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

**Ph. Eur. 6.2** (Alginic Acid). A mixture of polyuronic acids composed of residues of D-mannuronic and L-guluronic acids extracted from algae belonging to the Phaeophyceae. A white or pale yellowish-brown, crystalline or amorphous powder. It swells in water. Very slightly soluble or practically insoluble in alcohol; practically insoluble in organic solvents; dissolves in solutions of alkali hydroxides.

**USNF 26** (Alginic Acid). A hydrophilic colloidal carbohydrate extracted with dilute alkali from various species of brown seaweeds (Phaeophyceae). A white to yellowish-white, odourless or practically odourless, fibrous powder. Insoluble in water and in organic solvents; soluble in alkaline solutions. pH of a 3% dispersion in water is between 1.5 and 3.5.

## Propylene Glycol Alginate

E405; Propilenglicol, alginato de. Propane-1,2-diol Alginate.

*ATC — A02BX13.*

*ATC Vet — QA02BX13.*

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Propylene Glycol Alginate). A white to yellowish, practically odourless, fibrous or granular powder. Soluble in water, in solutions of dilute organic acids, and, depending on the degree of esterification, in hydroalcoholic mixtures containing up to 60% by weight of alcohol, to form stable, viscous colloidal solutions at a pH of 3.

## Sodium Alginate

Algin; Alginato sódico; E401; Natrii alginas; Natrio alginatas; Natriumalginaatti; Natriumalginat; Nátrium-alginát; Natrium-alginát; Sodium, alginate de; Sodium Polymannuronate; Sodyum Aljinat.

*CAS — 9005-38-3.*

*ATC — A02BX13.*

*ATC Vet — QA02BX13.*

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

**Ph. Eur. 6.2** (Sodium Alginate). It consists chiefly of the sodium salt of alginic acid. A white or pale yellowish-brown powder. Slowly soluble in water, forming a viscous, colloidal solution; practically insoluble in alcohol.

**USNF 26** (Sodium Alginate). A yellowish-white, practically odourless, coarse or fine powder. Soluble in water, forming a viscous, colloidal solution; insoluble in alcohol, in chloroform, and in ether, in hydroalcoholic solutions in which the alcohol content is greater than 30% by weight, and in acids when the pH of the resulting solution becomes lower than about 3. Store in airtight containers.

**Incompatibility.** Incompatibilities of sodium alginate have been observed with acridine derivatives, methylrosanilinium chloride, phenylmercuric acetate and nitrate, calcium salts, alcohol in concentrations greater than 5%, and heavy metals. High concentrations of electrolytes cause an increase in viscosity until salting-out of sodium alginate occurs; salting-out occurs if more than 4% of sodium chloride is present.

### Uses and Administration

Alginic acid and alginates such as propylene glycol alginate and sodium alginate are used in pharmaceutical manufacturing as suspending and thickening agents. They may be used as stabilisers for oil-in-water emulsions and as binding and disintegrating agents in tablets. Various grades are usually available commercially for different applications and yield solutions of varying viscosity. A reduction in viscosity has been said to occur following sterilisation by autoclaving of sodium alginate solutions.

Alginic acid and alginates (ammonium alginate, calcium alginate (p.1058), potassium alginate, propylene glycol alginate, and sodium alginate) are also used as emulsifiers and stabilisers in the food industry.

Alginic acid or the alginates, magnesium alginate and sodium alginate, are given, usually formulated with an antacid, in the management of gastro-oesophageal reflux disease (p.1696). Alginic acid or the alginate reacts with gastric acid to form a viscous gel (often termed a raft) that floats on top of the gastric contents. This raft then acts as a mechanical barrier to reduce reflux.

Alginic acid is also used, usually in the form of a mixed calcium-sodium salt, as a haemostatic and wound dressing; it is employed in the form of a fibre made into a dressing or packing material.

### Preparations

***BP 2008:*** Alginate Raft-forming Oral Suspension; Compound Alginate Antacid Oral Suspension.

**Proprietary Preparations** (details are given in Part 3)
***Arg.:*** Nu-Gel Hidrogel con Alginato; ***Austral.:*** Kaltostat†; ***Canad.:*** Kaltostat; Restore CalciCare; Tegagen†; ***Fr.:*** Nu-Gel; ***Irl.:*** Kaltostat; ***Israel:*** Nu-Gel; ***Ital.:*** Flaminal; Kaltostat; Nu-Gel; ***NZ:*** Gaviscon; ***Port.:*** Biafine; ***Rus.:*** Alginatol (Альгинатол); Natalsid (Натальсид); ***S.Afr.:*** Gaviscon; Gaviscon Advance; Kaltostat; ***UK:*** Comfeel SeaSorb.

