

boxy-benzoyl) groups, calculated on the anhydrous, acid-free basis. A white, free-flowing powder that may have a slight odour of acetic acid. Insoluble in water and in alcohol; soluble in acetone and in dioxan. Store in airtight containers.

## Uses

Cellacelate is unaffected by immersion in acid media in the stomach but softens and swells in intestinal fluid. It is used in pharmaceutical manufacturing as an enteric-coating material for tablets and capsules, usually with a plasticiser. Films of cellacelate are reported to be permeable to some ionic substances such as ammonium chloride and potassium iodide, and such substances require a sealing coat.

## Cellulose

Cellulosa.

**Description.** Cellulose is an unbranched polysaccharide polymer consisting of 1,4-β-linked glucopyranose units. It is the chief constituent of fibrous plant material.

## Dispersible Cellulose (BAN)

Cellulose microcrystalline et carbomellose sodique; Cellulosum microcrystallinum et carbomellosum natricum; Celulosa dispersable; Microcrystalline Cellulose and Carboxymethylcellulose Sodium; Microcrystalline Cellulose and Carbomellose Sodium.

**Pharmacopoeias.** In *Br.* Also in *USNF*.

**BP 2008** (Dispersible Cellulose). An odourless or almost odourless, white or off-white, coarse or fine powder consisting of a colloid-forming attrited mixture of microcrystalline cellulose and carbomellose sodium. Disperses in water to produce a white, opaque dispersion or gel; practically insoluble in organic solvents and in dilute acids. Store at a temperature between 8° and 15°.

**USNF 26** (Microcrystalline Cellulose and Carboxymethylcellulose Sodium). A colloid-forming, attrited mixture of microcrystalline cellulose and carbomellose sodium. A white to off-white, odourless, coarse to fine, powder. It swells in water, producing, when dispersed, a white, opaque dispersion or gel; insoluble in organic solvents and in dilute acids. Store in airtight containers in a dry place, and at a temperature not exceeding 40°.

## Microcrystalline Cellulose

Celiuloză, mikrokristalină; Cellulosa Microgranulare; Cellulosa, mikrokristallin; Cellulose Gel; Cellulose microcrystalline; Cellulosum microcrystallinum; Cellulosum Microcrystallinum; Cellulosum Microristallinum; Cellulosa microcristalina; Cellulosa mikrokristalická; Celuloza mikrokryształczna; Crystalline Cellulose; E460; Mikrokristályos cellulóz; Selluloosa, mikrokiteinen. CAS — 9004-34-6.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF*.

*Eur* also includes a mixture of microcrystalline cellulose with carbomellose sodium.

**Ph. Eur. 6.2** (Cellulose, Microcrystalline). A purified, partly depolymerised cellulose, prepared by treating alpha-cellulose, obtained as a pulp from fibrous plant materials, with mineral acids. It is a white or almost white, fine or granular powder. Practically insoluble in water, in dehydrated alcohol, in acetone, in toluene, in dilute acids, and in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid obtained from a 12.5% mixture in water after 20 minutes of shaking is 5.0 to 7.5.

**Ph. Eur. 6.2** (Microcrystalline Cellulose and Carbomellose Sodium). A colloid-forming, powdered mixture of microcrystalline cellulose with 5 to 22% of carbomellose sodium. It contains 75 to 125% of the nominal amount of carbomellose sodium, calculated with reference to the dried substance. A white or off-white, coarse or fine powder. Dispersible in water producing a white, opaque colloidal dispersion; practically insoluble in organic solvents and in dilute acids. pH of a 2% dispersion in water is 6 to 8.

**USNF 26** (Microcrystalline Cellulose). A purified, partly depolymerised cellulose, prepared by treating alpha-cellulose, obtained as a pulp from fibrous plant material, with mineral acids. It is a fine, white or almost white powder consisting of free-flowing, nonfibrous particles. Insoluble in water, in dilute acids, and in most organic solvents; practically insoluble in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid obtained from a 12.5% mixture in water after 20 minutes of shaking is between 5.0 and 7.5. Store in airtight containers.

