Uses
Magnesium silicate is used in the food industry and in pharmaceutical manufacturing as an anticaking agent.

Preparations
Proprietary Preparations (details are given in Part 3)
Port.: Acnoil Free.
Multi-ingredient: ***Braz.:*** Cutisanol; ***Fr.:*** ZeaSorb; ***Port.:*** Mucal†.

Methylcellulose *(rINN)*
E461; Méthylcellulose; Methylcellulosum; Methylcelulosa; Metilceliuliozė; Metilcellulóz; Metilcelulosa; Metylcellulosa; Metyloceluloza; Metyyliselluloosa.
Метилцеллюлоза
CAS — 9004-67-5.
ATC — A06AC06.
ATC Vet — QA06AC06.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn*, and *US*.
Ph. Eur. 6.2 (Methylcellulose). A cellulose having some of the hydroxyl groups in the form of the methyl ether. Various grades of methylcellulose are available and are distinguished by appending a number indicating the apparent viscosity in millipascal seconds of a 2% w/w solution at 20°. It is a white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Practically insoluble in hot water, in dehydrated alcohol, in acetone, and in toluene; dissolves in cold water, forming a colloidal solution. A 1% w/w solution in water has a pH of 5.0 to 8.0.
USP 31 (Methylcellulose). A methyl ether of cellulose. When dried at 105° for 2 hours, it contains 27.5 to 31.5% of methoxy groups. It is a white, fibrous powder or granules. It swells in water and produces a clear to opalescent, viscous, colloidal suspension; insoluble in alcohol, in chloroform, and in ether; soluble in glacial acetic acid and in a mixture of equal volumes of alcohol and chloroform. Its aqueous suspensions are neutral to litmus.

Incompatibility. Incompatibilities of methylcellulose have been reported with a number of compounds including chlorocresol, hydroxybenzoates, and phenol. Large amounts of electrolytes increase the viscosity of methylcellulose mucilages owing to salting-out of the methylcellulose; in very high concentrations of electrolytes, the methylcellulose may be completely precipitated.

Adverse Effects
Large quantities of methylcellulose may temporarily increase flatulence and distension and there is a risk of intestinal obstruction. Oesophageal obstruction may occur if compounds such as methylcellulose are swallowed dry.

Precautions
Methylcellulose and other bulk-forming agents should not be given to patients with intestinal obstruction or conditions likely to lead to intestinal obstruction. They should be taken with sufficient fluid to prevent faecal impaction or oesophageal obstruction, and should not be taken immediately before going to bed. Methylcellulose should not be used in infective bowel disease.

Interactions
Bulk laxatives such as methylcellulose lower the transit time through the gut and could affect the absorption of other drugs.

Uses and Administration
The various grades of methylcellulose are widely used in pharmaceutical manufacturing as emulsifying, suspending, and thickening agents and as binding, disintegrating, and coating agents in tablet manufacturing. Low-viscosity grades are preferred for use as emulsifying agents as the surface tension produced is lower than with the higher-viscosity grades. Low-viscosity grades may also be used as suspending or thickening agents for liquid oral dosage forms and solutions of methylcellulose may be used as replacements for sugar-based syrups or other suspension bases. For thickening topically applied products such as gels and creams a high-viscosity grade is usually used. In tablet technology low- or medium-viscosity grades are used as binding agents while high-viscosity grades act as tablet disintegrants by swelling on contact with the disintegration medium. For tablet coating, highly substituted low-viscosity grades are usually used. Methylcellulose may also be included in modified-release tablet formulations.
Methylcellulose is also used as an emulsifier and stabiliser in the food industry.
Methylcellulose is used clinically as a bulk-forming agent. Medium- or high-viscosity grades are used as bulk laxatives in the treatment of constipation (p.1693); by taking up moisture they increase the volume of the faeces and promote peristalsis. Methylcellulose is usually given in an oral dosage of up to 6 g daily in divided doses, taken with plenty of fluid. In the UK, the *BNFC* recommends a dose of 1 g twice daily for children aged from 7 to 12 years. Methylcellulose is also given in similar doses but with a minimum amount of water for the control of diarrhoea (p.1694) and for the control of faecal consistency in ostomies. It is also used in the management of diverticular disease (p.1695). Methylcellulose has also been used as an aid to appetite control in the management of obesity (p.2149) but there is little evidence of efficacy.
Solutions of high-viscosity grade methylcellulose (usually 0.5 to 1%) have been used as a vehicle for eye drops, as artificial tears, and in contact lens care, but hypromellose (above) is now generally preferred for this purpose.