**Multi-ingredient:** ***Arg.:*** Comfeel SeaSorb†; Gaviscon†; Glicalox†; Mylanta Reflux; Reduciet; Rennie; Seasorb; ***Austral.:*** Gaviscon; Gaviscon Double Strength; Infant Gaviscon; Meracote†; Mylanta Heartburn Relief†; ***Austria:*** Rennie Duo; ***Belg.:*** Gastriphar; Gaviscon; Gaviscon Advance; ***Canad.:*** Carboflex†; Gastrifom; Gaviscon Heartburn Relief; Heartburn Relief†; Maalox HRF; ***Chile:*** Algicote; Gaviscon; ***Cz.:*** Alginete†; Gaviscon; ***Denm.:*** Gaviscon; ***Fin.:*** Gaviscon; ***Fr.:*** Gaviscon; Gavisconell; Hyalogran; Pseudophage; Release Ag; Topaal; Topalkan; ***Ger.:*** Gaviscon; Gaviscon Advance; Nu-Gel†; Recatol Algin; ***Hong Kong:*** Gaviscon; ***India:*** Acigon†; Gaviscon; Raftace; Visco; ***Irl.:*** Acidex; Algicon†; Gaviscon; Gaviscon Advance; Gaviscon Infant; Gaviscon Lemon; Pyrogastrone; Rennie Duo†; ***Israel:*** Algical Kalzarevet; Kaltocarb; Kaltostat; ***Ital.:*** Digeral†; Gastrotuss; Gaviscon; Gaviscon Advance; Silvercel; ***Malaysia:*** Gaviscon; Gaviscon Advance; ***Mex.:*** Algicon†; ***Neth.:*** Aciflux; Algicon; Gaviscon; Rennie Duo; Rennie Refluxine; ***Norw.:*** Gaviscon; ***NZ:*** Gaviscon; Mylanta Heartburn Relief; ***Pol.:*** Gealcid; ***Port.:*** Carboflex†; Kaltostat; Rennie Duo; ***S.Afr.:*** Gaviscon; Gelacid; Infant Gaviscon; ***Singapore:*** Gaviscon; Gaviscon Advance; ***Spain:*** Dolcopin; ***Swed.:*** Gaviscon; ***Switz.:*** Gaviscon†; Refluxine†; ***Turk.:*** Gaviscon; Rennie Duo; ***UK:*** Acidex; Algicon†; Bisodol Extra; Bisodol Heartburn Relief; Gastrocote; Gaviscon Advance; Gaviscon Cool; Gaviscon Double Action; Gaviscon Infant; Gaviscon†; Peptac; Pyrogastrone†; Raft-Eze; Rennie Duo; Setlers Heartburn & Indigestion Liquid; Topal; ***USA:*** Foamicon†; Gaviscon; Genaton; Pretts Diet Aid.

## Aluminium Magnesium Silicate

Aliuminio-magnio silikatas; Alumiinimagnesiumsilikaatti; Aluminii magnesii silicas; Aluminium (silicate d') et de magnésium; Aluminiummagnesiumsilikat; Alumínium-magnézium-szilikát; Aluminosilicato magnésico; Křemičitan hořečnato-hlinitý; Magnesium Aluminium Silicate; Magnesium Aluminum Silicate; Saponite.

*CAS — 1327-43-1; 12511-31-8.*

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Int.* Also in *USNF*. *USNF* also includes Magnesium Aluminosilicate and Magnesium Aluminometasilicate.

**Ph. Eur. 6.2** (Aluminium Magnesium Silicate). A mixture of colloidal-size particles of montmorillonite and saponite, free from grit and nonswellable ore. Almost white powder, granules, or plates. Practically insoluble in water and in organic solvents; swells in water to form a colloidal dispersion. A 5% dispersion in water has a pH of 9.0 to 10.0.

**USNF 26** (Magnesium Aluminum Silicate). A blend of colloidal montmorillonite and saponite that has been processed to remove grit and nonswellable ore components. There are several types, differing in viscosity and in ratio of aluminium content to magnesium content. It is an odourless, fine (micronised) powder, small cream to tan granules, or small flakes that are creamy when viewed on their flat surfaces and tan to brown when viewed on their edges. Insoluble in water and in alcohol; swells when added to water or glycerol. pH of a 5% suspension in water is between 9.0 and 10.0. Store in airtight containers.