## Powdered Cellulose

Celiulozás miltellai; Cellulosapulver; Cellulose en poudre; Cellulose Powder; Cellulosi pulvis; Cellulózpor; Celulosa en polvo; Celulosový prášek; E460; Selluloosajauhe.

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Jpn.* Also in *USNF*.

**Ph. Eur. 6.2** (Cellulose, Powdered). A purified mechanically disintegrated cellulose prepared from alpha-cellulose obtained as a pulp from fibrous plant materials. It is a white or almost white, fine or granular powder. Practically insoluble in water, in dehydrated alcohol, in acetone, in toluene, in most organic solvents, and in dilute acids; slightly soluble in sodium hydroxide solution

(1 in 20). The pH of the supernatant liquid of an 11.1% mixture in water is between 5.0 and 7.5 one hour after preparation.

**USNF 26** (Powdered Cellulose). A purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from fibrous plant materials. It is a white or almost white powder. Exhibits degrees of fineness ranging from a free-flowing, dense powder to a coarse, fluffy, nonflowing material. Insoluble in water, in nearly all organic solvents, and in dilute acids; slightly soluble in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid of an 11.1% mixture in water is between 5.0 and 7.5 one hour after preparation. Store in airtight containers.

## Uses and Administration

Powdered cellulose and microcrystalline cellulose are used in pharmaceutical manufacturing as tablet binders and disintegrants and as capsule and tablet diluents. These two forms of cellulose are also used in the food industry. Dispersible cellulose (which also contains some carbomellose sodium) forms a thixotropic gel with water and is used pharmaceutically as a suspending and thickening agent.

Various forms of cellulose have been included in preparations used in the management of constipation and obesity. Cellulose is also used in adsorbent powder preparations used for skin disorders including hyperhidrosis.

## Preparations

**Proprietary Preparations** (details are given in Part 3)

**Ital.:** Fibrasan; **UK:** Nasaleze; Sterigel; **USA:** Unifiber.

**Multi-ingredient:** **Arg.:** Usar Fibra; **ZeaSorb;** **Austral.:** ZeaSorb; **Canada:** ZeaSorb; **Chile:** ZeaSorb; **Cz.:** Systogen; **Fr.:** Gelopectose; Hydroclean; ZeaSorb; **Irl.:** ZeaSorb; **Israel:** Celluspan; **Thai.:** ZeaSorb; **UK:** ZeaSorb.

## Ceratonia

Carob Bean Gum; Carob Gum; Cerat; Ceratonia Gum; E410; Goma de garrofin; Gomme de Caroube; Guma z nasion Carobe; Locust Bean Gum.

CAS — 9000-40-2.

ATC — A07XA02.

ATC Vet — QA07XA02.

## Uses

Ceratonia consists of the endosperms separated from the seeds of the locust bean tree, *Ceratonia siliqua* (Leguminosae). It is used as a thickening agent and stabiliser in the food industry.

## Preparations

**Proprietary Preparations** (details are given in Part 3)

**Austria:** Arobon; **Irl.:** Carobel; **Ital.:** Arobon; **Switz.:** Nestargel; **UK:** Carobel; Nestargel.

**Multi-ingredient:** **Austria:** China-Eisenwein; **Belg.:** Kestomatine Baby; **Fr.:** Gumik; **Indon.:** Polysilane; **Switz.:** Kestomatine Bebe.

## Dextrates (USAN)

Dextratos.

CAS — 39404-33-6.

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Dextrates). A purified, anhydrous or hydrated, mixture of saccharides obtained by the controlled enzymatic hydrolysis of starch. Free-flowing, porous, white, odourless, spherical granules consisting of aggregates of microcrystals. Freely soluble in water (heating increases its solubility in water); soluble in dilute acids and alkalis and in basic organic solvents such as pyridine; insoluble in the common organic solvents. pH of a 20% solution in water is between 3.8 and 5.8. Store in a dry place at a temperature of 8° to 15°.

