sulphated ash	Not more than 0,2 % expressed on dry weight basis
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulfonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis.
(II) SODIUM SACCHARIN	

Synonyms	Saccharin, sodium salt of saccharin
Definition	
Chemical name	Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisosulphonazole, oxobenzisosulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide sodium salt dihydrate
Einecs	204-886-1
Chemical formula	$C_7H_4NNaO_3S \cdot 2H_2O$
Relative molecular mass	241,19
Assay	Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline efflorescent powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 15 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis

Lead	Not more than 1 mg/kg expressed on dry weight basis
(III) CALCIUM SACCHARIN	
Synonyms	Saccharin, calcium salt of saccharin
Definition	
Chemical name	Calcium o-benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzisosulfonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs	229-349-9
Chemical formula	$C_{14}H_8CaN_2O_6S_2 \cdot 3^1/_2H_2O$
Relative molecular mass	467,48
Assay	Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
Identification	
Solubility	Freely soluble in water, soluble in ethanol
Purity	
Loss on drying	Not more than 13,5 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis

Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
(IV) POTASSIUM SACCHARIN	
Synonyms	Saccharin, potassium salt of saccharin
Definition	
Chemical name	Potassium o-benzosulphimide, potassium salt of 2,3-dihydro-3-oxobenzisosulphonazole, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate
Einecs	
Chemical formula	$C_7H_4KNO_3S \cdot H_2O$
Relative molecular mass	239,77
Assay	Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 8 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent

Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

3. The text concerning E 955 sucralose is replaced by the following:

E 955 SUCRALOSE	
Synonyms	4,1′,6′-Trichlorogalactosucrose
Definition	
Chemical name	1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside
Einecs	259-952-2
Chemical formula	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % of $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis.
Description	White to off-white, practically odourless crystalline powder.
Identification	
A. Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate
B. Infrared absorption	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard
C. Thin layer chromatography	The main spot in the test solution has the same Rf value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol
D. Specific rotation	$[\alpha]_D^{20}$ = + 84,0° to + 87,5° calculated on the anhydrous basis (10 % w/v solution)
Purity	

Water	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %
Lead	Not more than 1 mg/kg

4. The text concerning E 962 salt of aspartame-acesulfame is replaced by the following:

E 962 SALT OF ASPARTAME-ACESULFAME		
Synonyms		Aspartame-acesulfame, aspartame-acesulfame salt
Definition		The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone
Chemical name		6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-α-aspartic acid
Chemical formula		$C_{18}H_{23}O_9N_3S$
Molecular weight		457,46
Assay		63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37 % acesulfame (acid form on a dry basis)
Description		A white, odourless, crystalline powder
Identification		
A.	Solubility	Sparingly soluble in water, slightly soluble in ethanol
B.	Transmittance	The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022
C.	Specific rotation	$[\alpha]_{D^{20}}$ = + 14,5° to + 16,5° Determine at concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to

	correct for the aspartame content of the salt of aspartame-acesulfame
Purity	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg

5. The text concerning E 965 (i) maltitol is replaced by the following:

E 965 (i) MALTITOL	
Synonyms	D-Maltitol, hydrogenated maltose
Definition	
Chemical name	(α)-D-Glucopyranosyl-1,4-D-glucitol
Einecs	209-567-0
Chemical formula	$C_{12}H_{24}O_{11}$
Relative molecular mass	344,31
Assay	Content not less than 98 % of D-maltitol $C_{12}H_{24}O_{11}$ on the anhydrous basis
Description	Sweet tasting, white crystalline powder
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Melting range	148 to 151 °C
C. Specific rotation	$[\alpha]_{D}^{20}$ = + 105,5° to + 108,5° (5 % w/v solution)
Purity	
Water	Not more than 1 % (Karl Fischer method)
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Reducing sugars	Not more than 0,1 % expressed as glucose on dry weight basis
Chlorides	Not more than 50 mg/kg expressed on dry weight basis
Sulphates	Not more than 100 mg/kg expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis

Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

6. The text concerning E 965 (ii) maltitol syrup is replaced by the following:

E 965 (ii) MALTITOL SYRUP	
Synonyms	Hydrogenated high-maltose glucose syrup, hydrogenated glucose syrup
Definition	A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product
Assay	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis
Description	Colourless and odourless, clear viscous liquids or white crystalline masses
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Thin layer chromatography	Passes test
Purity	
Water	Not more than 31 % (Karl Fischer)
Reducing sugars	Not more than 0,3 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 50 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

7. The text concerning E 966 lactitol is replaced by the following:

E 966 LACTITOL	
Synonyms	Lactit, lactositol, lactobiosit
Definition	

Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Einecs	209-566-5
Chemical formula	$C_{12}H_{24}O_{11}$
Relative molecular mass	344,32
Assay	Not less than 95 % on the dry weight basis
Description	Sweet-tasting crystalline powders or colourless solutions. Crystalline products occur in anhydrous, monohydrate and dihydrate forms
Identification	
A. Solubility	Very soluble in water
B. Specific rotation	$[\alpha]_{D}^{20}$ = + 13° to + 16° calculated on the anhydrous basis (10 % w/v aqueous solution)
Purity	
Water	Crystalline products; not more than 10,5 % (Karl Fischer method)
Other polyols	Not more than 2,5 % on the anhydrous basis
Reducing sugars	Not more than 0,2 % expressed as glucose on dry weight basis
Chlorides	Not more than 100 mg/kg expressed on dry weight basis
Sulphates	Not more than 200 mg/kg expressed on dry weight basis
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis