Pharmacopoeias. In *US*.
USP 31 (Sodium Monofluorophosphate). A white to slightly grey, odourless powder. Freely soluble in water. pH of a 2% solution in water is between 6.5 and 8.0.

Profile
Sodium monofluorophosphate is used as a source of fluoride (see Sodium Fluoride, p.1962) in toothpastes for the prevention of dental caries. It may also be given by mouth in the management of osteoporosis.

In the UK, the maximum permitted fluoride level in toothpastes is 1.14% of sodium monofluorophosphate (0.15% or 1500 ppm of fluoride). Formulations for children under 7 years of age typically contain sodium monofluorophosphate 0.38% (500 ppm fluoride); higher concentrations may be used, but the amount applied should be supervised to avoid excessive use or ingestion.

Other monofluorophosphate salts permitted for use in oral hygiene products and dentifrices include ammonium monofluorophosphate, calcium monofluorophosphate, and potassium monofluorophosphate. Glutamine monofluorophosphate has been used for osteoporosis.

Osteoporosis. For reference to the use of fluorides, including sodium monofluorophosphate, in the treatment of osteoporosis, see under Uses of Sodium Fluoride, p.1964.

Preparations
Proprietary Preparations (details are given in Part 3)

Arg.: Osteomar†; ***Austral.:*** Fluorocare; ***Austria:*** Osteopro; ***Braz.:*** Emoform AP; Malvatricin Antitartaro; Unique Plus; ***Chile:*** Fluocaril Bi-Fluore; Gengisyl; Oralfresh; ***Cz.:*** Difluena†; ***Ger.:*** Mono-Tridin; ***Ital.:*** Clinomyn; Isifluor; Neo Emoform†; Neo Fluostomygen; Platinum.

Multi-ingredient: ***Arg.:*** Desensyl; Emoform Total; Fluocalcic†; Fluordent PX; Hexiben; Hexiben Plus†; Negaporosis; Odol Med Antiplaca†; Sensodyne-F; Squam; ***Austria:*** Fluocalcic; ***Belg.:*** Fluocalcic†; Fluocaril; ***Braz.:*** Emoform AT; Fluomint; Malvatricin Antiplaca; Malvatricin Branqueador; Malvatricin Dentes Sensiveis; Malvatricin Natural; Malvatricin Natural Organic; Malvatricin Natural Soft; Malvatricin Plus; Sensodyne-F; ***Canad.:*** Viadent†; ***Chile:*** Caristop; Gingilacer†; Sensilacer†; Tridin†; ***Cz.:*** Fluocalcic†; Fluocaril Bi-Fluore Vitamin E†; Fluocaril Bi-Fluore†; Tridin; ***Fr.:*** Emoform Dents Sensibles; Fluocaril Bi-Fluore; Fluocaril blancheur; Fluocaril Junior and Fluocaril Kids; Sanogyl Fluo†; Sanogyl Junior†; Sanogyl†; ***Ger.:*** Calcivit F†; Fluoril; Tridin; Tridin Forte; ***Hong Kong:*** Tridin; ***Hung.:*** Tridin; ***Ital.:*** Aqua Emoform†; Biogreen; Broxo al Fluoro; Broxodin†; Calcitridin†; Dentosan Carie & Alito†; Dentosan Junior; Emoform-Tat†; Eudent con Glysan†; Fluocaril Bi-Fluore; Formedico; Neo-Stomygen; Orosanyl†; Periogard Plus; Stomygen; Tridin; ***Mex.:*** Dentsiblen; Fluoxytil; Periodentyl; ***Pol.:*** Fluoro-zel; ***Port.:*** Fluocaril Bi-Fluore; ***Switz.:*** Emoform-F au fluor; Fluo-calc†; Fluocaril Bi-Fluore†; ***Turk.:*** Sensodyne-F; ***USA:*** Monocal; Optimoist; Sensodyne-F; ***Venez.:*** Sensident†; Topdent†.

Sodium Silicofluoride
Fluosilicato sódico; Sodium Fluorosilicate; Sodium Fluosilicate; Sodium Hexafluorosilicate.

Na_2SiF_6 = 188.1.
CAS — 16893-85-9.