## Uses

Dextrates is used as a capsule and tablet diluent and as a tablet binding agent.

## Ethylcellulose (rINN)

Cellulose Ethyl Ether; E462; Éthylcellulose; Ethylcellulosum; Ethylcellulosa; Etilceliuloză; Etilcellulóz; Etilcelulosa; Etylcellulosa; Etylcelluloosa.

Этилцеллюлоза

CAS — 9004-57-3.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), and *Int.* Also in *USNF*.

**Ph. Eur. 6.2** (Ethylcellulose). A partly *O*-ethylated cellulose. It contains 44 to 51% of ethoxy (–OC<sub>2</sub>H<sub>5</sub>) groups, calculated on the dried basis. A white to yellowish-white, odourless or almost odourless, powder or granular powder. Solutions of ethylcellulose may show a slight opalescence. Practically insoluble in water, in glycerol (85%), and in propylene glycol; soluble in dichloromethane and in a mixture of 20 parts alcohol and 80 parts toluene (w/w); slightly soluble in ethyl acetate and methyl alcohol.

**USNF 26** (Ethylcellulose). A partly *O*-ethylated cellulose. It contains 44.0 to 51.0% of ethoxy groups, calculated with reference to the dried substance. A free-flowing white to light tan powder.

Its aqueous suspensions are neutral to litmus. Insoluble in water, in glycerol, and in propylene glycol. Ethylcellulose containing less than 46.5% of ethoxy groups is freely soluble in chloroform, in methyl acetate, in tetrahydrofuran, and in mixtures of aromatic hydrocarbons with alcohol; ethylcellulose containing 46.5% or more of ethoxy groups is freely soluble in alcohol, in chloroform, in ethyl acetate, in methyl alcohol, and in toluene.

## Uses

Ethylcellulose is used as a binder in tablets and as a coating material for tablets, granules, and microcapsules. It is also used as a thickening agent.

## Preparations

**USNF 26:** Ethylcellulose Aqueous Dispersion.

## Gastric Mucin (BAN)

Mucina gástrica.

## Uses and Administration

Gastric mucin is a high-molecular-weight glycoprotein precipitated by alcohol (60%) after digestion of hogs' stomach linings by pepsin and hydrochloric acid. It is used in artificial saliva formulations for dry mouth (p.2140) as an oral spray containing 3.5% or as lozenges.

## Preparations

**Proprietary Preparations** (details are given in Part 3)

**Ger.:** Saliva medic; **Neth.:** Saliva Orthana.

**Multi-ingredient:** **UK:** Saliva Orthana.

## Hyetellose (rINN)

Hidroksietilceliuloză; Hidroksietilcellulóz; Hidroksietilcellulosa; Hidroksietilcelluloosa; Hidroksietilcelluloza; Hydroxyethylcellulosa; Hydroxyethyl Cellulose; Hydroxyethylcellulose; Hydroxyethylcellulose; Hydroxyethylcellulosum; Hyétellose; Hyetellosum; Hyetelloza.

Гие́тэллоза

CAS — 9004-62-0.

**NOTE.** HECL is a code approved by the BP 2008 for use on single unit doses of eye drops containing hyetellose and sodium chloride where the individual container may be too small to bear all the appropriate labelling information.

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Int.* Also in *USNF*.

**Ph. Eur. 6.2** (Hydroxyethyl Cellulose). A partially substituted 2-hydroxyethyl ether of cellulose. Various grades are available and are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% solution measured at 25°. A white, yellowish-white, or greyish-white, powder or granules. Soluble in cold or hot water, forming colloidal solutions; practically insoluble in alcohol, in acetone, and in toluene. A 1% solution in water has a pH of 5.5 to 8.5.

**USNF 26** (Hydroxyethyl Cellulose). A partially substituted poly(hydroxyethyl) ether of cellulose. It is available in several grades, varying in viscosity and degree of substitution, and some grades are modified to improve their dispersion in water. It may contain suitable anticaking agents. A white to light tan, practically odourless, hygroscopic, powder. Soluble in cold or hot water, giving a colloidal solution; practically insoluble in alcohol and in most organic solvents. pH of a 1% solution in water is between 6.0 and 8.5.

## Uses and Administration

Hyetellose is used in pharmaceutical manufacturing as a thickener and stabiliser and as a tablet coating and binding agent. It is present in lubricant preparations for dry eye (p.2140), contact lens care (p.1622), and dry mouth (p.2140).

## Preparations

**Proprietary Preparations** (details are given in Part 3)

**Austral.:** Rohto Zi Contact; **Ger.:** Lacrigel; **Israel:** V-Tears; **USA:** Comfort Tears; Gonioscopic; TearGard.

**Multi-ingredient:** **Arg.:** Hidratagel; **Austral.:** Minims Artificial Tears; **Fr.:** Premicia; **Ger.:** Lubrikano; Nu-Gel; **Irl.:** Minims Artificial Tears; **Israel:** V-Crima; **Turk.:** Gleitgel; **UK:** Minims Artificial Tears; **USA:** Biotene with Calcium; Optimoist.

## Hymetellose (rINN)

HEMC; Hidroksietilmetilcellulosa; Hydroxyethyl Methylcellulose; Hydroxyethylmethylcellulose; Hymétellose; Hymetellosum; Methylhydroxyethylcellulose; Methylhydroxyethylcellulose; Methylhydroxyethylcellulosum; Metilhidroksietilceliuloză; Metilhidroksietilcellulóz; Methylhydroxyethylcellulosa; Methylhydroksietilcelluloosa.

Гиме́теллоза

CAS — 9032-42-2.

**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Methylhydroxyethylcellulose; Hydroxyethylmethylcellulose BP 2008). A partially substituted ether of cellulose containing methoxyl and 2-hydroxyethyl groups. Various grades are available and are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% w/w

solution measured at 20°. 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 5.5 to 8.0.

**USNF 26** (Hymetellose). A partly *O*-(methylated) and *O*-(2-hydroxyethylated) cellulose. Various grades are available, labelled with the viscosity of a 2% w/w solution measured at 20°. A white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Insoluble in hot water, in alcohol, in acetone, in ether, and in toluene; dissolves in cold water forming a colloidal solution. pH of a 1% w/w solution in water is between 5.5 and 8.0.

### Uses

Hymetellose is used similarly to other cellulose ethers, such as methylcellulose (p.2145), as a pharmaceutical excipient.

### Preparations

**Proprietary Preparations** (details are given in Part 3)

**Austria:** Cellobexon.

**Multi-ingredient:** **Fr.:** Pharmatex.

## Hyprolose (rINN)

E463; Hidroksipropilceliuloz; Hidroxipropilcellulóz; Hidroxi-propilcellulosa; Hidroksipropilcelluloosa; Hydroxypropylcellulosa; Hydroxypropyl Cellulose; Hydroxypropylcellulose; Hydroxypropylcellulosum; Hydroxypropylcellulosa; Hyprolosum.

Гипролоза

CAS — 9004-64-2.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF* which has two separate monographs, for Hydroxypropyl Cellulose and for Low-substituted Hydroxypropyl Cellulose. **Ph. Eur. 6.2** (Hydroxypropylcellulose). A partially substituted 2-hydroxypropyl ether of cellulose. Various grades are available and may be distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% w/w solution measured at 20°. White or yellowish-white, granules or powder; hygroscopic after drying. Soluble in cold water, in dehydrated alcohol, in glacial acetic acid, in methyl alcohol, in propylene glycol, and in a mixture of 10 parts methyl alcohol and 90 parts dichloromethane, forming colloidal solutions; practically insoluble in hot water, in ethylene glycol, and in toluene; sparingly soluble or slightly soluble in acetone. A 1% w/w solution in water has a pH of 5.0 to 8.5.

**USNF 26** (Hydroxypropyl Cellulose). A partially substituted poly(hydroxypropyl) ether of cellulose. When dried at 105° for 1 hour, it contains not more than 80.5% of hydroxypropoxy groups. It may contain not more than 0.60% of silica or other suitable antikicking agent. A white to cream-coloured, practically odourless, granular solid or powder, hygroscopic after drying. Soluble in cold water, in alcohol, in chloroform, and in propylene glycol, giving a colloidal solution; insoluble in hot water. pH of a 1% solution in water is between 5.0 and 8.0.

**USNF 26** (Low-Substituted Hydroxypropyl Cellulose). It contains not less than 5.0% and not more than 16.0% of hydroxypropoxy groups. A white to yellowish-white, practically odourless, hygroscopic, fibrous or granular powder. Practically insoluble in dehydrated alcohol and in ether; dissolves in a solution of sodium hydroxide (1 in 10) and produces a viscous solution; swells in water, in sodium carbonate, and in 2N hydrochloric acid. pH of the suspension obtained by shaking 1.0 g with 100 mL of water is between 5.0 and 7.5. Store in airtight containers.

### Adverse Effects

Hyprolase used as a solid ocular insert may result in blurred vision and ocular discomfort or irritation including hypersensitivity and oedema of the eyelids.

**Hypersensitivity.** Allergic contact dermatitis was reported in a patient, associated with the hyprolase present in the reservoir layer of a transdermal estradiol patch.<sup>1</sup>

- Schwartz BK, Clendenning WE. Allergic contact dermatitis from hydroxypropyl cellulose in a transdermal estradiol patch. *Contact Dermatitis* 1988; **18**: 106–7.

### Uses and Administration

Hyprolase is used in pharmaceutical manufacturing in the film coating of tablets, as a tablet excipient, as a thickener, and in microencapsulation. It is used as an emulsifier and stabiliser in the food industry.

Hyprolase is also used as a modified-release solid ophthalmic insert in the management of dry eye (p.2140).

### Preparations

**USP 31:** Hydroxypropyl Cellulose Ocular System.

**Proprietary Preparations** (details are given in Part 3)

**Austral.:** Lacrisert†; **Canad.:** Lacrisert; **Fin.:** Lacrisert; **Fr.:** Lacrisert; **Neth.:** Lacrisert; **Norw.:** Lacrisert†; **Swed.:** Lacrisert; **USA:** Lacrisert.

## Hypromellose (BAN, rINN)

E464; Hipromelozé; Hipromellóz; Hipromelosa; Hipromeloz; Hydroxypropyl Methylcellulose; Hydroxypropylmethylcellulose; Hypromellose; Hypromellos; Hypromellosum; Hypromelosa; Hypromelosa; Methyl Hydroxypropyl Cellulose; Methylcellulose Propylene Glycol Ether; Methylhydroxypropylcellulose; Methylhydroxypropylcellulosum.

Гипромелоза

CAS — 8063-82-9; 9004-65-3.

ATC — S01KA02.

ATC Vet — QS01KA02.

**NOTE.** HPRM is a code approved by the BP 2008 for use on single unit doses of eye drops containing hypromellose where the individual container may be too small to bear all the appropriate labelling information.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.*, and *US*.

**Ph. Eur. 6.2** (Hypromellose). A mixed ether of cellulose containing a variable proportion of methoxy and 2-hydroxypropoxy groups. Various grades are available (see Labelling, below). A white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Dissolves in cold water, forming a colloidal solution; practically insoluble in hot water, in dehydrated alcohol, in acetone, and in toluene. A 1% w/w solution in water has a pH of 5.0 to 8.0.

