

Food Standards (Proposal P1025 – Code Revision) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on 1 March 2016.

Dated 25 March 2015



Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC 96 on 10 April 2015.

Schedule 3 Identity and purity

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Standard 1.1.1 relates to introductory matters and standards that apply to all foods. Section 1.1.1—15 requires certain substances to comply with relevant specifications. This Standard sets out the relevant specifications.

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

S3—1 Name

This Standard is *Australia New Zealand Food Standards Code – Schedule 3 – Identity and purity*.

Note Commencement:
This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

S3—2 Substances with specifications in primary sources

- (1) For subsection 1.1.1—15(2), the specifications are:
- (a) any relevant provision listed in the table to subsection (2); or
 - (b) Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005), Food and Agriculture Organisation of the United Nations, Rome, as superseded by specifications published in any of the following:
 - (i) FAO JECFA Monographs 3 (2006);
 - (ii) FAO JECFA Monographs 4 (2007);
 - (iii) FAO JECFA Monographs 5 (2008);
 - (iv) FAO JECFA Monographs 7 (2009);
 - (v) FAO JECFA Monographs 10 (2010);
 - (vi) FAO JECFA Monographs 11 (2011);
 - (vii) FAO JECFA Monographs 13 (2012); or
 - (c) United States Pharmacopeial Convention (2014) Food chemicals codex. 9th ed, United States Pharmacopeial Convention, Rockville, MD; or
 - (d) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives.
- (2) The table to this subsection is:

Relevant provisions

Substance	Provision
advantame	section S3—5
agarose ion exchange resin	section S3—6
bentonite	section S3—7
bromo-chloro-dimethylhydantoin	section S3—8
carboxymethyl cellulose ion exchange resin	section S3—9
dibromo-dimethylhydantoin	section S3—10
diethyl aminoethyl cellulose ion exchange resin	section S3—11
dimethyl ether	section S3—12
dried marine micro-algae (<i>Schizochytrium</i> sp.) rich in docosahexaenoic acid (DHA)	section S3—13

Substance	Provision
ice structuring protein type III HPLC 12 preparation	section S3—14
isomaltulose	section S3—15
<i>Listeria</i> phage P100	section S3—16
nucleotides	sections S3—17 and S3—18
oil derived from the algae <i>Cryptocodinium cohnii</i> rich in docosahexaenoic acid (DHA)	section S3—19
oil derived from the fungus <i>Mortierella alpina</i> rich in arachidonic acid (ARA)	section S3—20
oil derived from marine micro-algae (<i>Schizochytrium</i> sp.) rich in docosahexaenoic acid (DHA)	section S3—21
oil derived from marine micro-algae (<i>Ulkenia</i> sp.) rich in docosahexaenoic acid (DHA)	section S3—22
oxidised polyethylene	section S3—23
phytosterols, phytosterols and their esters	section S3—24
quaternary amine cellulose ion exchange resin	section S3—25
resistant maltodextrins	section S3—26
tall oil phytosterol esters	section S3—27
yeast—enriched selenium	section S3—28
yeast—high chromium	section S3—29
yeast—high molybdenum	section S3—30

S3—3

Substances with specifications in secondary sources

If there is no relevant specification under section S3—2, the specification is a specification listed in one of the following:

- (a) British Pharmacopoeia Commission (2014) British Pharmacopoeia 2014. TSO, Norwich;
- (b) United States Pharmacopeial Convention (2013) United States pharmacopeia and the national formulary. 37th revision. 32nd ed, United States Pharmacopeial Convention, Rockville, MD;
- (c) Royal Pharmaceutical Society of Great Britain. Lund W (1994) Pharmaceutical codex: principles and practice of pharmaceuticals, 12th ed, Pharmaceutical Press, London;
- (d) Sweetman SC (2011) Martindale: the complete drug reference. 37th ed, Pharmaceutical Press, London;
- (e) the European Pharmacopoeia 8th Edition, Council of Europe, Strasbourg (2014);
- (f) the International Pharmacopoeia 4th Edition, World Health Organization, Geneva (2006 and 2008 supplement);
- (g) the Merck Index, 15th Edition, (2013);
- (h) the Code of Federal Regulations;
- (i) the Specifications and Standards for Food Additives, 8th Edition (2007), Ministry of Health and Welfare (Japan); or
- (j) the International Oenological Codex (2013), Organisation Internationale de la Vigne et du Vin (OIV).

S3—4**Additional and supplementary requirements**

If there is no relevant specification under section S3—2 or S3—3, or if the monographs referred to in those sections do not contain a specification for identity and purity of a substance relating to arsenic or heavy metals, the specification is that the substance must not contain on a dry weight basis more than:

- (a) 2 mg/kg of lead; or
- (b) 1 mg/kg of arsenic; or
- (c) 1 mg/kg of cadmium; or
- (d) 1 mg/kg of mercury.

S3—5**Specifications for advantame**

For advantame, the specifications are:

- (a) purity, using the analytical methodology indicated:
 - (i) assay:
 - (A) specification—not less than 97.0% and not more than 102.0% on anhydrous basis; and
 - (B) analytical methodology—high pressure liquid chromatography; and
 - (ii) specific rotation $[\alpha]^{20}_D$:
 - (A) specification—between -45° and -38° ; and
 - (B) analytical methodology—Japanese Pharmacopeia; and
 - (iii) advantame-acid:
 - (A) specification—not more than 1.0%; and
 - (B) analytical methodology—HPLC; and
 - (iv) total other related substances:
 - (A) specification—not more than 1.5%; and
 - (B) analytical methodology—HPLC; and
 - (v) water:
 - (A) specification—not more than 5.0%; and
 - (B) analytical methodology—Karl Fischer coulometric titration; and
 - (vi) residue on ignition:
 - (A) specification—no more than 0.2%; and
 - (B) analytical methodology—Japanese Pharmacopeia; and
- (b) residual solvents, using gas chromatography:
 - (i) methyl acetate—no more than 500 mg/kg; and
 - (ii) isopropyl acetate—no more than 2 000 mg/kg; and
 - (iii) methanol—no more than 500 mg/kg; and
 - (iv) 2-Propanol—no more than 500 mg/kg.

S3—6**Specification for agarose ion exchange resin**

- (1) This specification relates to agarose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting amount of agarose.
- (2) The resins are limited to use in aqueous process streams for the removal of proteins and polyphenols from beer. The pH range for the resins shall be no less than 2 and no more than 5, and the temperatures of water and food passing through the resin bed shall not exceed 2°C. pH and temperature restrictions do not apply to cleaning processes.

- (3) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—7 Specification for bentonite

Bentonite must comply with a monograph specification in section S3—2 or section S3—3, except that the pH determination for a bentonite dispersion must be no less than 4.5 and no more than 10.5.

S3—8 Specification for bromo-chloro-dimethylhydantoin

- (1) In this section:
- bromo-chloro-dimethylhydantoin*** (CAS Number: 126-06-7) is the chemical with:
- (a) the formula $C_5H_6BrClN_2O_2$; and
 - (b) the formula weight 241.5.
- (2) For bromo-chloro-dimethylhydantoin, the chemical specifications are the following:
- (a) appearance—solid or free flowing granules;
 - (b) colour—white;
 - (c) odour—faint halogenous odour;
 - (d) melting point—163–164°C;
 - (e) specific gravity—1.8–2;
 - (f) solubility in water—0.2 g/100 g at 25°C;
 - (g) stability—stable when dry and uncontaminated.
- (3) Bromo-chloro-dimethylhydantoin must be manufactured in accordance with the following process:
- (a) solid dimethylhydantoin (DMH) must be dissolved in water with bromine and chlorine;
 - (b) the reaction must be 0.5 mole bromine and 1.5 mole chlorine for one mole DMH;
 - (c) during the reaction the pH must be kept basic by the addition of caustic soda;
 - (d) the wet product must be transferred to a drier where it is dried to a powder at low temperature;
 - (e) the powder may then be tableted or granulated.
- (4) Bromo-chloro-dimethylhydantoin may be assayed in accordance with various analytical methods, including GLC, HPLC, UV and NMR.

Note HPLC offers the best sensitivity.