Preparations
BP 2008: Methylcellulose Granules; Methylcellulose Tablets;
USP 31: Methylcellulose Ophthalmic Solution; Methylcellulose Oral Solution; Methylcellulose Tablets.

Proprietary Preparations (details are given in Part 3)
Austria: Bulk; ***Fr.:*** Dacryolarmes†; ***Irl.:*** Celevac; ***Ital.:*** Lacrimart; ***Malaysia:*** Methocel†; ***Spain:*** Muciplasma; ***UK:*** Celevac; ***USA:*** Citrucel; Murocel.
Multi-ingredient: ***Austral.:*** Bioglan 3B Beer Belly Buster; Citri Slim+Trim; Le Trim-BM†; Neo-Trim Fibre†; Parachoc; Pro-Shape†; ***Braz.:*** Kolantyl; Kolantyl DMP; ***S.Afr.:*** Kolantyl; Medigel; Merasyn.

Pectin
E440 (amidated pectin or pectin); Pectina; Pektin.
CAS — 9000-69-5.
ATC — A07BC01.
ATC Vet — QA07BC01.

Pharmacopoeias. In *US*.
USP 31 (Pectin). A purified carbohydrate product obtained from the dilute acid extract of the inner portion of the rind of citrus fruits or from apple pomace; it consists mainly of partially methoxylated polygalacturonic acids. A yellowish-white, almost odourless, coarse or fine powder. Almost completely soluble in 1 in 20 of water, forming a viscous, opalescent, colloidal solution which flows readily and is acid to litmus; practically insoluble in alcohol or in diluted alcohol and in other organic solvents. It dissolves more readily in water if first moistened with alcohol, glycerol, or simple syrup, or if mixed with 3 or more parts of sucrose. Store in airtight containers.

Interactions
Bulk-forming agents such as dietary fibre lower the transit time through the gut and may affect the absorption of other drugs.

Lipid regulating drugs. Pectin, used as a source of fibre, with a lipid-lowering diet and *lovastatin*, has resulted in a paradoxical increase in low-density lipoprotein (LDL)-cholesterol in patients with hypercholesterolaemia. It was believed the pectin reduced the absorption of lovastatin from the gut.[1]

1. Richter WO, *et al.* Interaction between fibre and lovastatin. *Lancet* 1991; **338:** 706.

Uses and Administration
Pectins are used as emulsifiers and stabilisers in the food industry. They are non-starch polysaccharide constituents of dietary fibre (see under Dietary Role in Bran, p.1713).
Pectin is an adsorbent and bulk-forming agent and is present in multi-ingredient preparations for the management of diarrhoea, constipation, and obesity. Pectin has also been tried for reducing or slowing carbohydrate absorption in the dumping syndrome (p.1695).