**USP 31** (Hypromellose). A methyl and hydroxypropyl mixed ether of cellulose. It contains methoxy and hydroxypropoxy groups conforming to the limits for the types 1828, 2208, 2906, and 2910, calculated on the dried basis (see Labelling, below). A white to slightly off-white fibrous or granular powder. Swells in water and produces a clear to opalescent, viscous, colloidal mixture; insoluble in dehydrated alcohol, in chloroform, and in ether.

**Labelling.** In Europe, grades of hypromellose are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% w/w solution measured at 20° (e.g. hypromellose 4500). In the USA, they are distinguished by appending a number in which the first 2 digits represent the approximate percentage content of methoxy groups, and the third and fourth digits the approximate percentage content of hydroxypropoxy groups.

## Hypromellose Phthalate (BANM, rINNM)

Ftalát hipromeloz; Ftalato de hipromelosa; Hipromeliozės ftalatas; Hipromellóz-ftalát; Hydroxypropyl Methylcellulose Phthalate; Hypromelloosftalatti; Hypromellose, phthalate d'; Hypromellos-ftalát; Hypromellosi phthalas; Methylhydroxypropylcellulose Phthalate; Methylhydroxypropylcellulosi Phthalas.

Гипромеллозы Фталат

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Jpn.* Also in *USNF*.

**Ph. Eur. 6.2** (Hypromellose Phthalate). A monophthalic acid ester of hypromellose containing methoxy, 2-hydroxypropoxy, and phthalyl groups, calculated with reference to the anhydrous substance. White or slightly off-white, free-flowing flakes or a granular powder. Practically insoluble in water and in dehydrated alcohol; very slightly soluble in acetone and in toluene; soluble in a mixture of equal volumes of acetone and methyl alcohol, and of dichloromethane and methyl alcohol. Store in airtight containers.

**USNF 26** (Hypromellose Phthalate). A monophthalic acid ester of hypromellose. It contains methoxy, hydroxypropoxy, and phthalyl groups. It contains 21.0 to 35.0% of phthalyl groups, calculated on the anhydrous basis. Store in airtight containers. A white, odourless, powder or granules. Practically insoluble in water, in dehydrated alcohol, and in hexane; produces a viscous solution in a mixture of dehydrated alcohol and acetone (1:1), or in a mixture of methyl alcohol and dichloromethane (1:1); dissolves in 1N sodium hydroxide. Store in airtight containers.

**Labelling.** Different grades of hypromellose phthalate in the USA are distinguished by appending a number in which the first 2 digits represent the approximate percentage content of the methoxy groups, the next 2 digits the approximate percentage content of hydroxypropoxy groups, and the last 2 digits the approximate percentage content of the phthalyl groups. Another system of nomenclature involves appending a number which indicates the pH value ( $\times 10$ ) at which the polymer dissolves in aqueous buffer solutions; letters such as S or F may also be used to indicate grades of high molecular-weight or small particle size respectively.

### Uses and Administration

Hypromellose has properties similar to those of methylcellulose (below). It is used in pharmaceutical manufacturing for film-coating tablets, as a tablet binder, as a modified-release matrix, and as an emulsifier, suspending agent, and stabiliser in topical gels and ointments. Hypromellose may also be used as an emulsifier and stabiliser in the food industry.

Hypromellose phthalate is used to provide enteric coating for tablets and granules, for the preparation of modified-release granules, and as a coating to mask the unpleasant taste of some tablets.

Hypromellose is widely used clinically in ophthalmic solutions; it is preferred to methylcellulose since mucilages of hypromel-

lose have greater clarity and usually contain fewer undispersed fibres. Hypromellose is used to prolong the action of medicated eye drops and, either alone or with other viscosity-increasing agents, in artificial tears preparations for the management of dry eye (p.2140); solutions containing 0.3 to 1% of hypromellose are commonly used. Solutions for contact lens care (p.1622) and for lubricating artificial eyes contain similar concentrations. Hypromellose is also used intra-ocularly, usually as a 2% solution, as an adjunct in ophthalmic surgery (below) and concentrations of up to 2.5% may be used topically to protect the cornea during gonioscopy procedures.