**USNF 26** (Magnesium Aluminosilicate). A synthetic material that contains 20.5 to 27.7% of magnesium oxide, 27.0 to 34.3% of aluminium oxide, and 14.4 to 21.7% of silicon dioxide, calculated on the dried basis. A white powder or granules having an amorphous structure. Practically insoluble in water and in alcohol; partially soluble in acids and alkalis. A 4% suspension in water has a pH of 8.5 to 10.5. Store at a temperature not exceeding 40° in airtight containers.

**USNF 26** (Magnesium Aluminometasilicate). A synthetic material that contains 29.1 to 35.5% of aluminium oxide, 11.4 to 14.0% of magnesium oxide, and 29.2 to 35.6% of silicon dioxide, calculated on the dried basis. It exists in two forms, Type I-A and Type I-B. A white powder or granules having an amorphous structure. Practically insoluble in water and in alcohol; partially soluble in acids and alkalis. A 4% suspension in water has a pH of 6.5 to 8.5 (Type I-A) and 8.5 to 10.5 (Type I-B). Store at a temperature not exceeding 40° in airtight containers.

### Uses

Aluminium magnesium silicate has a variety of pharmaceutical uses, including use as a suspending and thickening agent, as an emulsion stabiliser, and as a binder and disintegrating agent in tablets.

Other forms of aluminium magnesium silicate include an artificial hydrate known as almasilate (p.1705), which is used as an antacid, and attapulgite (p.1709), a purified native hydrated aluminium magnesium silicate that is highly adsorbent and is used in a wide range of products including fertilisers and pesticides. Activated attapulgite, which is attapulgite that has been carefully heated to increase its adsorptive capacity, is used in preparations for diarrhoea.

### Preparations

**Proprietary Preparations** (details are given in Part 3)
***Indon.:*** Neusilin.

**Multi-ingredient:** ***Denm.:*** Alkasid†; ***India:*** Digene; ***Indon.:*** Flatucid; Stomadon; ***Jpn:*** Cabe 2; ***Thai.:*** Diasgest; ***UAE:*** Alkasid.

## Bentonite

Bentoniitti; Bentonit; Bentonita; Bentonitas; Bentonitum; E558; Mineral Soap; Soap Clay; Wilkinite.

*CAS — 1302-78-9.*

**Pharmacopoeias.** In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF*, which also includes a purified form.

**Ph. Eur. 6.2** (Bentonite). A natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms may be replaced by other atoms such as magnesium and iron. A very fine, homogeneous, greyish-white powder with a more or less yellowish or pinkish tint. Practically insoluble in water and in aqueous solutions, but swells with a little water forming a malleable mass.

**USNF 26** (Bentonite). A native, colloidal, hydrated aluminium silicate. A very fine, odourless, hygroscopic, pale buff or cream-coloured to greyish powder, free from grit. Insoluble in water, but swells to about 12 times its volume when added to water; insoluble in, and does not swell in, organic solvents. pH of a 2% suspension in water, mixed vigorously to facilitate wetting, is between 9.5 and 10.5. Store in airtight containers.

**USNF 26** (Purified Bentonite). A colloidal montmorillonite that has been processed to remove grit and nonswellable ore components. An odourless, fine, micronised powder, or small flakes that are creamy when viewed on their flat surfaces and tan to brown when viewed on their edges. Insoluble in water and in alcohol. Swells when added to water or glycerol. pH of a 5% suspension in water is between 9.0 and 10.0. Store in airtight containers.

### Uses

Bentonite absorbs water readily to form sols or gels, depending on its concentration. It is used in pharmaceutical manufacturing as a suspending and stabilising agent and as an adsorbent or clarifying agent. It is also used as an anticaking agent in the food industry.

Bentonite may be used as an oral adsorbent in paraquat poisoning (p.2047).

### Preparations

***USNF 26:*** Bentonite Magma.

**Proprietary Preparations** (details are given in Part 3)
***Gr.:*** Bentonine†.

**Multi-ingredient:** ***Indon.:*** Stomagel; ***Malaysia:*** Clearasil Pimple Treatment; ***S.Afr.:*** Clearasil T; ***Singapore:*** Clearasil Pimple Treatment.

## Carbomers

Acrylic Acid Polymers; Carbomera; Carbomères; Carbómeros; Carbopols; Carboxypolymethylene; Carboxyvinyl Polymers; Karbomeerit; Karbomerai; Karbomerek; Karbomerer; Karbomerler; Karbomery; Poliakrilic Asit; Polyacrylic Acid.

*CAS — 9003-01-4; 54182-57-9.*

NOTE. Carbomer is *BAN*, *USAN*, and *rINN*.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), and *Int. USNF* has separate monographs for a range of carbomers.

