suggested rates of infusion are 500 mL of a 10% emulsion over a period of not less than 3 hours, and 500 mL of a 20% emulsion over not less than 5 hours. Where a 30% emulsion is used, a dose of 333 mL or about 4.75 mL/kg has been recommended, given over 5 hours or more; the first dose should not exceed 3 mL/kg.

Soya oil also has emollient properties and is used as a bath additive in the treatment of dry skin conditions.

Preparations made from whole soya beans, containing soya oil and soya protein, are used as the basis of lactose-free vegetable milks for infants and patients with lactose or similar disaccharide intolerance or with an allergy to cow's milk protein (see also below).

Administration. It has been suggested[1] that it is the concentration of phospholipid solubilisers, and particularly the excess present as free phospholipid liposomes, that determines the effect of lipid emulsions on plasma-lipid concentrations. In 20 premature infants requiring parenteral nutrition, infusion of up to 4 g/kg of fat daily as a 20% emulsion had less effect on plasma lipid concentrations than 2 g/kg daily as a 10% emulsion; the difference was thought to be due to the fact that the 20% emulsion was relatively liposome-poor, with a ratio of phospholipids to triglycerides of 0.06, whereas the liposome-rich 10% emulsion had a ratio of 0.12. The authors suggested that the 10% emulsion should not be used in preterm infants. Others noted similar results;[2] a 10% lipid emulsion with a reduced phospholipid content has, however, been reported to be relatively well tolerated in premature infants.[3]

For mention of the risk of kernicterus if lipid infusions are given to hyperbilirubinaemic neonates, see under Precautions, above.

1. Haumont D, *et al.* Effect of liposomal content of lipid emulsions on plasma lipid concentrations in low birth weight infants receiving parenteral nutrition. *J Pediatr* 1992; **121:** 759–63.
2. Cairns PA, *et al.* Tolerance of mixed lipid emulsion in neonates: effect of concentration. *Arch Dis Child Fetal Neonatal Ed* 1996; **75:** F113–F116.
3. Gohlke BC, *et al.* Serum lipids during parenteral nutrition with a 10% lipid emulsion with reduced phospholipid emulsifier content in premature infants. *J Pediatr Endocrinol Metab* 1997; **10:** 505–9.

Food intolerance. The American Academy of Pediatrics has recommended[1] that soya-based infant feeds are appropriate for use in galactosaemia and hereditary lactase deficiency, and documented allergy to cow's milk protein. However, infants with documented cow's milk protein enteropathy or enterocolitis should receive hydrolysed protein formula, as they are likely to be sensitive to soya protein. They concluded that soya-based infant feeds have no proven role in the prevention of atopic disease or in the management of infantile colic. In infants and children at high risk for developing food allergies or intolerance, a systematic review[2] found that there was no evidence that feeding with a soy formula compared to a cow's milk formula reduced the incidence of food allergies or intolerance.

The FDA has warned against the use of soya-based drinks intended for adults as the sole source for nutrition for infants.[3] It was stated that soya drinks can lead to severe protein and calorie malnutrition, multiple vitamin and mineral deficiency, and death in infants who receive no other source of nourishment, and should not be confused with soya-based infant formulas, which are specially formulated to meet the nutritional needs of infants.

For reference to the use of soya-based foods themselves causing allergic reactions, see under Hypersensitivity, above.

1. American Academy of Pediatrics. Soy protein-based formulas: recommendations for use in infant feeding. *Pediatrics* 1998; **101:** 148–53.
2. Osborn DA, Sinn J. Soy formula for prevention of allergy and food intolerance in infants. Available in The Cochrane Database of Systematic Reviews; Issue 4. Chichester: John Wiley; 2006 (accessed 08/11/05).
3. Nightingale S. Warnings issued about practices, products: soy drink warning. *JAMA* 1985; **254:** 1428.