Hypromellose has been included in artificial saliva preparations used in the management of dry mouth (p.2140), but other drugs are usually preferred.

**Ophthalmic surgery.** Intra-ocular hypromellose may be used as a visco-elastic agent to protect the eye during surgery. In cataract extraction it is used to maintain the anterior chamber and to coat the intra-ocular lens to facilitate its implantation. Although intra-ocular hypromellose is generally considered to be well tolerated, some<sup>1</sup> have reported an increased incidence of pupil abnormalities (non-reactive semi-dilated pupils) after such use; others<sup>2</sup> did not confirm this. There has also been a report<sup>3</sup> of corneal opacities in a number of patients after use of intra-ocular hypromellose.

- Tan AKK, Humphry RC. The fixed dilated pupil after cataract surgery—is it related to intraocular use of hypromellose? *Br J Ophthalmol* 1993; **77**: 639–41.
- Eason J, Seward HC. Pupil size and reactivity following hydroxypropyl methylcellulose and sodium hyaluronate. *Br J Ophthalmol* 1995; **79**: 541–3.
- Newton JN, *et al.* Corneal opacities after cataract surgery with hypromellose. *Lancet* 2000; **355**: 290.

### Preparations

**BP 2008:** Hypromellose Eye Drops;

**USP 31:** Hypromellose Ophthalmic Solution.

**Proprietary Preparations** (details are given in Part 3)

**Arg.:** Artelac; Cool Tears; Gentel; Lacrisif†; Lagrima Dor†; Natura Lagrimas; Oftalook Plus; **Austral.:** Gentel Lubricant; Isopto Tears†; Methopt†; **Austria:** Artelac; Okuzell; Proscia; **Belg.:** Artelac; Isopto Tears; **Braz.:** Artelac†; Filmcel; Gentel; Lubrik†; **Canad.:** Eyleube; Gentel; Isopto Tears; Lacril; Visine Advance True Tears; Visine Contact Lens; **Chile:** Gentel; **Cz.:** Isopto Tears†; Lacrisyn†; **Denm.:** Artelac; **Fin.:** Artelac; Isopto Alkaline; Isopto Plain; **Fr.:** Artelac; **Ger.:** Artelac; Berberil Dry Eye; Cellugel; Celofalt; Gentel; HPMC-Optalt†; Methocel; Sic-Optalt; Sicca-Stuln†; **Gr.:** Lubrilac; Vidilac; **Hong Kong:** Blueye; Eye Glo Moist; Gentel; Isopto Tears; Lac-Oph; Methocel†; **Hung.:** Artelac†; Humalac B; Lacrisyn†; **India:** Hyprosol; Moiso; Nova Vizol; Occu System†; Sanvisc; **Indon.:** Gentel; **Ir.:** Artelac; Isopto Alkaline; Isopto Plain; **Israel:** Adato-Cel†; Gentel; Ocucot; **Ital.:** Gel 4000; Gentel; Lacrimil†; Lacrisif; Lacrisol; Methocel; **Malaysia:** Cellugel; Eye Glo Moist; **Mex.:** Artelac; Celulose; Filmexil†; Gentel; Luvistar; Meticel; **Norw.:** Artelac; **NZ:** Gentel; Methopt; **Philipp.:** Artelac; Gentel; Methopt; **Pol.:** Artelac; **Port.:** Artelac; Davilose; Hidroclif; **Rus.:** Defislez (Дедислэз); Lacrisif (Лакрисиф); Lacrisyn (Лакрисин); **S.Afr.:** Cellugel; Methocel; Spersstear; Viscotran; **Singapore:** Eye Mo Moist†; Gentel; Lacrisif†; Methocel†; **Spain:** Acucolens; Artific; **Swed.:** Artelac; Isopto Plain; **Switz.:** Isopto Tears; Methocel; **Thai.:** Gentel; Isopto Tears; Lac-Oph; Natar; Opsi Tears; Simoph Tears†; **Turk.:** Lacrisif; **UK:** Artelac; Brolene Cool Eyes; Isopto Alkaline; Isopto Plain; **USA:** Artificial Tears; Entrocel; Gentel; Gonak; Goniosoft; Goniosol; Isopto Plain; Isopto Tears; Lacril; Ocucot; Tearsol; Tears Again MC; Ultra Tears; **Venez.:** Celofalt†; Gentel.