Preparations
Proprietary Preparations (details are given in Part 3)
Braz.: Kaogel†; ***Fr.:*** Arhemapectine Antihemorragique†; Hydrocoll.
Multi-ingredient: ***Arg.:*** Bismuto con Pectina; Crema De Bismuto; Endomicina†; Mucobase; Opocler†; ***Austral.:*** Betaine Digestive Aid; Bioglan 3B Beer Belly Buster; Bioglan Psylli-Mucil Plus; Bioglan Zellulean with Escin; Bis-Pectin†; Citri Slim+Trim; Diarcalm; Diareze; Donnagel; Kaomagma with Pectin†; Orabase; Orahesive†; PC Regulax†; Pro-Shape†; Stomahesive†; ***Austria:*** Diarrhoesan; ***Belg.:*** Tanalone; ***Braz.:*** Atalin†; Atapec†; Enterobion†; Kaomagma; Kaopectin†; Parenterin; Sanadiar†; ***Canad.:*** Orabase†; Orahesive†; Tegasorb; ***Chile:*** Enterol; Furazolidona; ***Fr.:*** Gelopectose; ***Ger.:*** Diarrhoesan; Kaoprompt-H; ***Gr.:*** Kaopectate†; ***Hong Kong:*** Enterocin Compound; Uni-Kaotin; ***Indon.:*** Andikap; Arcapec; Diagit; Entrogard; Kaopectate; Licopec; Molagit; Neo Diaform; Neo Diastop; Neo Entrostop; Neo Kaocitin; Neo Kaolana; Neo Kaominal; Neo Koniform; ***Irl.:*** Kaopectate†; Orabase; ***Israel:*** Kaopectin; Kapectin Forte†; Orabase†; ***Ital.:*** Cruscasohn; Streptomagma; ***Malaysia:*** Beakopectin†; Kaopectate†; ***Mex.:*** Ameban; Caopecfar; Colfur; Contefur†; Coralzul; Depofin; Dia-Par Compuesto; Dibapec Compuesto; Estibal; Exofur; Facetin-D; Farpectol; Furoxona CP; Fuzotyl†; Hidromagma†; Isocar; K-Omistron; Kaomycin; Kaopectate; Kapecfuran; Kediar; Lactopectin; Neokap; Neoxil; Olam; Optazol; Quimefuran; Suyodil; Tapzol con Neomicina†; Treda; Trilor†; Yodozona; ***NZ:*** Orabase; Stomahesive; ***Port.:*** Cloranpectina†; Varihesive†; ***S.Afr.:*** Betapect; Bipectinol; Biskapect; Chloropect; Collodene; Enterolyte; Gastropect; Granuflex; Granugel; Kantrexil; Kao†; Kaopectin†; Kaostatex; Orabase; Pectin-K; Pectrolyte; ***Singapore:*** Beakopectin; Kaopectate†; ***Spain:*** Dextricea; Estreptoenterol†; ***Switz.:*** HEC; ***Thai.:*** Biodan†; Carbonpectate; Cenopec; Di-Su-Frone†; Difuran; Disento PF; Furasian; Furopectin†; Kaopectal; Med-Kafuzone†; ***Turk.:*** Streptomagma; ***UAE:*** Kaptin; ***UK:*** Goodypops; KLN; Orabase; Orahesive; Stomahesive; ***USA:*** K-C; Kao-Paverin; Kao-Spen; Kaodene Non-Narcotic; Sucrets Herbal; ***Venez.:*** Kaopecon†; Kaopectate†; Klincosal; Micyn-2; Mycin-2†; Parepectolin†; Pec-Kao†; Sendafur†; Strediazin c Atapulguita†; Streptomagma.

Polyethylene Oxide
Polietileno, óxido de.

Pharmacopoeias. In *USNF*.
USNF 26 (Polyethylene Oxide). A nonionic homopolymer of ethylene oxide, represented by the formula $(OCH_2CH_2)_n$, in which *n* represents the average number of oxyethylene groups (about 2000 to over 100 000). It is obtainable in several grades, varying in viscosity profile in an aqueous isopropyl alcohol solution. It may contain not more than 3% of silicon dioxide. A white to off-white powder. Miscible with water; freely soluble in acetonitrile, in dichloromethane, in ethylene dichloride, and in trichloroethylene; insoluble in aliphatic hydrocarbons, in ethylene glycol, in diethylene glycol, and in glycerol. Store in airtight containers. Protect from light.

Uses
Polyethylene oxide is used as a tablet binder and as a suspending and thickening agent in pharmaceutical preparations. Polyethylene oxide has been used in hydrogel wound dressings.

Preparations

Polyvinyl Acetate
Poli(vinil-acetát); Polivinilacetatas; Poly(acétate de vinyle); Poly(vinylacetat); Polyvinyl-acetát; Polyvinylis Acetas; Poly(vinylis acetas); Poly(vinyyliasetaatti).
CAS — 9003-20-7.

Pharmacopoeias. In *Eur.* (see p.vii). *Eur.* also includes a 30% dispersion.
Ph. Eur. 6.2 (Poly(vinyl acetate)). A white or almost white powder or colourless granules or beads. Practically insoluble in water; soluble in alcohol; freely soluble in ethyl acetate. It is hygroscopic and swells in water. It softens at temperatures above 40° to 50°.
Ph. Eur. 6.2 (Poly(Vinyl Acetate) Dispersion 30 per cent). A dispersion in water of polyvinyl acetate having a mean relative molecular mass of about 450 000. It may contain povidone and a suitable surface-active agent, such as sodium laurilsulfate, as stabilisers.
An opaque, white or almost white, slightly viscous liquid. Miscible with water and with alcohol. It is sensitive to spoilage by microbial contaminants. Store at a temperature of 5° to 30°.

Polyvinyl Acetate Phthalate
Polivinilo, acetato ftalato de.

Pharmacopoeias. In *USNF*.
USNF 26 (Polyvinyl Acetate Phthalate). A reaction product of phthalic anhydride and a partially hydrolysed polyvinyl acetate. It contains 55.0 to 62.0% of phthalyl groups, calculated on an anhydrous acid-free basis. It is a free-flowing white powder that may have a slight odour of acetic acid. Insoluble in water, in chloroform, and in dichloromethane; soluble in alcohol and in methyl alcohol. Store in airtight containers.

