

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.: Acnol Free.

Multi-ingredient: **Braz.:** Cutisanol; **Fr.:** ZeaSorb; **Port.:** Mucafl†.

Methylcellulose (rINN)

E461; Méthylcellulose; Methylcellulosum; Methylcellulosa; Metilceliulozė; Metilcellulóz; Metilcelulosa; Metylcellulosa; Metyloceluloza; Metylcelluloosa.

МЕТИЛЦЕЛЮЛОЗА

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 typically 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 disintegrating 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.

The symbol † denotes a preparation no longer actively marketed

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 hyromellose (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.:** Dacryolames†; **Irl.:** Celevac; **Ital.:** Lacrimart; **Malaysia:** Methocef†; **Spain:** Muciplasma; **UK:** Celevac; **USA:** Citrucel; Murocel.

Multi-ingredient: **Austral.:** Bioglan 3B Beer Belly Buster; Citri Slim+Trim; Le Trim-BM†; Neo-Trim Fibrefit; Parachoc; Pro-Shape†; **Braz.:** Kolantyl; Kolantyl DMP; **S.Afr.:** Kolantyl; Medigek; 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; Opoder†; **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; Orabase†; PC Regulax†; Pro-Shape†; Stomahesive†; **Austria:** Diarhones; **Belg.:** Tanalone; **Braz.:** Atalint†; Atapec†; Enterobion†; Kaomagma; Kaopectin†; Parenterin; Sanadiar†; **Canada:** Orabase†; Orabase†; Tegasar†; **Chile:** Enterol; Furazolidona; **Fr.:** Gelopectose; **Ger.:** Diarhonesan; 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 Fort†; Orabase†; **Ital.:** Cruscasohn; Streptomagma; **Malaysia:** Beakopectin†; Kaopectate†; **Mex.:** Ameban; Caopecfar; Colfur; Contefur†; Coraluz; Depofin†; Dia-Par Compuesto; Dibapec Compuesto; Estibal; Exofur; Facetin-D; Farpectol; Furonexa CP; Fuzoty†; Hidromagma†; Isocar; K-Omiston; Kaomycin; Kaopectate; Kapecfuran; Kediar; Lactopectin; Neokap; Neoxil; Olam; Optazol; Quimefuran; Suyodil; Tapzol con Neomicina†; Treda; Trior†; Yodozona; **NZ:** Orabase; Stomahesive; **Port.:** Cloranpectin†; Varihesive†; **S.Afr.:** Betapec; Bipectinol; Biskapec; Chloropect; Collodene; Enterolyte; Gastropect; Granulflex; Granugel; Kantrexil; Kao†; Kaopectin†; Kaostate; Orabase; Pectin-K; Pectolyte; **Singapore:** Beakopectin; Kaopectate†; **Spain:** Dextrice; Estreptoterofol†; **Switz.:** HEC; **Thai.:** Biodan†; Carbonpectate; Cenopec; Di-Su-Frone†; Difuran; Disento PF; Furasin; Furpectin†; Kaopactal; Med-Kafuzone†; **Turk.:** Streptomagma; **UAE:** Kaplin†; **UK:** Goodpops; KLN; Orabase; Orabase†; Stomahesive; **USA:** K-C; Kao-Paverin; Kao-Spen; Kaodene Non-Narcotic; Surets Herbal; **Venez.:** Kaopcon†; Kaopectate†; Klincosak; Micyn-2; Mycin-2†; Pparectolin†; Pec-Kao†; Sendafur†; Strediazin c Atapul-guita†; Streptomagma.

Polyethylene Oxide

Polietileno, óxido de.

Pharmacopoeias. In *USNF*.

USNF 26 (Polyethylene Oxide). A nonionic homopolymer of ethylene oxide, represented by the formula $(\text{OCH}_2\text{CH}_2)_n$, 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 ace-

tonitrile, 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 vinylo); Poly(vinylacetate); Polivinil-acetát; Polivinilyls Acetas; Poly(vinylis acetatas); Poly(vinylisetaatti).

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 polivinilico; Alcohol Polyvinilicus; Alkohol polivinilowy; Polivinil Alkol; Poli(vinil-alkohol); Polivinilo alkoholis; Poly(alcohol vinylicus); Poly(alcool vinylique); Polyvinylalkohol; Poly(vinylalkohol); Poly(vinylalkoholi).

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 $(\text{CH}_2\text{CHOH})_n$, 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