*USNF* also includes Carbomer Copolymer and Carbomer Interpolymer.

**Ph. Eur. 6.2** (Carbomers). High-molecular-weight polymers of acrylic acid cross-linked with polyalkenyl ethers of sugars or polyalcohols. They are produced in several grades characterised by the viscosity of a defined solution. White or almost white, fluffy, hygroscopic powders. They swell in water and in other polar solvents after dispersion and neutralisation with sodium hydroxide solution. Store in airtight containers.

**USNF 26** (Carbomer 934; Carbomer 934P; Carbomer 940; Carbomer 941; Carbomer 1342). Carbomers are high-molecular-weight polymers of acrylic acid cross-linked with allyl ethers of pentaerythritol. The viscosity of a neutralised aqueous dispersion for each carbomer is:

- Carbomer 934 (0.5%), 30 500 to 39 400 cP
- Carbomer 934P (0.5%), 29 400 to 39 400 cP
- Carbomer 940 (0.5%), 40 000 to 60 000 cP
- Carbomer 941 (0.5%), 4000 to 11 000 cP
- Carbomer 1342 (1.0%), 9500 to 26 500 cP

They are white, fluffy, hygroscopic powders having a slight characteristic odour. pH of a 1% dispersion in water is about 3. When neutralised with alkali hydroxides or with amines, they dissolve in water, in alcohol, and in glycerol. Store in airtight containers.

**USNF 26** (Carbomer Copolymer). A high-molecular-weight copolymer of acrylic acid and a long chain alkyl methacrylate cross-linked with allyl ethers of polyalcohols. Different types of Carbomer Copolymer are characterised by the viscosity of a defined solution. Carbomer Copolymer does not constitute the official title when benzene is used in the manufacturing process, in which case the name will be Carbomer 1342 if it complies with the requirements of that monograph. Store in airtight containers at a temperature not exceeding 45°.

**USNF 26** (Carbomer Interpolymer). A carbomer homopolymer or copolymer that contains a block copolymer of macrogol and a long chain alkyl acid ester. Different types of Carbomer Interpolymer are characterised by the viscosity of a defined solution. Store in airtight containers at a temperature not exceeding 45°.

### Uses and Administration

Carbomers are used in pharmaceutical manufacturing as suspending agents, gel bases, emulsifiers, and binding agents in tablets.

Carbomers, in liquid gel formulations containing typically 0.2 or 0.3%, are used topically as tear substitutes in the management of dry eye (p.2140).

### Preparations

***BP 2008:*** Carbomer Eye Drops.

**Proprietary Preparations** (details are given in Part 3)
***Arg.:*** Acrylarm; Lacryvisc†; Liposic; Refresh Gel; Siccafluid; Teargel†; Viscotears; ***Austral.:*** Poly Gel; Viscotears; ***Austria:*** AquaTears; Liposic; Tears Naturale; Vidisic; ***Belg.:*** Alcon Eye Gel; Lacrinorm; Liposic; Ocugel; Thilo Tears; Vidisic; ***Braz.:*** Refresh Gel; Vidisic†; Viscotears; ***Canad.:*** Lacrinorm†; Tear-Gel; ***Chile:*** Feels; Lacryvisc; Nicotears; Viscotears; ***Cz.:*** Lacryvisc†; Oftagel; Vidisic; ***Denm.:*** Oftagel; Viscotears; ***Fin.:*** Oftagel; Viscotears; ***Fr.:***