Uses
Polyvinyl acetate phthalate is a viscosity-modifying agent that is used in the manufacture of enteric coating for tablets. Polyvinyl acetate is used in tablet coating; it is also widely used as a glue.

Polyvinyl Alcohol
Alcohol polivinílico; Alcohol Polyvinylicus; Alkohol poliwinylowy; Polivinil Alkol; Poli(vinil-alkohol); Polivinilo alkoholis; Poly(alcohol vinylicus); Poly(alcool vinylique); Polyvinylalkohol; Poly(vinylalkohol); Poly(vinyylialkoholi).
CAS — 9002-89-5.

Pharmacopoeias. In *Eur.* (see p.vii) and *US*.
Ph. Eur. 6.2 (Poly(Vinyl Alcohol)). It is obtained by polymerisation of vinyl acetate followed by partial or complete hydrolysis of polyvinyl acetate in the presence of catalytic amounts of alkali or mineral acids. Various grades are available and they differ in their degree of polymerisation and their degree of hydrolysis, which determine the physical properties of the different grades. They are characterised by the viscosity and the ester value of the substance. The mean relative molecular mass lies between 20 000 and 150 000. The viscosity is 3 to 70 millipascal seconds. The ester value, which characterises the degree of hydrolysis, is not greater than 280.
Polyvinyl alcohol occurs as a yellowish-white powder or translucent granules. Soluble in water; slightly soluble in dehydrated alcohol; practically insoluble in acetone. A 4% solution in water has a pH of 4.5 to 6.5.
USP 31 (Polyvinyl Alcohol). A synthetic resin represented by the formula $(CH_2CHOH)_n$, where the average value of *n* is 500 to 5000. It is prepared by 85 to 89% hydrolysis of polyvinyl acetate. White to cream-coloured, odourless, granules or powder. Freely soluble in water at room temperature; solution may be effected more rapidly at somewhat higher temperatures. pH of a 4% solution in water is between 5.0 and 8.0.

Uses and Administration
Polyvinyl alcohol is a nonionic surfactant that is used in pharmaceutical manufacturing as a stabilising agent and as a viscosity-increasing agent and lubricant.
Polyvinyl alcohol has also been used in the preparation of jellies that dry rapidly when applied to the skin to form a soluble plastic film.
Polyvinyl alcohols of various grades are used for a wide variety of industrial applications.
Polyvinyl alcohol has been used to increase the viscosity of ophthalmic preparations thus prolonging contact of the active ingredient with the eye. It is included in artificial tears preparations

used for dry eye (p.2140) and in contact lens solutions (p.1622). For dry eye it is often used in a concentration of 1.4% with or without povidone.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Bio Tears; Lagrima Artificial; Lagrima Humectante†; Lentisol; Lersan; Liquifilm Lagrimas†; Natura Wet; Total Solucion; ***Austral.:*** Liquifilm; PVA†; ***Belg.:*** Liquifilm; ***Braz.:*** Duracare†; Lacril; Totalens†; ***Canad.:*** Artificial Tears; Hypotears; Liquifilm; Optilube PVA; Scheinpharm Artificial Tears†; Total†; ***Chile:*** Lagrimas Artificiales; Liquifilm Lagrimas†; Visidic; ***Cz.:*** Liquifilm†; ***Denm.:*** Lacril; ***Fin.:*** Liquifilm; Oftan; ***Ger.:*** Lacrimal†; Liquifilm; Vistil; ***Gr.:*** Liquifilm Tears; ***Hong Kong:*** Liquifilm; PMS-Artificial Tears; ***Hung.:*** Humalac A and C; ***India:*** Aquatears; ***Indon.:*** Optifresh; ***Irl.:*** Liquifilm; Sno Tears; ***Israel:*** Hypotears†; Liquifilm Tears; ***Ital.:*** Lacrilux; Vistil; ***Malaysia:*** Liquifilm†; ***Mex.:*** Acuafil Ofteno; Lubrik; ***Norw.:*** Ocufri; ***NZ:*** Liquifilm; ***Pol.:*** Lacrimal; ***Port.:*** Liquifilm; ***S.Afr.:*** Liquifilm Tears; ***Singapore:*** Hypotears; Liquifilm Tears; ***Spain:*** Hypo Tears; Liquifilm Lagrimas; ***Swed.:*** Sincon; ***Switz.:*** Liquifilm†; Liquitears; ***Thai.:*** Liquifilm Tears; ***Turk.:*** Liquifilm; ***UK:*** Liquifilm Tears; Refresh; Sno Tears; ***USA:*** Akwa Tears; Dry Eyes; Liquifilm; Nu-Tears; Ocu-Tears; Puralube; Tears Again; ***Venez.:*** Acuafil Ofteno; Lacril.

