

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; Liquefilm Lagrimas†; Natura Wet; Total Solucion; **Austral.:** Liquefilm; PVA†; **Belg.:** Liquefilm; **Braz.:** Duracare†; Lacril; Totalest†; **Canad.:** Artificial Tears; Hypotears; Liquefilm; Optilube PVA; Scheinpharm Artificial Tears†; **Chile:** Lagrimas Artificiales; Liquefilm Lagrimas†; **Visidic. Cz.:** Liquefilm†; **Denm.:** Larin; **Fin.:** Liquefilm; **France.:** Lacrima†; Liquefilm; **Vistil. Gr.:** Liquefilm Tears; **Hong Kong:** Liquefilm; PMS-Artificial Tears; **Hung.:** Humalac; A and C; **India:** Aquatears; **Indon.:** Optifresh; **Irl.:** Liquefilm; **Sno Tears. Israel:** Hypotears†; Liquefilm Tears; **Ital.:** Lacriluc; **Malaysia:** Liquefilm†; **Mex.:** Acuallif Ofleno; **Lubric. Norw.:** Ocufril; **NZ:** Liquefilm; **Pol.:** Lacrimil; **Port.:** Liquefilm; **S.Afr.:** Liquefilm Tears; **Singapore:** Hypotears; Liquefilm Tears; **Spain:** Hypo Tears; Liquefilm Lagrimas; **Sweden.:** Sincon; **Switz.:** Liquefilm†; **Ukraine.:** Liquefilm Tears; **Turk.:** Liquefilm; **UK:** Liquefilm Tears; Refresh; **USA:** Akwa Tears; Dry Eyes; Liquefilm; Nu-Tears; Ocu-Tears; Puralube; Tears Again; **Venez.:** Acuallif Ofleno; Lacril.

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

Povidone (BAN, USAN, rINN)

E1201; Polivinylpirrolidon; Polyvidone; Polyvidonum; Polyvinylpyrrolidone; Povidon; Povidona; Povidonas; Povidoni; Povidonium; Povidon; PVP; Vinylpyrrolidone Polymer; Poly (2-oxopyrrolidin-1-ylethylene).

Повидон

(C₄H₅NO)_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; Copovidonium; 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-pyrrolidinone 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; Krosponidone; Krosponidas; Krosponidoni; Krosponidon; Polyplasdon 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 Moisturizing; Rohto Zi Fresh†; Spray-on Bande†; **Austria:** Oculetect; Protagent; **Belg.:** Oculetect; Siccagel; **Braz.:** Hypotears Plus; **Chile:** Lepex; Oculetect; **Cz.:** Anufil; Hypotears Plus; **Denm.:** Oculac; **Fin.:** Bolinart; Dulcimar; Fluidabak; Larmecran; Nu-Gel†; Nutrivis; Unifluid; **Ger.:** Alodair; Anufil; Lacophalt; Lacri-Stullin; Oculetect Fluid; Protagent; Vidirakt S; Vidisept; Wet-COMOD; **Yuan Tears. Gr.:** Oculetect; Protagent; **Hong Kong:** Hypotears Plus; Protagent; **Hung.:** Anufil; Oculetect; **Israel:** Hypotears E; Lacrimol; **Ital.:** Clarover; Nu-Gel; Protagent†; Wet-COMOD; **Malaysia:** Oculetect; Vidisept N†; **Mex.:** Hypotears Plus; Logical; Renu Plus; **Neth.:** Duratears Free; Oculetect; Protagens; **Pol.:** Oculetect; **Norw.:** Oculetect; **Philipp.:** Oculetect; Vidisept N; **Pol.:** Oculetect; Vidisept; **Port.:** Oculetect; **Rus.:** Vid-COMOD (ВИА-КОМОД); **S.Afr.:** Hypotears; **Singapore:** Oculetect; Vidisept N; **Spain:** Oculetect; **Sweden.:** Oculac; **Switz.:** Oculac; Protagent; **Thai.:** Hypotears Plus; **Turk.:** Oculetect; Protagent; **UK:** Alodair; Oculetect; **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.:** Lacrimil OK; Lacrisic; Liquefilm OK; Visine Trockene Augen; **Gr.:** Onufrid; Refresh; **India:** I-Lube; **Israel:** Aphantone; Apha-X; Geldair†; Refresh; V-Crima; **Ital.:** Filmabak; **Malaysia:** Murine NTF†; Murine Plus†; Refresh†; **Mex.:** Lagnifilm Plus; Soyaloid; Soydex; Visine Extra; **Neth.:** Tears Plus; **NZ:** Refresh; Tears Plus†; Visine Advanced Relief; **Rus.:** Gluconodesum (ГЛЮКОНОДЕС); Haemodes-N (ГЕМОДЕС-Н); **S.Afr.:** Moisture Drops†; Refresh; Tears Plus; **Singapore:** Refresh†; **Spain:** Liquefresh; **Switz.:** Collyria; Tears Plus†; **Thai.:** Refresh; **Turk.:** Refresh; **UK:** Geldair; **USA:** Advanced Relief Visine; Gelclair; Murine; Murine Plus; Refresh Classic; Tears Plus.

Silicas

Silice.

Purified Siliceous Earth

Diatomaceous Earth; Diatomite; Purified Infusorial Earth; Purified Kieselerde; Terra Silicea Purificata; 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; Kolloidinis silicio dioksidas, hidratuotas; Oxid křemicity koloidni hydratovany; Pidiodiksi; kolloidin, hydratoitu; Precipitated Silica; Silica colloidalis hydrica; Silica Gel; Silice colloidal hydrate; Silicio, dióxido de; Viztartalmú, kolloid szilícium-dioxid. SiO₂·xH₂O = 60.08 (anhydrous).
CAS — 83231-67-4; 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; Kolloidinis silicio dioksidas, bevandenis; Krzemu dwutlenek kolooidalny; Oxid křemicity koloidni bezvodý; Pidiodiksi, kolloidin, vedetön; Silica colloidalis anhydrica; Silice colloidalis anhydricae; Silicii Dioxidum Colloidale; Silicio coloidal, dióxido de; Vizmentes, kolloid, szilícium-dioxid.

SiO₂ = 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-Teknosol; Gela†; Sklerosol N†; **NZ:** Biosil†; **Rus.:** Polysorb (Полисорб); **UK:** Aero-sil.

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