Hyperlipidaemias. Soya protein has been tried in the treatment of hyperlipidaemia (p.1169). Soya isoflavones such as genistein (p.2391) and daidzein (p.2391) can mimic oestrogen and should therefore have a beneficial effect on blood lipids.[1,2] Other constituents of soya protein, including fytic acid and saponins, may also contribute and thus intact soya protein may provide the maximum cholesterol-lowering effect.[2,3] A meta-analysis of controlled trials found that the substitution of soya protein for animal protein in the diet resulted in significant decreases in serum total cholesterol, low-density lipoprotein (LDL)-cholesterol, and triglyceride concentrations.[4] A subsequent systematic review of studies reached similar conclusions,[1] and the FDA considered that a low-fat diet including 25 g daily of soya protein might reduce the risk of ischaemic heart disease.[2] A later analysis by the American Heart Association[5] considered that cardiovascular benefit was very modest and appeared only when large amounts of animal protein were substituted with soya protein. The effect appeared to be more to do with a broader modification of diet than any effect of soya isoflavones. Soya protein does not appear to have a cholesterol-lowering effect in subjects with normal cholesterol concentrations,[2] although a small study found it to be beneficial in type 2 diabetes patients with near-normal lipid concentrations.[6]

1. Costa RL, Summa MA. Soy protein in the management of hyperlipidemia. *Ann Pharmacother* 2000; **34:** 931–5.
2. Erdman JW. Soy protein and cardiovascular disease: a statement for healthcare professionals from the Nutrition Committee of the AHA. *Circulation* 2000; **102:** 2555–9.
3. Demonty I, *et al.* Role of isoflavones in the hypocholesterolemic effect of soy. *Nutr Rev* 2003; **61:** 189–203.
4. Anderson JW, *et al.* Meta-analysis of the effects of soy protein intake on serum lipids. *N Engl J Med* 1995; **333:** 276–82.
5. Sacks FM, *et al.* Soy protein, isoflavones, and cardiovascular health: an American Heart Association Science Advisory for professionals from the Nutrition Committee. *Circulation* 2006; **113:** 1034–44.
6. Hermansen K, *et al.* Beneficial effects of a soy-based dietary supplement on lipid levels and cardiovascular risk markers in type 2 diabetic subjects. *Diabetes Care* 2001; **24:** 228–33.

Menopausal disorders. Soya contains phytoestrogens in the form of isoflavones, in particular genistein (p.2391) and daidzein (p.2391), which have been investigated for their oestrogen-modulating effects in the treatment of menopausal symptoms (p.2077).[1] It is thought that genistein may exert oestrogenic effects in the presence of low oestrogen concentrations, but that it may be anti-oestrogenic when concentrations of oestrogen are high.[2]

A small reduction in the incidence of hot flushes has been noted with soya isoflavone extract.[3] A systematic review,[4] however, concluded that phytoestrogens available as soya foods, soya extracts, or red clover extracts (p.2285) do not improve hot flushes or other menopausal symptoms.

Isoflavones may have a beneficial effect on cholesterol and lipid concentrations (see Hyperlipidaemias, above). Some epidemiological studies and *animal* data suggest that they may also provide protection against breast cancer.[1,2,5] However, phytoestrogens could also stimulate breast tumour growth due to oestrogenic activity.[6] These stimulating and inhibitory effects may be concentration-dependent; soya products contain only small amounts of phytoestrogens and it may be difficult to consume enough soy to have any beneficial effect on breast cancer growth.[7] A meta-analysis[8] concluded that soya intake may be associated with a small reduction in breast cancer risk, but that this result should be interpreted with caution due to confounding factors and a lack of dose response. Given the possibility of adverse effects, recommendations for high-dose soya isoflavone supplementation to prevent breast cancer or its recurrence are premature.

A few small studies have shown that soya isoflavones can decrease bone turnover, leading to speculation that they could be used to prevent osteoporosis (p.1084).[1] The effects of these isoflavones should be investigated in larger trials before they can be recommended as alternatives to conventional HRT.[5-7,9] (For the view that they may lack cardiovascular benefits see Hyperlipidaemias, above.) In a trial to investigate effects on cognitive function, bone mineral density, and plasma lipids in postmenopausal women, no differences were noted between soya protein containing isoflavones, and placebo.[10]