Multi-ingredient: ***Arg.:*** Consil; Latlas; Panoptic Lagrimas; Refresh Free†; Soquette; ***Austral.:*** Murine Revital Eyes; Murine Tears for Eyes; Refresh; Tears Plus; ***Austria:*** Siccaprotect; ***Braz.:*** Refresh; ***Canad.:*** Artificial Tears Extra; Artificial Tears Plus; Murine; Refresh; Scheinpharm Artificial Tears Plus†; Teardrops; Tears Plus; ***Chile:*** Red Off Aqua; ***Cz.:*** Siccaprotect; ***Fr.:*** Refresh; ***Ger.:*** Dispatenol; Lacrimal OK; Liquifilm OK; Siccaprotect; ***Gr.:*** Onufrid; Refresh; ***Hong Kong:*** Hypotears; ***India:*** I-Lube; ***Israel:*** Refresh; ***Ital.:*** Collyria†; Hypotears; ***Malaysia:*** Hypotears; Murine NTF†; Murine Plus†; Refresh†; ***Mex.:*** Lagrifilm Plus; Soltrictor con Lagrifilm; ***Neth.:*** Tears Plus; ***NZ:*** Refresh; Tears Plus†; ***S.Afr.:*** Refresh; Tears Plus; ***Singapore:*** Refresh†; ***Spain:*** Liquifresh; ***Switz.:*** Collylarm; Hypotears; Siccaprotect; Tears Plus†; ***Thai.:*** Refresh; ***Turk.:*** Refresh; Siccaprotect; ***UK:*** Blink; Hypotears†; ***USA:*** Hypotears; Murine; Murine Plus; Nu-Tears II; Refresh Classic; Tears Plus; VasoClear†.

Povidone *(BAN, USAN, rINN)*

E1201; Polivinilpirolidon; Polyvidone; Polyvidonum; Polyvinylpyrrolidone; Povidon; Povidona; Povidonas; Povidoni; Povidonum; Powidon; PVP; Vinylpyrrolidinone Polymer. Poly (2-oxopyrrolidin-1-ylethylene).

Повидон

$(C_6H_9NO)_n$.

CAS — 9003-39-8.
ATC — A07BC03.
ATC Vet — QA07BC03.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn*, and *US*.
Ph. Eur. 6.2 (Povidone). Linear polymers of 1-ethenylpyrrolidin-2-one. The different types of povidone are characterised by their viscosity in solution. A white or yellowish-white, hygroscopic powder or flakes. Freely soluble in water, in alcohol, and in methyl alcohol; very slightly soluble in acetone. A 5% solution in water has a pH of 3.0 to 7.0 depending on the viscosity. Store in airtight containers.
USP 31 (Povidone). A synthetic polymer consisting essentially of linear 1-vinyl-2-pyrrolidinone groups, the degree of polymerisation of which results in polymers of various molecular weights. The different types of povidone are characterised by their viscosity in aqueous solution, relative to that of water, expressed as a K-value. A white to slightly creamy-white, hygroscopic powder. Freely soluble in water, in alcohol, and in methyl alcohol; slightly soluble in acetone; practically insoluble in ether. pH of a 5% solution in water is between 3.0 and 7.0. Store in airtight containers.

Copovidone

Copolyvidone; Copolyvidonum; Copovidona; Copovidonum; Kopovidon; Kopovidonas; Kopovidoni.

ATC — A07BC03.
ATC Vet — QA07BC03.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Ph. Eur. 6.2 (Copovidone). A copolymer of 1-vinylpyrrolidin-2-one and vinyl acetate in the mass proportion 3:2. A white or yellowish-white, hygroscopic powder or flakes. Freely soluble in water, in alcohol, and in dichloromethane. Protect from moisture.
USNF 26 (Copovidone). A copolymer of 1-vinyl-2-pyrrolidone and vinyl acetate in a mass proportion of 3:2. A white to yellowish-white, hygroscopic, powder or flakes. Freely soluble in water, in alcohol, and in dichloromethane; practically insoluble in ether. Store in airtight containers.

Crospovidone *(BAN, rINN)*

Crospovidona; Crospovidonum; Krospovidon; Krospovidonas; Krospovidoni; Kroszpovidon; Polyplasdone XL.