Aqualarm; Civigel; Gel-Larmes; Lacrinorm; Lacryvisc; Liposic; Siccafluid; ***Ger.:*** Arufil C; Liposic; Liquigel; Siccapos; Thilo-Tears; Vidisic; Visc-Ophtal; ***Gr.:*** Dacrio Gel; Liposic; Tear drops†; Thilogel; Viscoter; ***Hong Kong:*** Lacryvisc; Liposic; Viscotears; ***Hung.:*** Oftagel; Vidisic; ***Irl.:*** GelTears; Liquivisc; Vidisic; ***Israel:*** Viscotears; ***Ital.:*** Dacriogel; Droppgel; Lacrigel; Lacrinorm; Lipovisc; Siccafluid; Viscotirs; ***Malaysia:*** Vidisic†; ***Mex.:*** Conforgel; Lacryvisc; Lipolac; Refresh; Viscotears; ***Neth.:*** Dry Eye Gel; Lacrinorm; Liposic; Siccafluid; Thilo-Tears; Vidisic; ***Norw.:*** Oftagel; Viscotears; ***NZ:*** Viscotears; ***Philipp.:*** Lacryvisc; Lipolin; Siccafluid; Vidisic; ***Pol.:*** Oftagel; Oftipan; Vidisic; ***Port.:*** Lacryvisc; Liposic; Siccafluid; Vidisic; ***Rus.:*** Oftagel (Офтагель); Vidisic (Видисик); ***S.Afr.:*** Teargel; ***Singapore:*** Lacryvisc; Vidisic; ***Spain:*** Lacryvisc; Lipolac; Siccafluid; Viscotears; ***Swed.:*** Oftagel; Viscotears; ***Switz.:*** Lacrinorm; Lacryvisc; Siccafluid; Viscotears; ***Thai.:*** Lacryvisc; Vidisic; ***Turk.:*** Lacryvisc; Siccapos; Thilo-Tears; Viscotears; ***UK:*** GelTears; Liposic; Liquivisc; Viscotears; ***Venez.:*** Acrylarm; Lacryvisc; Siccafluid; Viscotears.

**Multi-ingredient:** ***Arg.:*** Latlas; ***Austral.:*** Genteal Moisturising; ***Chile:*** Gelsolets; ***Cz.:*** Hypotears; ***Hong Kong:*** Clinac OC; Hypotears†; ***Indon.:*** Genteal; Oculotect; ***Irl.:*** Liposic; ***Ital.:*** Dropyal; ***Pol.:*** Oculotect; ***Port.:*** Hidratante VG; ***Switz.:*** Lacrycon; ***USA:*** Maxilube; ***Venez.:*** Genteal.

## Carmellose *(rINN)*

Carboxymethylcellulose; Carmellosum; Carmelosa; CMC; E466.

Кармеллоза

*CAS — 9000-11-7.*

**Pharmacopoeias.** In *Jpn.*

## Carmellose Calcium *(rINNM)*

Calcii Carmellosum; Calcium Carboxymethylcellulose; Carboxymethylcellulose Calcium; Carmellose calcique; Carmellosum calcicum; Carmellosum Calcium; Carmelosa cálcica; Karmeliozés kalcio druska; Karmelloosikalsium; Karmelloskalcium; Karmellóz-kalcium; Karmelosa vápenatá sůl.

Кальций Кармеллоза

*CAS — 9050-04-8.*

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

**Ph. Eur. 6.2** (Carmellose Calcium). A white or yellowish-white, hygroscopic powder. It swells in water to form a suspension; practically insoluble in alcohol, in acetone, and in toluene. Store in airtight containers.

**USNF 26** (Carboxymethylcellulose Calcium). A white to yellowish-white, hygroscopic powder. It swells in water to form a suspension; practically insoluble in alcohol, in acetone, in chloroform, in ether, and in benzene. pH of a 1% suspension in water is between 4.5 and 6.0. Store in airtight containers.

## Carmellose Sodium *(BAN, rINNM)*

Carboxymethylcellulose Sodium; Carboxymethylcellulosum Natricum; Carmellose sodique; Carmellosum natricum; Carmelosa sódica; Cellulose Gum; E466; Karmeliozés natrio druska; Karmelloosinatrium; Karmellosnatrium; Karmellóz-nátrium; Karmelosa sodná sůl; Karmeloza sodowa; Natrii Carmellosum; SCMC; Sodium Carboxymethylcellulose; Sodium Cellulose Glycollate.

Натрий Кармеллоза

*CAS — 9004-32-4.*

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

*Eur.* and *USNF* also include low-substituted carmellose sodium.

*USNF* also includes Carboxymethylcellulose Sodium 12.

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

**Ph. Eur. 6.2** (Carmellose Sodium). A white or almost white, hygroscopic granular powder. It has a sodium content of 6.5 to 10.8% calculated on the dry substance. Easily dispersed in water forming colloidal solutions; practically insoluble in dehydrated alcohol, in acetone, in ether, and in toluene. A 1% colloidal solution in water has a pH of 6.0 to 8.0.

**Ph. Eur. 6.2** (Carmellose Sodium, Low-substituted; Carmellosum Natricum, Substitutum Humile). It contains not less than 2.0% and not more than 4.5% of sodium, calculated with reference to the dried substance. A white or almost white powder or short fibres. It swells in water to form a gel; practically insoluble in dehydrated alcohol, in acetone, and in toluene. A 1% suspension in water has a pH of 6.0 to 8.5.