1. Vincent A, Fitzpatrick LA. Soy isoflavones: are they useful in menopause? *Mayo Clin Proc* 2000; **75:** 1174–84.
2. Goldwyn S, *et al.* Promotion of health by soy isoflavones: efficacy, benefit and safety concerns. *Drug Metabol Drug Interact* 2000; **17:** 261–89.
3. Upmalis DH, *et al.* Vasomotor symptom relief by soy isoflavone extract tablets in postmenopausal women: a multicenter, double-blind, randomized, placebo-controlled study. *Menopause* 2000; **7:** 236–42. Correction. *ibid.*; 422.
4. Krebs EE, *et al.* Phytoestrogens for treatment of menopausal symptoms: a systematic review. *Obstet Gynecol* 2004; **104:** 824–36.
5. Sirtori CR. Risks and benefits of soy phytoestrogens in cardiovascular diseases, cancer, climacteric symptoms and osteoporosis. *Drug Safety* 2001; **24:** 665–82.
6. Mason P. Isoflavones. *Pharm J* 2001; **266:** 16–19.
7. de Lemos ML. Effects of soy phytoestrogens genistein and daidzein on breast cancer growth. *Ann Pharmacother* 2001; **35:** 1118–21.
8. Trock BJ, *et al.* Meta-analysis of soy intake and breast cancer risk. *J Natl Cancer Inst* 2006; **98:** 459–71.
9. Anonymous. The role of isoflavones in menopausal health: consensus opinion of the North American Menopause Society. *Menopause* 2000; **7:** 215–29.
10. Kreijkamp-Kaspers S, *et al.* Effect of soy protein containing isoflavones on cognitive function, bone mineral density, and plasma lipids in postmenopausal women: a randomized controlled trial. *JAMA* 2004; **292:** 65–74.

Preparations

USP 31: Lipid Injectable Emulsion.

Proprietary Preparations (details are given in Part 3)

Arg.: Ivelip; Lipofundin N; Lipovenos; Piascledine; Sojar Pro; Soyacal; ***Austral.:*** Intralipid; Ivelip†; ***Austria:*** Balneum; Elolipid; Intralipid; Lipovenos; Olbad Cordes; ***Belg.:*** Gynosoya; ***Braz.:*** Endolipid†; Fisiogen; Isofarma†; ***Canad.:*** Intralipid; ***Chile:*** Lipofundin; Lipovenos; ***Cz.:*** Balneum Hermal; Elolipid†; Intralipid; Ivelip†; Lipofundin N†; Lipovenoes; Soyacal; ***Denm.:*** Intralipid; ***Fin.:*** Intralipid; ***Fr.:*** Endolipide†; Gastro'Aid; Gydrelle Phyto; Gynalpha; Intralipide; Ivelip; Phyto Soya; ***Ger.:*** Allergika†; Balneoconzen N; Balneovit; Balneum; Deltalipid; Eucerin Omega Olbad†; Intralipid; Lipofundin N; Lipopharm; Lipostabil; Lipovenos; Olbad Cordes; Penatoel†; salvilipid; Soyacal; ***Gr.:*** Intralipid; Lipovenoes†; ***Hong Kong:*** Intralipid; Lipofundin N; ***Hung.:*** Intralipid; Lipofundin; Lipovenos†; Structolipid; ***Indon.:*** Intralipos; ***Irl.:*** Balneum; Intralipid; ***Israel:*** Balneum; Intralipid; Ivelip; ***Ital.:*** Balneum Hermal; Elolipid; Intralipid; Ivelip†; Lipofundin S; Lipovenos; Soyacal†; ***Jpn:*** Intrafat†; ***Malaysia:*** Intralipid; Intralipos†; ***Mex.:*** Ivelip†; Lipofundin N; Lipovenoes; ***Neth.:*** Intralipid; Lipovenos; ***Norw.:*** Intralipid; ***NZ:*** Intralipid; Ivelip; ***Philipp.:*** Soyacal; ***Pol.:*** Balneum Hermal; Intralipid; Ivelip; Lipofundin N; Soya Meno; Soyfem; ***Port.:*** Banholeum; Emulsao de Lipidos; Endolipide; Intralipid; Lipovenoes; Soyacal; ***Singapore:*** Intralipid; Intralipos; ***Spain:*** Aquiflav; Bluna; Fitoladius; Flavodrei; Intralipid; Isodonna; Ivelip; Lipovenos; Malena; Phyto Soya; Pleginer; Primsoja; Soyacal; ***Swed.:*** Intralipid; Lipovenos†; ***Switz.:*** Balmed Hermal; Balmed Hermal Plus; Balneum Hermal†; Intralipid; Lipovenos; ***Thai.:*** Intralipid; Intralipos†; Ivelip; Lipofundin N; Lipofundin S; Lipovenoes†; ***Turk.:*** Intralipid; Ivelip; Lipovenos; ***UK:*** Balneum; Intralipid; Ivelip; Lipofundin; ***USA:*** Intralipid; Liposyn III; ***Venez.:*** Intralipid†; Ivelip; Lipofundin N†.