Кросповидон

CAS — 9003-39-8.
ATC — A07BC03.
ATC Vet — QA07BC03.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Ph. Eur. 6.2 (Crospovidone). A cross-linked homopolymer of 1-vinylpyrrolidin-2-one. A white or yellowish-white, hygroscopic powder or flakes. Practically insoluble in water, in alcohol, and in dichloromethane. Protect from moisture.
USNF 26 (Crospovidone). A synthetic cross-linked homopolymer of *N*-vinyl-2-pyrrolidinone. A white to creamy-white, hygroscopic powder having a faint odour. Insoluble in water and in ordinary organic solvents. pH of a 1% suspension in water is between 5.0 and 8.0. Store in airtight containers.

Adverse Effects

Some products intended for parenteral use contain povidone as an excipient and injection has led to deposition of povidone in the tissues with consequent lesions and pain. There have been occasional reports of liver involvement.

◊ Reviews of adverse effects associated with pharmaceutical excipients including povidone.

1. Golightly LK, *et al.* Pharmaceutical excipients: adverse effects associated with 'inactive ingredients' in drug products (part II). *Med Toxicol* 1988; **3:** 209–40.

Hypersensitivity. For reference to anaphylaxis caused by the povidone component of povidone-iodine, see p.1659.

Uses and Administration

Povidone is used in pharmaceutical manufacturing as a suspending and dispersing agent and as a tablet binding, granulating, and coating agent. It is used as a carrier for iodine (see Povidone-Iodine, p.1659). An insoluble cross-linked form of povidone known as crospovidone is used as a tablet disintegrant. Copovidone, a copolymer with vinyl acetate, is used as a tablet binding and coating agent.

Povidone is included in artificial tears preparations used in the management of dry eye (p.2140) and in solutions for contact lens care (p.1622). For dry eye it is often used in a concentration of 0.6% with other viscosity-increasing agents (such as polyvinyl alcohol); it may also be used alone in solutions containing 1.5 to 5%.

Povidone has also been used as an adsorbent in gastrointestinal disorders.

Povidone was formerly used as a plasma expander but other compounds are now preferred.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Hypotears Plus; Megatears†; Sol-O-Flex; ***Austral.:*** In A Wink Moisturing†; Rohto Zi Fresh†; Spray-on Bande†; ***Austria:*** Oculotect; Protagent; ***Belg.:*** Oculotect; Siccagent; ***Braz.:*** Hypotears Plus; ***Chile:*** Lepex; Oculotec; ***Cz.:*** Arufil; Hypotears Plus; ***Denm.:*** Oculac; ***Fin.:*** Oculac; ***Fr.:*** Bolinan; Dulcilarmes; Fluidabak; Larmecran; Nu-Gel†; Nutrivisc; Unifluid; ***Ger.:*** Aloclair; Arufil; Lacophtal; Lacri-Stulln; Oculotect Fluid; Protagent; Vidirakt S; Vidisept; Wet-COMOD; Yxin Tears; ***Gr.:*** Oculotect; Protagent; ***Hong Kong:*** Hypotears Plus; Protagent; ***Hung.:*** Arufil; Oculotect; ***Israel:*** Hypotears E; Lacrimol; ***Ital.:*** Clarover; Nu-Gel; Protagent†; Wet-COMOD; ***Malaysia:*** Oculotect; Vidisept N†; ***Mex.:*** Hypotears Plus; Logical; Renu Plus; ***Neth.:*** Duratears Free; Oculotect; Protagens; Vidisic PVP; ***Norw.:*** Oculac; ***Philipp.:*** Oculotect; Vidisept N; ***Pol.:*** Oculotect; Vidisept; ***Port.:*** Oculotect; ***Rus.:*** Vid-COMOD (Вид-КОМОД); ***S.Afr.:*** Hypotears; ***Singapore:*** Oculotect; Vidisept N; ***Spain:*** Oculotect; ***Swed.:*** Oculac; ***Switz.:*** Oculac; Protagent; ***Thai.:*** Hypotears Plus; ***Turk.:*** Oculotect; Protagent; ***UK:*** Aloclair; Oculotect; ***Venez.:*** Hipotears Plus†; Hypotears Plus.