S3—9 Specification for carboxymethyl cellulose ion exchange resin

- (1) This specification relates to regenerated cellulose that has been cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with carboxymethyl groups, as a result of which the amount of epichlorohydrin plus propylene oxide is no more than 70% by weight of the starting amount of cellulose.
- (2) The resins are limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates. The pH range for the resins shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin bed must be no more than 40°C.
- (3) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—10 Specification for dibromo-dimethylhydantoin

- (1) In this section:
dibromo-dimethylhydantoin means the chemical with CAS Number 77-48-5 and formula $C_5H_6Br_2N_2O_2$.
- (2) For dibromo-dimethylhydantoin, the specifications (which relate to purity) are the following:
- (a) dibromo-dimethylhydantoin—no less than 97%;
 - (b) sodium bromide—no more than 2%;
 - (c) water—no more than 1%.

S3—11 Specification for diethyl aminoethyl cellulose ion exchange resin

- (1) This specification relates to:
- (a) regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide is no more than 70% by weight of the starting amount of cellulose; and
 - (b) regenerated cellulose, cross-linked and alkylated with epichlorohydrin then derivatised with tertiary amine groups whereby the amount of epichlorohydrin is no more than 10% by weight of the starting amount of cellulose.
- (2) The resins are limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates. The pH range for the resins shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin bed must be no more than 50°C.
- (3) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—12 Specification for dimethyl ether

For dimethyl ether, the specifications are the following:

- (a) purity—minimum of 99.8%;
- (b) methanol—not greater than 200 mg/kg.

S3—13 Specification for dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)

For docosahexaenoic acid (DHA)-rich dried marine micro-algae (*Schizochytrium* sp.), the specifications are the following:

- (a) full chemical name—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);
- (b) solids (%)—minimum 95.0;
- (c) DHA (%)—minimum 15.0;
- (d) lead (mg/kg)—maximum 0.5;
- (e) arsenic (mg/kg)—maximum 0.5.

S3—14 Specification for ice structuring protein type III HPLC 12 preparation

- (1) In this section:
ice structuring protein type III HPLC 12 preparation means the protein excreted from the fermentation of a genetically modified yeast (*Saccharomyces cerevisiae*) to which a synthetic gene encoding for the protein has been inserted into the yeast's genome.

- (2) For ice structuring protein type III HPLC 12 preparation, the specifications are the following:
- (a) assay—not less than 5 g/L active ice structuring protein type III HPLC 12;
 - (b) pH—3.0+/-0.5;
 - (c) ash—not more than 2%;
 - (d) appearance—light brown aqueous preparation;
 - (e) heavy metals—not more than 2 mg/L;
 - (f) microbial limits:
 - (i) total microbial count—<3 000/g; and
 - (ii) coliforms—<10/g; and
 - (iii) yeast and mould count—<100/g; and
 - (iv) *listeria* sp.—absent in 25 g; and
 - (v) *salmonella* sp.—absent in 25 g; and
 - (vi) *bacillus cereus*—<100/g.

S3—15

Specification for isomaltulose

For isomaltulose, the specifications are the following:

- (a) chemical name—6-O- α -D-glucopyranosyl-D-fructofuranose;
- (b) description—white or colourless, crystalline, sweet substance, faint isomaltulose specific odour;
- (c) isomaltulose (%)—not less than 98% on a dry weight basis;
- (d) water—maximum 6%;
- (e) other saccharides—maximum 2% on a dry weight basis;
- (f) ash—maximum 0.01% on a dry weight basis;
- (g) lead—maximum 0.1 ppm on a dry weight basis.

S3—16

Specification for *Listeria* phage P100

For *Listeria* phage P100, the biological classification is the following:

- (a) order—*Caudovirales*;
- (b) family—*Myoviridae*;
- (c) subfamily—*Spounaviridae*;
- (d) genus—twort-like;
- (e) species—*Listeria* phage P100;
- (f) GenBank Accession Number—DQ004855.

S3—17

Descriptions and physical constraints for nucleotides

Uridine-5'-monophosphate disodium salt (UMP)

- (1) For uridine-5'-monophosphate disodium salt (UMP), the specifications are the following:
- (a) empirical chemical formula— $C_9 H_{11} N_2 O_9 PNa_2$;
 - (b) the compound must be of the 5 species, with the disodium monophosphate structure attached to the fifth carbon in the central structure;
 - (c) molecular weight—368.15;
 - (d) structure or physical character—occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste;
 - (e) solubility—freely soluble in water; very slightly soluble in alcohol.