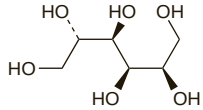
Profile
Sodium silicofluoride is used as a source of fluoride (see Sodium Fluoride, p.1962) for the fluoridation of drinking water. It has also been considered for inclusion in oral hygiene products.

Other silicofluoride (fluorosilicate) salts permitted for use in oral hygiene products include ammonium silicofluoride, magnesium silicofluoride, and potassium silicofluoride.

Sodium silicofluoride has also been used in insecticides.

Sorbitol
E420; D-Sorbitol; Sorbitoli; Sorbitolis; Sorbitolum; Szorbit. D-Glucitol.

$C_6H_{14}O_6$ = 182.2.
CAS — 50-70-4.
ATC — A06AD18; A06AG07; B05CX02; V04CC01.
ATC Vet — QA06AD18; QA06AG07; QB05CX02; QV04CC01.



Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Jpn*, and *Viet.* Also in *USNF*.
US includes only Sorbitol Solution.
Ph. Eur. 6.2 (Sorbitol). A white or almost white crystalline powder. It exhibits polymorphism. Very soluble in water; practically insoluble in alcohol.
USNF 26 (Sorbitol). White, odourless, hygroscopic powder, granules, or crystalline masses having a sweet taste with a cold sensation. Soluble 1 in 0.45 of water; sparingly soluble in alcohol; practically insoluble in solvent ether. pH of a 10% w/w solution in water is between 3.5 and 7.0.

Incompatibility. For reference to the incompatibility of sorbitol with hydroxybenzoates, see p.1649.

Adverse Effects and Precautions
As for Fructose, p.1945.

Effects on electrolyte balance. Sorbitol is used as a vehicle in some proprietary preparations of activated charcoal intended to reduce drug absorption after poisoning; the sorbitol increases the palatability of the preparation and also produces an osmotic diarrhoea that facilitates elimination of the activated charcoal and adsorbed drug. Repeated doses of such preparations are often advocated but there have been reports[1-3] of severe sorbitol-induced hypernatraemia in adults and children. In all cases, charcoal in a 70% sorbitol suspension had been given. It has been recommended that fluid and electrolyte balance be monitored closely, and that preparations with lower concentrations of sorbitol be used if possible.[2,3] For debate about such multiple dose therapy see Poisoning, under Activated Charcoal, p.1436.

1. Gazda-Smith E, Synhavsky A. Hypernatraemia following treatment of theophylline toxicity with activated charcoal and sorbitol. *Arch Intern Med* 1990; **150:** 689 and 692.
2. Allerton JP, Strom JA. Hypernatremia due to repeated doses of charcoal-sorbitol. *Am J Kidney Dis* 1991; **17:** 581–4.
3. Farley TA. Severe hypernatremic dehydration after use of an activated charcoal-sorbitol suspension. *J Pediatr* 1986; **109:** 719–22.

Effects on the gastrointestinal tract. Sorbitol is often used as a sweetener in sugar-free preparations and the risk of sorbitol-induced diarrhoea associated with such products has been highlighted.[1-4] Chronic sorbitol-induced diarrhoea with associated pneumatosis intestinalis has been reported in a child given 21.7 g sorbitol daily in liquid medications.[5] Colonic and upper gastrointestinal necrosis, including some fatalities, have been reported after use of sodium polystyrene sulfonate in sorbitol, and may have been associated with the sorbitol component, see p.1465.

It has also been suggested that sorbitol contributed to the morbidity in a patient who developed septicaemia as a complication of intestinal pseudo-obstruction, after the use of charcoal with sorbitol to treat self-poisoning with theophylline.[6] It was suggested that gaseous distension after bacterial metabolism of sorbitol had rendered the bowel wall ischaemic, facilitating passage of bacteria or of endotoxin into the systemic circulation.