Multi-ingredient: ***Arg.:*** Maxilac; Panoptic Lagrimas; Refresh Free†; Visine Plus; ***Austral.:*** Murine Revital Eyes; Murine Tears for Eyes; Refresh; Tears Plus; Visine Advanced Relief; ***Austria:*** Lacrisic; ***Braz.:*** Refresh; ***Canad.:*** Artificial Tears Extra; Artificial Tears Plus; Moisture Drops†; Murine; Refresh; Scheinpharm Artificial Tears Plus†; Teardrops; Tears Plus; Visine Advance Triple Action; ***Fr.:*** Poly-Karaya; Refresh; ***Ger.:*** Lacrimal OK; Lacrisic; Liquifilm OK; Visine Trockene Augen; ***Gr.:*** Onufrid; Refresh; ***India:*** I-Lube; ***Israel:*** Aphtagone; Aptha-X; Gelclair†; Refresh; V-Crima; ***Ital.:*** Filmabak; ***Malaysia:*** Murine NTF†; Murine Plus†; Refresh†; ***Mex.:*** Lagrifilm Plus; Soyaloid; Soydex; Visine Extra; ***Neth.:*** Tears Plus; ***NZ:*** Refresh; Tears Plus†; Visine Advanced Relief; ***Rus.:*** Gluconeodesum (Глюконеодез); Haemodez-N (Гемодез-Н); ***S.Afr.:*** Moisture Drops†; Refresh; Tears Plus; ***Singapore:*** Refresh†; ***Spain:*** Liquifresh; ***Switz.:*** Collylarm; Tears Plus†; ***Thai.:*** Refresh; ***Turk.:*** Refresh; ***UK:*** Gelclair; ***USA:*** Advanced Relief Visine; Gelclair; Murine; Murine Plus; Refresh Classic; Tears Plus.

Silicas

Silice.

Purified Siliceous Earth

Diatomaceous Earth; Diatomite; Purified Infusorial Earth; Purified Kieselguhr; Terra Silicea Purificada; Tierra de diatomeas; Ziemia okrzemkowa.

CAS — 7631-86-9.

Pharmacopoeias. In *USNF*.
USNF 26 (Purified Siliceous Earth). A form of silicon dioxide consisting of frustules and fragments of diatoms purified by calcining. A very fine, white, light grey, or pale buff mixture of amorphous powder and lesser amounts of crystalline polymorphs, including quartz and cristobalite. It is gritty and readily absorbs moisture, and retains about four times its weight of water before becoming fluid. Insoluble in water, in acids, and in dilute solutions of alkali hydroxides.

Silicon Dioxide

Colloidal Hydrated Silica; E551; Kiseldioxid, kolloidal, hydratiserad; Koloidinis silicio dioksidas, hidratuotas; Oxid křemičitý koloidní hydratovaný; Piidioksidi, kolloidinen, hydratoitu; Precipitated Silica; Silica colloidalis hydrica; Silica Gel; Silice colloïdale hydratée; Silicio, dióxido de; Víztartalmú, kolloid szilicium-dioxid.

$SiO_2.xH_2O$ = 60.08 (anhydrous).

CAS — 63231-67-4; 7631-86-9.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*. *Eur.* and *USNF* also include dental-type silica.
Ph. Eur. 6.2 (Silica, Colloidal Hydrated). A light, fine, white or almost white, amorphous powder. Practically insoluble in water, and in mineral acids except hydrofluoric acid; dissolves in hot solutions of alkali hydroxides.
Ph. Eur. 6.2 (Silica, Dental Type). An amorphous silica (precipitated, gel, or obtained by flame hydrolysis). A white or almost white, light, fine amorphous powder. Practically insoluble in water and in mineral acids; dissolves in hydrofluoric acid and in hot solutions of alkali hydroxides.
USNF 26 (Silicon Dioxide). It is obtained by insolubilising the dissolved silica in sodium silicate solution. Where obtained by the addition of sodium silicate to a mineral acid, the product is termed silica gel; where obtained by the destabilisation of a solution of sodium silicate in such a manner as to yield very fine particles, the product is termed precipitated silica. A fine, white, odourless, hygroscopic, amorphous powder in which the diameter of the average particles ranges from 2 to 10 micrometres. Insoluble in water, in alcohol, and in other organic solvents; soluble in hot solutions of alkali hydroxides. pH of 5% slurry in water is between 4.0 and 8.0. Store in airtight containers. Protect from moisture.
USNF 26 (Dental-Type Silica). It is obtained from sodium silicate solution by destabilising with acid in such a way as to yield very fine particles. A fine, white, odourless, hygroscopic, amorphous powder in which the diameter of the average particles ranges from 0.5 to 40 micrometres. Insoluble in water, in alcohol, and in acid (except hydrofluoric acid); soluble in hot solutions of alkali hydroxides. pH of 5% slurry in water is between 4.0 and 8.5. Store in airtight containers.