Adenosine-5'-monophosphate (AMP)

- (2) For adenosine-5'-monophosphate (AMP), the specifications are the following:
- (a) empirical chemical formula— $C_{10}H_{14}N_5O_7P$;
 - (b) the compound must be of the 5 species, with the monophosphate structure attached to the fifth carbon in the central structure;
 - (c) molecular weight—347.22;
 - (d) structure or physical character—occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic acidic taste;
 - (e) solubility—very slightly soluble in water; practically insoluble in alcohol.

Cytidine-5'-monophosphate (CMP)

- (3) For cytidine-5'-monophosphate (CMP), the specifications are the following:
- (a) empirical chemical formula— $C_9H_{14}N_3O_8P$;
 - (b) the compound must be of the 5 species, with the monophosphate structure attached to the fifth carbon in the central structure;
 - (c) molecular weight—323.20;
 - (d) structure or physical character—occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic slightly acidic taste;
 - (e) solubility—very slightly soluble in water; practically insoluble in alcohol.

S3—18

Testing requirements for nucleotides

The testing requirements for nucleotides are as follows:

- (a) physical inspection—white crystals or crystalline powder;
- (b) identification:
 - (i) ultraviolet absorbance: a 1 in 12 500 solution of the powder in 0.01N hydrochloric acid exhibits an absorbance maximum at an absorbance of:
 - (A) for inosine-5'-monophosphate disodium salt— $250 \pm 2\text{nm}$; and
 - (B) for uridine-5'-monophosphate disodium salt— $260 \pm 2\text{nm}$; and
 - (C) for adenosine-5'-monophosphate— $257 \pm 2\text{nm}$; and
 - (D) for cytidine-5'-monophosphate (CMP)— $280 \pm 2\text{nm}$; and
 - (E) guanosine-5'-monophosphate disodium salt (gMP)— $256 \pm 2\text{nm}$; and
 - (ii) IMP, UMP and gMP must test positive for sodium phosphate; and
 - (iii) IMP, UMP, AMP, CMP and gMP must test positive for organic phosphate;
- (c) assay (HPLC)—optimum of not less than 96% (corrected for moisture content);
- (d) IMP and gMP have a pH of a 1 in 20 solution: between 7.0 and 8.5;
- (e) clarity and colour of solution:
 - (i) 500 mg/10 mL H_2O for IMP: is colourless and shows only a trace of turbidity; and
 - (ii) 100 mg/10 mL H_2O for gMP: is colourless and shows only a trace of turbidity;
- (f) moisture:
 - (i) for inosine-5'-monophosphate disodium salt—not more than 28.5%: Karl Fischer; and
 - (ii) for uridine-5'-monophosphate disodium salt—not more than 26.0%: Karl Fischer; and

- (iii) guanosine-5'-monophosphate disodium salt (gMP)—loss in drying of not more than 25% (4 hrs @ 120°C); and
- (iv) for cytidine-5'-monophosphate (CMP)—loss in drying of not more than 6.0% (4 hrs @ 120°C); and
- (v) adenosine-5'-monophosphate—loss in drying of not more than 6.0% (4 hrs @ 120°C);
- (g) impurities—all nucleotides:
 - (i) for IMP, gMP—amino acids: negative; and
 - (ii) for IMP, gMP—ammonium salts: negative; and
 - (iii) for IMP, UMP, AMP, CMP, gMP—arsenic: not more than 2 ppm; and
 - (iv) for IMP, UMP, AMP, CMP, gMP—heavy metals: not more than 10 ppm;
- (h) related foreign substances:
 - (i) for IMP—only 5'-inosinic acid is detected by thin layer chromatography; and
 - (ii) for gMP—only 5'-guanylic acid is detected by thin layer chromatography;
- (i) bacteriological profile:
 - (i) *SPC—not more than 1 000/g, test per current FDA/BAM procedures; and
 - (ii) coliforms—negative by test; test per current FDA/BAM procedures; and
 - (iii) yeast and mould—not more than 300/g, test per current FDA/BAM procedures; and
 - (iv) *salmonella*—negative, test per current FDA/BAM procedures.

S3—19

Specification for oil derived from the algae *Cryptocodinium cohnii* rich in docosahexaenoic acid (DHA)

For oil derived from the algae *Cryptocodinium cohnii* rich in docosahexaenoic acid (DHA), the specifications are the following:

- (a) full chemical name for DHA—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3);
- (b) DHA (%)—minimum 35;
- (c) *trans fatty acids (%)—maximum 2.0;
- (d) lead (mg/kg)—maximum 0.1;
- (e) arsenic (mg/kg)—maximum 0.1;
- (f) mercury (mg/kg)—maximum 0.1;
- (g) hexane (mg/kg)—maximum 0.3.