Multi-ingredient: ***Arg.:*** Clinoleic; Derrumal; Kabiven; Lipofundin MCT/LCT-E; Lipofundin MCT/LCT†; Liposomas; Sigmafem; Sojar Plus-Calcio; ***Austral.:*** Bioglan Mens Super Soy/Clover; Bioglan Soy Power Plus; Extralife Meno-Care; Hypol; Lifechange Menopause Formula†; PhytoLife; Soy Forte with Black Cohosh†; ***Austria:*** Balneum Plus; Clinoleic; Clinomel; Compleven†; Gesamtnahrlosung; KabiMix; Kabiven; Lipofundin mit MCT; Nutriflex Lipid; Olbad Cordes comp; Oleosint; OliClinomel; PE-Mix; SMOFlipid; Structolipid; TriMix; Vitromix; ***Belg.:*** Medialipide†; ***Braz.:*** Borag; Piascledine; ***Chile:*** Kabiven; Lipofundin MCT/LCT; Liposyn†; Lipovenos MCT/LCT; ***Cz.:*** Balneum Hermal Plus; Clinoleic; Clinomel†; Kabiven; Lipofundin MCT/LCT; Lipoplus; Nutralipid MCT†; Nutralipid P†; Nutriflex Lipid; OliClinomel; Piascledine; SMOFlipid; ***Denm.:*** Clinoleic; Kabiven; Liposyn†; OliClinomel; SMOFlipid; Vitrimix†; ***Fin.:*** Clinoleic; Compleven†; Kabiven; Lipoplus; Liposyn†; Nutriflex Lipid; OliClinomel; Structolipid; Vamin Glukos Combi†; Vasolipid; ***Fr.:*** Biopause; Biopause solution intime; Clinoleic; Clinomel†; Gynosoja; KabiMix†; Kabiven; Medialipide; Nutriflex Lipide; OliClinomel; Perikabiven; Piascledine; StructoKabiven; Structolipide; Vitrimix KV; ***Ger.:*** Abbolipid†; Balneum Plus; Clinoleic; Clinomel†; Compleven†; Kabiven; Lipofundin MCT; Lipovenos MCT; Nutriflex Lipid; Oleobal; OliClinomel; SMOFlipid; Sulfo-Olbad Cordes†; Windol Basisbad†; ***Gr.:*** Clinoleic; Clinomel; Kabiven; Lipofundin MCT/LCT; Nutriflex Lipid; OliClinomel; SMOFlipid; ***Hong Kong:*** Apaisac; Kabiven; Lipofundin MCT/LCT; Nutriflex Lipid; Sawmetto Vivo-Livo†; Vitrimix KV; ***Hung.:*** Clinomel†; Kabiven; Lipofundin MCT; Lipovenos PLR†; OliClinomel; SMOFlipid; ***Indon.:*** Hepabion; Ivelip; Kabiven; Lanaven; Lipofundin MCT/LCT; Lipovenoes; Maxitrin; Vitrimix; ***Irl.:*** Balneum Plus; Vitrimix KV; ***Israel:*** Balneum Plus; Clinoleic; Kabiven; Lipofundin MCT/LCT; Liposyn; ***Ital.:*** Acumel; Climil Complex; Climil-80; Clinoleic; Clinomel†; Demalit; Fitogen; Ginil; KabiMix†; Kabiven; Lipofundin MCT; Liposyn†; Nutriperi Lipid; Nutriplus Lipid; Nutrispecial Lipid; OliClinomel; Periven; Piascledine; Pluvio; Pulsalux; Sojyam†; Soymen; Structolipid; Triacid; Trivemil†; ***Malaysia:*** Kabiven; Vitrimix KV†; ***Mex.:*** Bano Coloide; Caltrate + S; Clinoleic†; Clinomel†; Kabiven; Lipofundin MCT/LCT; Liposyn; Lipovenoes MCT†; Piascledine; Riban; Soyaloid; Soyaloid Apruri; Soydex; Sy-Clinomel†; ***Neth.:*** Clinoleic; KabiMix†; Kabiven; Lipofundin MCT/LCT; Lipoplus; Nutriflex Lipid; OliClinomel; SMOFlipid; Structolipid; Vitrimix KV; ***Norw.:*** Ivamix†; KabiMix†; Kabiven; Nutriflex Lipid; SMOFlipid; Vasolipid; Vitrimix†; ***NZ:*** Kabiven; ***Philipp.:*** Her Soy Plus; ***Pol.:*** Balneum Hermal Plus; Clinoleic; Clinomel; Compleven; Kabiven; Lecigal†; Lipofundin MCT/LCT; Naturapia Menopauza; Piascledine; SMOFlipid; ***Port.:*** Banholeum Composto; Banholeum Gele; Clinoleic; Lipofundina MCT/LCT; Lipoplus; Nutribraun; Nutriplasmal; OliClinomel; Structolipid; Vitrimix; ***Rus.:*** Kabiven (Кабивен); Piascledine (Пиаскледин); ***S.Afr.:*** Clinomel; Lipofundin MCT/LCT; ***Singapore:*** Celatrac; Kabiven; Lipofundin MCT/LCT†; ***Spain:*** Clinoleic; Clinomel†; Fitogyn; KabiMix†; Kabiven; Lipofundina MCT/LCT; Nutriflex Lipid; Nutriplasmal†; OliClinomel; Structolipid; ***Swed.:*** Clinoleic; Clinomel†; Compleven†; KabiMix†; Kabiven; Lipoplus; Liposyn†; Nutriflex Lipid; OliClinomel; SMOFlipid; Structolipid; Vasolipid; Vitrimix†; ***Switz.:*** Antidry; Balneum Hermal Plus†; Clinoleic; Lipofundin MCT/LCT; Nutriflex Lipid; OliClinomel; Structolipid; ***Thai.:*** Kabiven; Lipofundin MCT/LCT; OliClinomel; Vitrimix; ***Turk.:*** Lipofundin MCT/LCT; Liposyn; Vitrimix; ***UK:*** Balneum Plus; Clinoleic; Compleven†; Kabiven; Lipidem; Lipofundin MCT/LCT; OliClinomel; Phytolife Plus; SMOFlipid; Structolipid; Vitrimix KV†; Ymea; ***USA:*** Liposyn II; Tucks; ***Venez.:*** Lipofundin MCT/LCT.