Colloidal Silicon Dioxide

Acidum Silicicum Colloidale; Colloidal Anhydrous Silica; Colloidal Silica; Hochdisperses Silicumdioxid; Kiseldioxid, kolloidal, vattenfri; Koloidinis silicio dioksidas, bevandenis; Krzemu dwutlenek koloidalny; Oxid křemičitý koloidní bezvodý; Piidioksidi, kolloidinen, vedetön; Silica colloidalis anhydrica; Silice colloïdale anhydre; Silicii Dioxidum Colloidalle; Silicio coloidal, dióxido de; Vízmentes, kolloid, szilicium-dioxid.

SiO_2 = 60.08.

CAS — 7631-86-9.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Eur. and *USNF* also include hydrophobic colloidal silica.
Ph. Eur. 6.2 (Silica, Colloidal Anhydrous). A light, fine, white or almost white, amorphous powder. It has a particle size of about 15 nm. Practically insoluble in water and in mineral acids except hydrofluoric acid; dissolves in hot solutions of alkali hydroxides. A 3.3% suspension in water has a pH of 3.5 to 5.5.
Ph. Eur. 6.2 (Silica, Hydrophobic Colloidal; Silica Hydrophobica Colloidalis). Colloidal silicon dioxide partly alkylated for hydrophobation. A light, fine, white or almost white, amorphous powder, not wettable by water. Practically insoluble in water and mineral acids except hydrofluoric acid. It dissolves slowly in hot solutions of alkali hydroxides.
USNF 26 (Colloidal Silicon Dioxide). A submicroscopic fumed silicon dioxide, prepared by the vapour-phase hydrolysis of a silicon compound. A light, white, non-gritty powder of extremely fine particle size (about 15 nm). Insoluble in water and in acid (except hydrofluoric acid); soluble in hot solutions of alkali hydroxides. pH of a 4% dispersion in water is between 3.5 and 5.5.
USNF 26 (Hydrophobic Colloidal Silica). Prepared by partial alkylation for hydrophobation. A light, fine, white or almost white, amorphous powder, not wettable by water. Practically insoluble in water and in mineral acids, except hydrofluoric acid; dissolves slowly in hot solutions of alkali hydroxides.

Adverse Effects

Prolonged inhalation of some forms of silica dust may be associated with the development of fibrosis of the lung (silicosis). The forms of silica described here and used as pharmaceutical excipients may cause irritation of the respiratory tract if inhaled but do not appear to be associated with silicosis.

Uses

The different forms of silica have various pharmaceutical uses. Purified siliceous earth is used as a filtering medium and adsorbent. Silicon dioxide is used as a suspending and thickening agent and, in the form of silica gel, as a desiccant. Colloidal silicon dioxide is used as a suspending agent and thickener, as a stabiliser in emulsions, and as an anticaking agent and desiccant. Silicon dioxide is also used as an anticaking agent in the food industry.

Homoeopathy. Silicon dioxide has been used in homoeopathic medicines under the following names: Acidum silicicum; Silicea; Sil.

Preparations

Proprietary Preparations (details are given in Part 3)
Austral.: Celloids S 79; ***Cz.:*** Original Silicea Balsam†; ***Ger.:*** Entero-Teknosal; Gela†; Sklerosol N†; ***NZ:*** Biosil†; ***Rus.:*** Polysorb (Полисорб); ***UK:*** Aerosil.

Multi-ingredient: ***Austral.:*** Bio-Disc; Duo Celloids SCF; Duo Celloids SPS; Duo Celloids SSS; Silicic Complex†; ***Austria:*** CO Granulat; Kephalodoron; ***Chile:*** Cartilago T-500; Xeragel; ***Cz.:*** Acne Cream†; CO Granulat†; ***Fin.:*** Wicne; ***Fr.:*** Gelopectose; Topaal; Topalkan; ***Ger.:*** Aplona; CO Granulat†; Equisil N; Rosatum Heilsalbe; ***Gr.:*** Gastrovison†; ***Hong Kong:*** Disflatyl; ***Israel:*** Adinol; Kelo-Cote; ***Ital.:*** Lacalut; ***Malaysia:*** Rowarolan; ***NZ:*** Lamisil Odor Eze; ***Philipp.:*** BioSil; ***S.Afr.:*** Lotio Pruni Comp cum Cupro; ***Singapore:*** Disflatyl; ***Switz.:*** Acne Creme; Fissan†.