S3—20

Specification for oil derived from the fungus *Mortierella alpina* rich in arachidonic acid (ARA)

For oil derived from the fungus *Mortierella alpina* rich in arachidonic acid (ARA), the specifications are the following:

- (a) full chemical name for ARA—5,8,11,14-eicosatetraenoic acid (20:4n-6 ARA);
- (b) ARA (%)—minimum 35;
- (c) *trans fatty acids (%)—maximum 2.0;
- (d) lead (mg/kg)—maximum 0.1;
- (e) arsenic (mg/kg)—maximum 0.1;
- (f) mercury (mg/kg)—maximum 0.1;
- (g) hexane (mg/kg)—maximum 0.3.

S3—21 Specification for oil derived from marine micro-algae (*Schizochytrium sp.*) rich in docosahexaenoic acid (DHA)

For oil derived from marine micro-algae (*Schizochytrium sp.*) rich in docosahexaenoic acid (DHA), the specifications are the following:

- (a) full chemical name—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);
- (b) DHA (%)—minimum 32;
- (c) *trans fatty acids (%)—maximum 2.0;
- (d) lead (mg/kg)—maximum 0.1;
- (e) arsenic (mg/kg)—maximum 0.1;
- (f) mercury (mg/kg)—maximum 0.1;
- (g) hexane (mg/kg)—maximum 0.3.

S3—22 Specification for oil derived from marine micro-algae (*Ulkenia sp.*) rich in docosahexaenoic acid (DHA)

For oil derived from marine micro-algae (*Ulkenia sp.*) rich in docosahexaenoic acid (DHA), the specifications are the following:

- (a) full chemical name for DHA—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);
- (b) DHA (%)—minimum 32;
- (c) *trans fatty acids (%)—maximum 2.0;
- (d) lead (mg/kg)—maximum 0.2;
- (e) arsenic (mg/kg)—maximum 0.2;
- (f) mercury (mg/kg)—maximum 0.2;
- (g) hexane (mg/kg)—maximum 10.

S3—23 Specification for oxidised polyethylene

- (1) In this section:

ASTM refers to standard test methods prepared by the American Society for Testing and Materials.

CAS means the Chemical Abstracts Service (CAS) Registry Number.

oxidised polyethylene (CAS 68441-17-8) is the polymer produced by the mild air oxidation of polyethylene.

- (2) For oxidised polyethylene, the specifications are the following:

- (a) average molecular weight—min 1200 (osmometric);
- (b) viscosity at 125°C—min 200cP;
- (c) oxygen content—max 9.1%;
- (d) acid value—max 70 mgKOH/g (ASTM D 1386);
- (e) drop point—min 95°C (ASTM D 566);
- (f) density (20°C)—0.93-1.05 g/cm³ (ASTM D 1298, D 1505);
- (g) extractable constituents:
 - (i) in water—maximum 1.5%; and
 - (ii) in 10% ethanol—max 2.3%; and
 - (iii) in 3% acetic acid—max 1.8%; and
 - (iv) in n-pentane—max 26.0%.

Note Extraction of oxidised polyethylene—25.0 g of finely ground oxidised polyethylene powder (particle size 300–1 000 µm) is extracted for 5 hours in the Soxhlet apparatus with 350 mL of solvent. The solvent is then distilled off and the distillation residue is dried in a vacuum oven at 80–90°C. After weighing the obtained residue, the components soluble in the solvent are calculated in % weight (based on the initial weight used).

S3—24**Specification for phytosterols, phytostanols and their esters**

- (1) Subject to subsections (2) and (3), *phytosterols, phytostanols and their esters must comply with a monograph specification in section S3—2 or section S3—3.
- (2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols, the concentration of hexane, isopropanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 2 g/kg.
- (3) The *total plant sterol equivalents content must contain no less than 95% des-methyl sterols.