Stannous Fluoride

Fluoruro estañoso; Stannosi Fluoridum. Tin fluoride.

SnF_2 = 156.7.

CAS — 7783-47-3.

ATC — A01AA04.

ATC Vet — QA01AA04.

Pharmacopoeias. In *US*.

USP 31 (Stannous Fluoride). A white crystalline powder. Freely soluble in water; practically insoluble in alcohol, in chloroform, and in ether. pH of a freshly prepared 0.4% solution in water is between 2.8 and 3.5.

Stability. Aqueous solutions of stannous fluoride decompose within a few hours with the formation of a white precipitate; they slowly attack glass.

Profile

Stannous fluoride is used as a source of fluoride (see Sodium Fluoride, p.1962) for the prophylaxis of dental caries. Dental gels containing concentrations of stannous fluoride 0.4% are available for daily use. Higher concentrations have been applied under professional supervision. Stannous fluoride has also been used in dentifrices and mouth rinses.

Stannous fluoride has an unpleasant taste.

Preparations

USP 31: Stannous Fluoride Gel.

Proprietary Preparations (details are given in Part 3)

Fr.: Emoform; ***Ital.:*** Fluorigard Gel-Kam; Gel-Kam†; Oral-B Pasta Dentificia Denti e Gengive; ***Switz.:*** Parocare†; ***UK:*** Fluorigard Gel-Kam; ***USA:*** Gel Kam; Gel-Kam; Gel-Tin; PerioMed; Stop.

Multi-ingredient: ***Fr.:*** Meridol†; ***Israel:*** Meridol; ***Ital.:*** Actifluor†.

Starch

Almidón; Amido; Amidon; Amidon de blé (wheat starch); Amidon de maïs (maize starch); Amidon de pomme de terre (potato starch); Amidon de riz (rice starch); Amidon prégélatinisé (pregelatinised starch); Amilo; Amylum; Amylum pregelificatum (pregelatinised starch); Bulvių krakmolas (potato starch); Burgonyakeményítő (potato starch); Búzakeményítő (wheat starch); Hidegenduzzadó keményítő (pregelatinised starch); Kukoricakeményítő (maize starch); Kukurūzų krakmolas (maize starch); Kviečių krakmolas (wheat starch); Maissitärkkelys (maize starch); Majsstärkelse (maize starch); Maydis amylum (maize starch); Oryzae amylum (rice starch); Perunatärkkelys (potato starch); Potatisstärkelse (potato starch); Pregelifikuotas krakmolas (pregelatinised starch); Pšeničný škrob (wheat starch); Riisitärkkelys (rice starch); Risstärkelse (rice starch); Rizskeményítő (rice starch); Ryžių krakmolas (rice starch); Škrob bramborový (potato starch); Škrob kukuřičný (maize starch); Škrob předbobtnalý (pregelatinised starch); Škrob rýžový (rice starch); Skrobia kukurydziana (maize starch); Skrobia pszeniczna (wheat starch); Skrobia ziemniaaczana (potato starch); Solani amylum (potato starch); Stärke; Tritici amylum (wheat starch); Vehnätärkkelys (wheat starch); Vetestärkelse (wheat starch).