**Ph. Eur. 6.2** (Microcrystalline Cellulose and Carmellose Sodium). A colloid-forming, powdered mixture of microcrystalline cellulose with 5 to 22% of carmellose sodium. It contains 75 to 125% of the nominal amount of carmellose 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.

**USP 31** (Carboxymethylcellulose Sodium). A white to cream-coloured, hygroscopic powder or granules. It contains not less than 6.5% and not more than 9.5% of sodium, calculated on the dried basis. Easily dispersed in water to form colloidal solutions; insoluble in alcohol, in ether, and in most other organic solvents. pH of a 1% solution in water is between 6.5 and 8.5. Store in airtight containers.

**USNF 26** (Low-Substituted Carboxymethylcellulose Sodium). It has a sodium content of 2.0 to 4.5%, calculated on the dried basis. A white or almost white powder or short fibres. Practically insoluble in alcohol, in acetone, and in toluene. It swells in water to form a gel. pH of a 1% suspension in water is between 6.0 and 8.5. Store in airtight containers.

**USNF 26** (Carboxymethylcellulose Sodium 12). A colourless or white to off-white, odourless, powder or granules. Water solubility depends on degree of substitution (easily dispersed in water at all temperatures, forming a clear, colloidal solution). Insoluble in alcohol, in acetone, in ether, and in toluene. It has a sodium content of 10.4 to 12.0%, calculated on the dry substance. Store in airtight containers.

**Incompatibility.** Incompatibilities of carmellose sodium have been reported with strongly acidic solutions, with soluble salts of iron and some other metals, and with xanthan gum.

## Croscarmellose Sodium *(USAN)*

Carmellosum natricum conexum; Croscarmellose sodique; Croscarmelosa sódica; Crosslinked Carboxymethylcellulose Sodium; E468; Kroskarmeliozés natrio druska; Kroskarmelloosi natrium; Kroskarmellosnatrium; Kroskarmelosa sodná sůl; Kroskarmeloza sodowa; Kroszkarmellóz-nátrium; Modified Cellulose Gum.

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

**Ph. Eur. 6.2** (Croscarmellose Sodium). A cross-linked polymer of carmellose sodium. A white or greyish-white powder. Practically insoluble in dehydrated alcohol, in acetone, and in toluene. A 1% suspension in water has a pH of 5.0 to 7.0.

**USNF 26** (Croscarmellose Sodium). The sodium salt of a cross-linked partly *O*-(carboxymethylated) cellulose. A white, free-flowing powder. Partially soluble in water; insoluble in alcohol, in ether, and in other organic solvents. pH of a dispersion containing 1 g mixed with 100 mL of water for 5 minutes is between 5.0 and 7.0.

### Uses and Administration

Carmellose calcium and carmellose sodium have a variety of pharmaceutical uses, including use as suspending, thickening, and emulsifying agents, and as disintegrants, binders, and coating agents in tablets. Carmellose sodium is also used as an emulsifier or stabiliser in the food industry. Croscarmellose sodium is used as a tablet disintegrant.

Carmellose sodium is used topically as an ingredient of protective preparations for stoma care, in the management of wounds, and for the mechanical protection of oral and perioral lesions, such as mouth ulceration (p.1700). It is also used, in concentrations of up to 1%, in artificial saliva preparations for the treatment of dry mouth (p.2140), and in eye drops for the management of dry eye (p.2140).

Carmellose sodium given orally absorbs water and acts as a bulk-forming agent; the volume of faeces is increased and peristalsis promoted. It is used in the treatment of constipation (p.1693). Carmellose sodium has been included in preparations to control appetite in the management of obesity (p.2149) but there is little evidence of efficacy. For precautions to be observed with bulk-forming agents, see under Methylcellulose, p.2145.

### Preparations

***BP 2008:*** Carmellose Sodium Eye Drops;
***USP 31:*** Carboxymethylcellulose Sodium Paste; Carboxymethylcellulose Sodium Tablets.