S3—25**Specification for quaternary amine cellulose ion exchange resin**

- (1) This specification relates to regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with quaternary amine groups whereby the amount of epichlorohydrin plus propylene oxide is no more than 250% by weight of the starting amount of cellulose.
- (2) The resins are limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates. The pH range for the resins shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin bed must be no more than 50°C.
- (3) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—26**Specification for resistant maltodextrins**

For resistant maltodextrins, the specifications are the following:

- (a) chemical structure—glucopyranose linked by $\alpha(1-4)$, $\alpha(1-6)$, $\alpha/\beta(1-2)$, and $\alpha/\beta(1-3)$ glucosidic bonds; and contains levoglucosan;
- (b) dextrose equivalent—8-12;
- (c) appearance—free-flowing fine powder;
- (d) colour—white;
- (e) taste/odour—slightly sweet/odourless;
- (f) solution—clear;
- (g) pH (in 10% solution)—4-6;
- (h) moisture (%)—maximum 5;
- (i) ash (%)—maximum 0.2;
- (j) arsenic (ppm)—maximum 1;
- (k) heavy metals (ppm)—maximum 5;
- (l) microbiological:
 - (i) standard plate count (cfu/g)—maximum 300;
 - (ii) yeast and mould (cfu/g)—maximum 100;
 - (iii) *salmonella*—negative to test;
 - (iv) coliforms—negative to test.

S3—27**Specification for tall oil phytosterol esters**

- (1) In this section:

tall oil phytosterol esters are phytosterols derived from tall oil pitch esterified with long-chain fatty acids derived from edible vegetable oils
- (2) For tall oil phytosterol esters, the specifications are the following:
 - (a) phytosterol content:

- (i) phytosterol esters plus free phytosterols—no less than 97%; and
- (ii) free phytosterols after saponification—no less than 59%; and
- (iii) free phytosterols—no more than 6%; and
- (iv) steradienes—no more than 0.3%;
- (b) sterol profile based on input sterols:
 - (i) campesterol—no less than 4.0% and no more than 25.0%; and
 - (ii) campsteranol —no more than 14.0%; and
 - (iii) B-sitosterol—no less than 36.0% and no more than 79.0%; and
 - (iv) B-sitostanol—no less than 6.0% and no more than 34%; and
 - (v) fatty acid methylester—no more than 0.5%; and
 - (vi) moisture—no more than 0.1%; and
 - (vii) solvents—no more than 50 mg/kg; and
 - (viii) residue on ignition—no more than 0.1%;
- (c) heavy metals:
 - (i) iron—no more than 1.0 mg/kg; and
 - (ii) copper—no more than 0.5 mg/kg; and
 - (iii) arsenic—no more than 3 mg/kg; and
 - (iv) lead—no more than 0.1 mg/kg;
- (d) microbiological:
 - (i) total aerobic count—no more than 10 000 cfu/kg; and
 - (ii) combined moulds and yeasts—no more than 100 cfu/g; and
 - (iii) coliforms—negative; and
 - (iv) *E. coli*—negative; and
 - (v) *salmonella*—negative.

S3—28

Specification for yeast—selenium-enriched

- (1) Selenium-enriched yeasts are produced by culture in the presence of sodium selenite as a source of selenium.
- (2) These yeasts must contain selenium according to the following criteria:
 - (a) total selenium content—no more than 2.5 mg/kg of the dried form as marketed;
 - (b) levels of organic selenium (% total as extracted selenium):
 - (i) selenomethionine—no less than 60% and no more than 85%; and
 - (ii) other organic selenium compounds (including selenocysteine)—no more than 10%;
 - (c) levels of inorganic selenium (% total extracted selenium)—no more than 1%.

S3—29

Specification for yeast—high chromium

For high chromium yeast:

- (a) the physical specifications are the following:
 - (i) appearance—fine, free-flowing powder;
 - (ii) colour—light off-white or light tan;
 - (iii) odour—slight yeast aroma;
 - (iv) particle size—minimum 90% through a #100 USS screen; and
- (b) the chemical specifications are the following:
 - (i) moisture—maximum 6%;
 - (ii) chromium—1.8-2.25 g/kg.

Specification for yeast—high molybdenum

For high molybdenum yeast:

- (a) the physical specifications are the following:
 - (i) appearance—fine, free-flowing powder;
 - (ii) colour—light off-white or light tan;
 - (iii) odour—slight yeast aroma;
 - (iv) particle size—minimum 85% through a #100 USS screen; and
 - (b) the chemical specifications are the following:
 - (i) moisture—maximum 6%;
 - (ii) molybdenum—1.8–2.25 g/kg.
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