**Multi-ingredient:** **Arg.:** Alcon Lagrimas; Irix Lagrimas; Kalopsis Lagrimas; Oxysept Comfort†; Phoenix Lagrimas; Solucion Oral; Tears Naturale; Visine Lagrimas; **Austral.:** Bion Tears; Blink-N-Clean; Gentel Moisturising; Opti-Free Comfort†; Poly-Tears; Tears Naturale; Visine True Tears†; **Austria:** Lacrisic; **Belg.:** Alcon Adequad; Lacrystat; Tears Naturale; **Braz.:** Lacribell; Lacrima Plus; Lacrima†; Opti-Tears; Trisorb; **Canad.:** Artificial Tears; Bion Tears; Moisture Drops†; Tears Naturale; Tears Naturale Forte; **Chile:** Lagrimas Artificiales; Nicio Drops; Nicotears; Novo-Tears; Tears Naturale; **Cz.:** Tears Naturale; **Denm.:** Dacriosol; **Ger.:** Gellipur; Isopto Naturale; Lacrisic; Oculotect; **Gr.:** Tears Naturale; **Hong Kong:** Bion Tears; Tears Naturale Forte; Visine for Contacts; **Hung.:** Dacrolux; Tears Naturale; **Indon.:** Gentel; Isotic Tearin; Tears; Tears Naturale II; **Ir.:** Ilube; Tears Naturale; **Israel:** Tears Naturale; **Ital.:** Dacriosol; Hamamilli†; Ipragocet†; Tirs; **Malaysia:** Bion Tears; Dacrolux; Tears Naturale; **Mex.:** Lacrima Plus; Naphacel; Naphtears; Naturalag; Tears Naturale; **Neth.:** Duratears; **Norw.:** Tears Naturale; **NZ:** Poly-Tears; Tears Naturale; **Philipp.:** Gentle Tears; Tears Naturale; Visine Refresh; **Pol.:** Tears Naturale; **Port.:** Tears Naturale†; **Rus.:** Tears Naturale (Слезя Натуральная); **S.Afr.:** Moisture Drops†; Tears Naturale; **Singapore:** Bion Tears; Dacrolux†; Tears Naturale; **Spain:** Dacrolux; Humectant; Tears Humectant; **Swed.:** Bion Tears; **Switz.:** Tears Naturale; **Thai.:** Bion Tears; Tears Naturale; **Turk.:** Dacrolux; Tears Naturale; **UK:** Ilube; Tears Naturale; Uvistat Eye Drops; **USA:** Bion Tears; Clear Eyes CLR; Lacri-Tears; LubriTears; Maximum Strength Allergy Drops; Moisture Drops; Nature's Tears; Ocucot; Tears Naturale; Tears Renewed; Visine Pure Tears; Visine Tears; **Venez.:** Gentel; Optifresh.

## Magnesium Silicate

E553(a); Silicato de magnesio.

CAS — 1343-88-0.

ATC — A02AA05.

ATC Vet — QA02AA05.

**NOTE.** The code E553(a) has also been applied to magnesium trisilicate.

**Pharmacopoeias.** In *Jpn.* Also in *USNF*.

**USNF 26** (Magnesium Silicate). A compound of magnesium oxide and silicon dioxide. It contains not less than 15.0% of magnesium oxide and not less than 67.0% of silicon dioxide, calculated on the ignited basis. It is a fine, white, odourless powder, free from grittiness. Insoluble in water and in alcohol. It is readily decomposed by mineral acids. pH of a well-mixed 10% suspension in water is between 7.0 and 10.8.