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

***Arg.:*** Aqua Lent Lagrima†; Aqua Lent Lubricante; Aquacel; Aucic; Cellufresh†; Celluvisc†; Comfeel; Comfeel Plus Transparente; Natura Fresh; Nu-Derm Hidrocoloide; Refresh Liquigel; Refresh Tears; ***Austral.:*** Aquacel†; Cellufresh; Celluvisc; Refresh Liquigel; Refresh Tears Plus†; ***Austria:*** Celluvisc; ***Belg.:*** Gelilact; ***Braz.:*** Cellufresh; Ecofilm; Fresh Tears; Lacrifilm; Salivan; ***Canad.:*** Aquacel†; Refresh Celluvisc; Refresh Liquigel; Refresh Plus; Refresh Tears; ***Chile:*** Refresh Liquigel; Refresh Tears; ***Cz.:*** Cellufluid; ***Denm.:*** Celluvisc; ***Fin.:*** Celluvisc; ***Fr.:*** Aquacel; Askina Biofilm†; Biatain; Celluvisc; Clip Ampoules; Clip Brulures; Comfeel; Hydrocoll; Physiotulle; Sureskin; Urgomed; Urgotul; ***Ger.:*** Algoplaque; Alione; Cellufresh; Cellumed; Celluvisc; Comfeel Plus Transparenter; Physiotulle; Urgotul; ***Gr.:*** Cellufluid; Celluvisc; ***Hong Kong:*** Refresh; ***Irl.:*** Celluvisc; ***Israel:*** Refresh Tears; ***Ital.:*** Cellufresh; Celluvisc; Lacrilens; ***Malaysia:*** Refresh Plus†; Refresh Tears†; ***Mex.:*** Celluvisc†; Novafix Ultra Fuerte; Refresh Liquigel; Refresh Tears; Thera Tears†; ***Neth.:*** Celluvisc; ***NZ:*** Cellufresh†; Celluvisc†; Refresh Tears Plus; ***Philipp.:*** Cellufresh; Celluvisc; ***Port.:*** Aquacel†; Askina Biofilm†; Cellufluid; Celluvisc; ***S.Afr.:*** Cellufresh; Celluvisc; Comfeel; Refresh Liquigel; Refresh Tears; ***Singapore:*** Celluvisc; Refresh Plus†; Refresh Tears†; ***Spain:*** Cellufresh; Celluvisc; Viscofresh; ***Swed.:*** Celluvisc; ***Switz.:*** Cellufluid; Celluvisc; ***Thai.:*** Cellufresh; Celluvisc; ***UK:*** Celluvisc; Comfeel; Intrasite; Physiotulle; ***USA:*** Celluvisc; Clear Eyes for Dry Eyes; Optive; Refresh Plus; Refresh Tears; Tears Again; TheraTears; ***Venez.:*** Refresh Liquigel; Refresh Tears.

**Multi-ingredient:** ***Arg.:*** Comfeel Plus; Comfeel Purilon†; Comfeel Sea-Sorb†; Humectante Bucal; Mucobase; Purilon; Razagleda Plus†; Seasorb; ***Austral.:*** Aquae; Orabase; Orahesive†; SoloSite; Stomahesive†; ***Austria:*** Glandosane; Sialin; ***Braz.:*** Chofranina; ***Canad.:*** Appedrine†; Carboflex†; Orabase†; Orahesive†; Salivart; Tegasorb; ***Chile:*** Delgadol Fibra; K.C.M.C; Novafix Extra Fuerte; Reduceform-F; Salivart†; ***Cz.:*** Alginete†; Spofax; ***Fr.:*** Altreet Ag; Amivia†; Aquacel Ag; Artisial; Askina Sorb†; Biatain Argent; Cellosorb; Clip Hemo; Intrasite; Melgisorb; Purilon; Release Ag; Seasorb; Urgosorb; Urgotul S.Ag; ***Ger.:*** Cellosorb; Comfeel Plus; Glandosane; Lary-Phary; Nu-Gel†; Purilon; Recatol Algin; SeaSorb Soft; ***Hong Kong:*** Aquae; Glandosane; Salivart; ***India:*** Digene; ***Irl.:*** Orabase; ***Israel:*** Orabase†; ***Ital.:*** Aquacel Ag; ***NZ:*** Orabase; Stomahesive; ***Port.:*** Askina Sorb†; Carboflex†; Glandosane; Varihesive†; ***S.Afr.:*** Granuflex; Granugel; Orabase; ***Spain:*** Laxvital; ***Switz.:*** Glandosane; ***Thai.:*** Bisolax; Emulax; Glandosane†; ***UK:*** Comfeel Plus; Glandosane; Luborant; Orabase; Orahesive; Physiotulle-Ag; SeaSorb Soft; Seprafilm; Stomahesive; ***USA:*** Entertainer's Secret; Moi-Stir; Pretts Diet Aid; Salivart; Seprafilm; Surgel; ***Venez.:*** Klincosal; Novafix; Polantac.

## Carrageenan

Carrageenanum; Carrageenin; Carragenina; Carraghénanes; Carraghénates; Chondrus Extract; E407; Irish Moss Extract.