CAS — 9005-25-8 (starch); 9005-82-7 (α-amylose); 9004-34-6 (β-amylose); 9037-22-3 (amylopectin).

Description. Starch consists of polysaccharide granules obtained from the caryopsis of maize, *Zea mays*, rice, *Oryza sativa*, wheat, *Triticum aestivum* (*T. vulgare*), from the tubers of potato, *Solanum tuberosum* or from the rhizomes of cassava, *Manihot utilissima*. Maize starch is also known as corn starch. Starch contains amylose and amylopectin, both polysaccharides based on α-glucose.

Pharmacopoeias. Some or all of the starches described are included in *Chin.*, *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF*. *Chin.* and *Eur.* also include Pregelatinised Starch, *USNF* also includes Pregelatinized Starch, Modified Starch, and Pregelatinized Modified Starch. *US* includes Absorbable Dusting Powder and Topical Starch.

Ph. Eur. 6.2 (Maize Starch; Maydis Amylum). It is obtained from the caryopsis of *Zea mays*. It is a tasteless, matt, white to slightly yellowish, very fine powder that creaks when pressed between the fingers. The presence of granules with cracks or irregularities on the edge is exceptional. Practically insoluble in cold water and in alcohol. Store in airtight containers.

Ph. Eur. 6.2 (Potato Starch; Solani Amylum). It is obtained from the tuber of *Solanum tuberosum*. It is a very fine, white or almost white powder which creaks when pressed between the fingers. It does not contain starch grains of any other origin but may contain a minute quantity, if any, of fragments of the tissue of the original plant. Practically insoluble in cold water and in alcohol. The pH of a 20% mixture in water after 15 minutes is 5.0 to 8.0. Store in airtight containers.

Ph. Eur. 6.2 (Rice Starch; Oryzae Amylum). It is obtained from the caryopsis of *Oryza sativa*. It is a tasteless, very fine, white or almost white powder which creaks when pressed between the fingers. The presence of granules with cracks or irregularities on the edge is exceptional. Practically insoluble in cold water and in alcohol. Store in airtight containers.

Ph. Eur. 6.2 (Wheat Starch; Tritici Amylum). It is obtained from the caryopsis of *Triticum aestivum* (*T. vulgare*). It is a very fine, white or almost white powder which creaks when pressed between the fingers. It does not contain starch grains of any other origin but may contain a minute quantity, if any, of fragments of the tissue of the original plant. Practically insoluble in cold water and in alcohol. The pH of a 20% mixture in water after 15 minutes is 4.5 to 7.0. Store in airtight containers.

Ph. Eur. 6.2 (Pregelatinised Starch; Amylum Pregelificatum). It is prepared from maize starch, potato starch, or rice starch by mechanical processing in the presence of water, with or without heat, to rupture all or part of the starch granules, and subsequent drying. It contains no added substances but it may be modified to render it compressible and to improve its flow characteristics. It is a white or yellowish white powder that swells in cold water.

BP 2008 (Tapioca Starch). It is obtained from the rhizomes of *Manihot utilissima*. It is a very fine powder which creaks when pressed between the fingers. Practically insoluble in cold water and in alcohol. Store in airtight containers.

The BP 2008 gives Cassava Starch as an approved synonym.

The BP 2008 directs that when starch is specified and the type is not indicated, Maize Starch, Potato Starch, Rice Starch, Wheat Starch, or in tropical countries where these are not available, Tapioca Starch may be supplied or used.

USNF 26 (Corn Starch). It consists of the starch granules separated from the mature grain of corn, *Zea mays* (Gramineae). Irregular, angular, white masses or fine powder. Is odourless, and has a slight, characteristic taste. Insoluble in cold water and in alcohol. A 20% slurry in water, allowed to stand for 15 minutes after 1 minute of moderate agitation, has a pH of 4.0 to 7.0.