1. Brown AM, Masson E. 'Hidden' sorbitol in proprietary medicines - a cause for concern? *Pharm J* 1990; **245:** 211.
2. Edes TE, *et al*. Diarrhea in tube-fed patients: feeding formula not necessarily the cause. *Am J Med* 1990; **88:** 91–3.
3. Johnston KR, *et al*. Gastrointestinal effects of sorbitol as an additive in liquid medications. *Am J Med* 1994; **97:** 185–91.
4. Bauditz J, *et al*. Severe weight loss caused by chewing gum. *BMJ* 2008; **336:** 96–7.
5. Duncan B, *et al*. Medication-induced pneumatosis intestinalis. *Pediatrics* 1997; **99:** 633–6.
6. Longdon P, Henderson A. Intestinal pseudo-obstruction following the use of enteral charcoal and sorbitol and mechanical ventilation with papaveretum sedation for theophylline poisoning. *Drug Safety* 1992; **7:** 74–7.

Pharmacokinetics
Sorbitol is poorly absorbed from the gastrointestinal tract after oral or rectal use. It is metabolised mainly in the liver, to fructose (see p.1945), a reaction catalysed by the enzyme sorbitol dehydrogenase. Some sorbitol may be converted directly to glucose by the enzyme aldose reductase.

Uses and Administration
Sorbitol is a polyhydric sugar alcohol (polyol) with half the sweetening power of sucrose. It occurs naturally in many fruits and vegetables and is prepared commercially by the reduction of glucose.

It has been given as a 30% solution as an alternative to glucose in parenteral nutrition (p.1923) but its use is not recommended because of the risk of lactic acidosis.

Sorbitol may be given orally or rectally as an osmotic laxative in the management of constipation (p.1693); doses of 20 to 50 g have been suggested.

Solutions containing about 3% of sorbitol are used as irrigating fluids in transurethral surgical procedures.

Sorbitol was formerly given intravenously as a 50% solution as an osmotic diuretic.

Sorbitol also acts as a bulk sweetening agent. It is used in limited quantities as a sweetener in energy-reduced diabetic food products. It is also used as an alternative to sucrose in many sugar-free oral liquid preparations and in sugar-free foods as it is less likely to cause dental caries.

Sorbitol also has humectant and stabilising properties and is used in various pharmaceutical and cosmetic products including toothpaste.

Preparations
Ph. Eur.: Sorbitol, Liquid (Crystallising); Sorbitol, Liquid (Non-crystallising); Sorbitol, Liquid, Partially Dehydrated;
USNF 26: Noncrystallizing Sorbitol Solution;
USP 31: Sorbitol Solution.

Proprietary Preparations (details are given in Part 3)

Arg.: Progras†; ***Austral.:*** Sorbilax; ***Braz.:*** Minilax; ***Cz.:*** Ardeanutrisol SO†; ***Hung.:*** Szorbit†; ***Swed.:*** Cystosol†; Resulax.

Multi-ingredient: ***Arg.:*** Humectante Bucal; Micronema; ***Austral.:*** Aquae; Carbosorb S; Fleet Micro-Enema; Medevac†; Microlax; ***Austria:*** Glandosane; Lemazol; Microklist; Resectal; Trommgallol; Yal; ***Belg.:*** Microlax; Spagulax Sorbitol; ***Braz.:*** Anekron; Bilifluxt†; Colachofra; Hepalin; Hepatobe†; Hepatox; Hormo Hepatico†; ***Canad.:*** Charac Tol; Charcodote; Microlax; Salivart; ***Chile:*** Salivart†; Secand; Tabletas Phillips; ***Cz.:*** Yal; ***Denm.:*** Klyx; ***Fin.:*** Klyx; Microlax; Somanol + Ethanol; ***Fr.:*** Apilaxe†; Artisial; Exova†; Hepacholine†; Hepagrume; Hepargitol; Microlax; Nivabetol; Ornitaine; Parapsyllium; Schoum; Spagulax au Sorbitol; SST; ***Ger.:*** Flacar; Freka-Drainjet Purisole; Glandosane; Klysma Sorbit; Microklist; Tutofusin S†; Yal; ***Hong Kong:*** Aquae; Glandosane; Microlax; Salivart; ***Hung.:*** Balansol; Yal†; ***India:*** Alkasol-P; Livocip; Mecolin; Sorbiline; Sorliv; ***Indon.:*** Laxarec; Microlax; ***Israel:*** Charcodote; Spray Mint; ***Ital.:*** Citroepatina; Macrolax; Magisbile†; Novilax; Sorbiclis; ***Malaysia:*** Microlax†; ***Mex.:*** Clyss-Go; ***Neth.:*** Klyx; Microlax; ***Norw.:*** Klyx; Microlax; ***NZ:*** Carbosorb S†; Carbosorb XS; Medevac†; Microlax; ***Pol.:*** Purisole SM; Rektiolax; ***Port.:*** Clyss-Go; Glandosane; Purisole; ***Rus.:*** Microlax (Микролакс); ***S.Afr.:*** Agofell; Microlax†; ***Spain:*** Sugarbil; Vitaphakol; ***Swed.:*** Klyx; Microlax; Vi-Siblin S; ***Switz.:*** Agarol Soft; Citral†; Glandosane; Microklist; Pursana; Yal; ***Thai.:*** Glandosane†; ***Turk.:*** Charflo Sorbitol; Kansilak; Libalaks; Sabalax; ***UK:*** Glandosane; Luborant; Relaxit; Saliva Natura; SST; ***USA:*** Actidose with Sorbitol; Moi-Stir; Numoisyn; Plax; Salivart; ***Venez.:*** Clys-Go†.