*CAS — 9000-07-1 (carrageenan); 11114-20-8 (κ-carrageenan); 9064-57-7 (λ-carrageenan).*

**Pharmacopoeias.** In *Fr.* Also in *USNF.*

**USNF 26** (Carrageenan). The hydrocolloid obtained by extraction with water or aqueous alkali from some members of the class Rhodophyceae (red seaweeds). It consists chiefly of a mixture of the ammonium, calcium, magnesium, potassium, and sodium sulfate esters of galactose and 3,6-anhydrogalactose copolymers. The prevalent copolymers in the hydrocolloids are κ-carrageenan, ι-carrageenan, and λ-carrageenan.

A yellowish or tan to white, coarse to fine, practically odourless, powder. Soluble in water at 80° forming a viscous, clear or slightly opalescent solution that flows readily. It disperses more readily in water if first moistened with alcohol, with glycerol, or with a saturated solution of glucose in water. Store in airtight containers at a temperature of 8° to 15°.

### Uses and Administration

Carrageenan is used in pharmaceutical manufacturing and the food industry as a suspending and gelling agent.

It has been used as a bulk-forming laxative to treat constipation; for precautions to be observed with bulk-forming laxatives, see under Methylcellulose, p.2145. Carrageenan is also included in topical preparations for the symptomatic relief of anorectal disorders. A gel containing carrageenan has been investigated as a topical microbicide.

A degraded form of carrageenan was formerly used in gastrointestinal disorders but it was associated with lesions in *animals* and is no longer used.

Irish moss (*Chondrus crispus*), a source of carrageenan, is used in herbal medicine.

◊ Refined non-degraded carrageenan and furcellaran, a similar extract from Rhodophyceae that is included in the specifications for food-grade carrageenan, have generally been considered safe for use as food additives, although this may not be the case with degraded and 'semi-refined' forms.[1] However, in the UK the Food Advisory Committee has recommended that carrageenan should not be permitted as an additive for infant formulas because of the possibility of immunological consequences after absorption from the immature gut.[2] Carrageenans affect the immune system of experimental *animals* after parenteral or oral use, and small amounts of food-grade carrageenan cross the intestinal epithelium in *rats* and are taken up by gut-associated lymphoid tissue.[3]


1. FAO/WHO. Evaluation of certain food additives and contaminants: twenty-eighth report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser 710* 1984.
2. MAFF. Food Advisory Committee: report on the review of the use of additives in foods specially prepared for infants and young children. FdAC/REP/12. London: HMSO, 1992.
3. MAFF. Food Advisory Committee: report on the review of the emulsifiers and stabilisers in food regulations. FdAC/REP/11. London: HMSO, 1992.


### Preparations

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

***Austria:*** Coreine.

**Multi-ingredient:** ***Austral.:*** Bonningtons Irish Moss; ***Austria:*** Anoreine; Anoreine mit Lidocain; ***Cz.:*** Titanoreine†; ***Fr.:*** Anoreine; Titanoreine; Titanoreine Lidocaine; ***Ger.:*** Saseem; ***Ital.:*** Resource Gelificata; ***NZ:*** Bonningtons Irish Moss; ***Pol.:*** Tytanoreina†; ***Spain:*** Titanorein; ***Switz.:*** Flogecyl; Titanoreine†; ***UK:*** Fam-Lax Senna.

## Cellacefate *(BAN, rINN)*

CAP; Celacefát; Celacefat; Celacefato; Celiuliozés acetatas-ftalatas; Cellacéfate; Cellacefatum; Cellacephate; Cellulosaacetatftalat; Cellulose, acétate phtalate de; Cellulose Acetate Phthalate; Cellulosi acetas phthalas; Cellulosum Acetylphthalicum; Cellulóz-acetát-ftalát; Celophthalum; Selluloosa-asetaattiftalaatti.

Целлацефат

*CAS — 9004-38-0.*

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

**Ph. Eur. 6.2** (Cellulose Acetate Phthalate; Cellacefate BP 2008). Cellulose in which some of the hydroxyl groups are acetylated (21.5 to 26.0%) and some are phthalylated (30.0 to 36.0%), both calculated with reference to the anhydrous, acid-free substance. A hygroscopic, white or almost white, free-flowing powder or colourless flakes. Practically insoluble in water, in dehydrated alcohol, and in dichloromethane; freely soluble in acetone; soluble in diethylene glycol; it dissolves in dilute solutions of alkalis. Store in airtight containers.

**USNF 26** (Cellacefate). A reaction product of phthalic anhydride and a partial acetate ester of cellulose. It contains 21.5 to 26.0% of acetyl groups, and 30.0 to 36.0% of phthalyl(*o*-car-