USNF 26 (Potato Starch). It is obtained from the tuber of *Solanum tuberosum*. Irregular, angular, white masses or fine powder. Is odourless, and has a slight, characteristic taste. Insoluble in cold water and in alcohol. A 20% slurry in water, allowed to stand for 15 minutes after 1 minute of moderate agitation, has a pH of 5.0 to 8.0.

USNF 26 (Tapioca Starch). Granules separated from the tubers of tapioca (cassava), *Manihot utilissima* (Euphorbiaceae). Irregular, angular, white to pale yellow masses or fine powder. Insoluble in cold water and in alcohol. A 20% slurry in water after 5 minutes of continuous agitation has a pH of 4.5 to 7.0.

USNF 26 (Wheat Starch). It is obtained from the caryopsis of *Triticum aestivum* (*T. vulgare*). Irregular, angular, white masses or fine powder. Is odourless and has a slight, characteristic taste. Insoluble in cold water and in alcohol. A 20% slurry in water, allowed to stand for 15 minutes after 1 minute of moderate agitation, has a pH of 4.5 to 7.0.

USNF 26 (Pregelatinized Starch). It is starch that has been chemically and/or mechanically processed to rupture all or part of the granules in the presence of water and subsequently dried. It may be modified to render it compressible and flowable.

USNF 26 (Modified Starch). It is starch modified by chemical means. Food starch may be acid-modified, bleached, oxidised, esterified, etherified, or treated enzymatically to change its functional properties. A 20% slurry in water, after 5 minutes stirring at a moderate rate, has a pH of 3.0 to 9.0.

USNF 26 (Pregelatinized Modified Starch). It is Modified Starch that has been chemically or mechanically processed, or both, to rupture all or part of the granules to produce a product that swells in cold water. Moderately coarse to fine, white to off-white powder. It is odourless and has a slight, characteristic taste. Slightly soluble to soluble in cold water; insoluble in alcohol.

Adverse Effects

Effects of cassava. In 1985 WHO added *malnutrition-related diabetes* (which included the type previously known as tropical diabetes) to its classification of diabetes mellitus.[1] Epidemiological evidence had suggested an association between fibrocalculous pancreatic diabetes (a subclass of malnutrition-related diabetes) and the consumption of cassava root (tapioca, manioc), which for many people living in tropical developing countries, where protein intake was low, was the main source of food energy.

Cassava root contains several cyanogenic substances and although food preparation and processing could reduce the cyanide content, there was the possibility that in persons with an inadequate protein intake, particularly if deficient in sulfur-containing amino acids which are involved in detoxification pathways, accumulation of cyanides might occur. WHO, however, did consider that further research was necessary to firmly establish any relation between this type of diabetes and high levels of cassava consumption. In a review that appeared in the following year[2] the cassava/malnutrition hypothesis was thought to be attractive, but unproven; also there was strong evidence against it being the only cause.

WHO deleted malnutrition-related diabetes from its most recent report on the classification of diabetes.[3] Fibrocalculous pancreatic diabetes is now fibrocalculous pancreatopathy, a disease which may cause diabetic mellitus but is not considered a form of diabetes.

Konzo, an upper motor neurone disease characterised by spastic paraparesis,[4] and commonly associated with optic neuropathy,[5] has been reported to be caused by dietary exposure to cyanide after ingestion of cassava root. *Growth retardation* has also been associated with consumption of inadequately processed cassava.[6]

1. WHO. Diabetes mellitus: report of a WHO study group. *WHO Tech Rep Ser 727* 1985.
2. Abu-Bakare A, *et al.* Tropical or malnutrition-related diabetes: a real syndrome? *Lancet* 1986; **i:** 1135–8.
3. Alberti KGMM, Zimmet PZ. Definition, diagnosis, and classification of diabetes mellitus and its complications. Part I: diagnosis and classification of diabetes mellitus. Provisional report of a WHO consultation. *Diabet Med* 1998; **15:** 539–53.
4. Ernesto M, *et al.* Persistent konzo and cyanogen toxicity from cassava in northern Mozambique. *Acta Trop* 2002; **82:** 357–62.
5. Mwanza J-C, *et al.* Neuro-ophthalmologic findings in konzo, an upper motor neuron disorder in Africa. *Eur J Ophthalmol* 2003; **13:** 383–9.
6. Banea-Mayambu J-P, *et al.* Dietary cyanide from insufficiently processed cassava and growth retardation in children in the Democratic Republic of Congo (formerly Zaire). *Ann Trop Paediatr* 2000; **20:** 34–40.