Soya Bean
Habas de soja; Soja Bean; Soyabean; Soybean.

Description. Soya bean is the seed of the soya plant *Glycine max* (*G. hispida*; *G. soja* (L.) Merr.). It is a source of soya oil and soya protein.*G.soja* Siebold & Zucc. is wild soybean.

Soya Oil
Aceite de soja; Soiae Oleum; Soijaöljy; Soja Bean Oil; Soja, huile de; Sojae oleum; Sojaolja; Sójový olej; Sojų aliejus; Soya Yağı; Soyabean Oil; Soya-bean Oil; Soybean Oil; Szójababolaj.

Pharmacopoeias. In *Chin.*, *Jpn*, and *US*.
Eur. (see p.vii) includes both hydrogenated and refined oils. *Ger.* also includes a partially hydrogenated oil. *USNF* includes the hydrogenated oil.
Ph. Eur. 6.2 (Soya-bean Oil, Refined; Soiae Oleum Raffinatum). It is the fatty oil obtained from seeds of *Glycine soja* and *G. max* (*G. hispida*) by extraction and subsequent refining. It may contain a suitable antoxidant and is a clear, pale yellow liquid. Practically insoluble in alcohol; miscible with petroleum spirit. Store in well-filled containers at a temperature not exceeding 25°. Protect from light.
The BP 2008 directs that when Soya Oil, Soyabean Oil, or Soyabean Oil is demanded, Refined Soya Oil shall be supplied.
Ph. Eur. 6.2 (Soya-bean Oil, Hydrogenated; Soiae Oleum Hydrogenatum). It is obtained by refining, bleaching, hydrogenation, and deodorisation of soya oil. It consists mainly of triglycerides of palmitic and stearic acids and is a white or almost white mass or powder which melts to a clear, pale yellow liquid when heated. Practically insoluble in water; very slightly soluble in alcohol; freely soluble in dichloromethane, in petroleum spirit after heating, and in toluene. Protect from light.
USP 31: (Soybean Oil). The refined fixed oil obtained from the seeds of the soya plant *Glycine max* (Fabaceae). It may contain suitable antoxidants. A clear, pale yellow, oily liquid having a characteristic odour. Insoluble in water; miscible with chloroform and with ether. Store in airtight containers at a temperature not exceeding 40°. Protect from light.
USNF 26 (Hydrogenated Soybean Oil). The product obtained by refining, bleaching, hydrogenation, and deodorisation of oil obtained from seeds of the soya plant, *Glycine max* (Fabaceae). It consists mainly of triglycerides of palmitic and stearic acids. A white mass or powder that melts to a clear, pale yellow liquid when heated. M.p. between 66° and 72°. Practically insoluble in water; very slightly soluble in alcohol; freely soluble in dichloromethane, in petroleum spirit after heating, and in toluene. Store in airtight containers. Protect from light.

Incompatibility. For mention of the compatibility and stability of solutions and emulsions for parenteral nutrition see under Enteral and Parenteral Nutrition, p.1924.