Glove powder. The use of starch glove powders by surgeons has resulted in contamination of surgical wounds by starch and in the development of complications such as inflammation, adhesions, and granulomatous lesions. In addition, glove starch powder may be a risk factor in the development of latex allergy, and may act as a vector for bacterial pathogens. Because of these risks, it has been proposed that the use of powder in latex gloves be banned.[1-4]

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Uses and Administration

Starch is absorbent and is widely used in dusting powders, either alone or mixed with zinc oxide or other similar substances. Starch is used as a surgical glove powder, but such use has been discouraged (see above). It is incorporated in many tablets as a binder, diluent, or disintegrating agent. Pregelatinised starch is used similarly as a tablet binder.

Starch mucilage is given by mouth in the treatment of iodine poisoning; it has been used topically as a skin emollient.

Rice-based solutions may be used in the prevention and treatment of dehydration due to acute diarrhoeal diseases (p.1694).

Glycogen storage disease type I. Type I glycogen storage disease is an autosomal recessive metabolic disorder in which glucose-6-phosphatase is not expressed, resulting in hypoglycaemia due to lack of glucose production. Accumulation of glycogen and other metabolic derangements can lead to complications including renal impairment, hepatomegaly and hepatic adenoma, hyperuricaemia, hyperlipidaemias, and lactic acidosis. The condition has been successfully managed by continuous nocturnal nasogastric infusion of glucose and frequent daytime feedings. However, such a regimen requires good patient compliance and monitoring of the night-time infusions.[1] As an alternative, a more standard diet together with uncooked corn starch suspensions prepared with tap water at room temperature and taken every 6 hours in doses of 1.75 to 2.5 g/kg have been reported[2] to be very satisfactory in maintaining normoglycaemia. In one infant, in whom starch was unsatisfactory, the lack of response was considered to be due to inadequate pancreatic amylase activity and although it was subsequently reported[3] that addition of a pancreatic enzyme concentrate had produced some improvement, the response was still inadequate to maintain normoglycaemia for more than 2 hours. It was considered that other amylase preparations should be identified for possible use in such patients. A small study of 7 young adults with glycogen storage disease type I found that a single dose of uncooked corn starch maintained plasma glucose concentrations for 7 hours in 5 of the patients.[4] A long-term study of the effects of corn starch therapy found that complications were less among patients with near normal metabolic control and in those having started therapy at a younger age, but other factors appeared to be involved in the pathogenesis.[5] Corn starch therapy has nonetheless been reported to have caused the amelioration of proximal renal tubular dysfunction in 3 patients who had previously only received frequent daytime feeding as therapy. In 16 other patients who had previously received treatment with corn starch or glucose infusions such renal dysfunction was not identified and it was considered that the rapid response to therapy may explain why renal tubular dysfunction is not found more frequently in these patients.[6]

Because optimal metabolic control reduces the risk of developing long-term complications, an attempt has been made to define guidelines for long-term management of the disease.[7] Continuous nocturnal nasogastric feeding with a glucose or glucose polymer or a sucrose-free maltodextrin formula low in lactose may be introduced in very young infants. Uncooked corn starch should not be started in patients under 1 year of age as pancreatic amylase activity may be immature. Thereafter, since no significant differences in growth or biochemical parameters have been found between the use of nocturnal nasogastric infusions and uncooked corn starch overnight, corn starch may be started at a dose of 250 mg/kg and increased slowly to prevent adverse effects. It is recommended that the corn starch be mixed with water in a ratio of 1:2 and that an uncooked corn starch tolerance test be performed to establish the duration of the fasting period. The total dietary plan should aim to provide 60 to 65% of the total energy intake from carbohydrates, 10 to 15% from protein, and the remainder from fat, preferably vegetable oils with a high linoleic acid content. Lactose, fructose, and sucrose should be restricted. Drug therapy for metabolic complications may be necessary, such as allopurinol for hyperuricaemia, and bicarbonate for correction of lactic acidosis.[7]

For mention of the possible role of starch in glycogen storage disease type V, see under Sucrose, p.1970.

For a brief description of glycogen storage disease type II, see under Acid Alpha Glucosidase, p.2245.

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