

Paraffins and Similar Bases

This chapter includes substances used mainly as bases for the preparation of creams, ointments, other topical preparations, and suppositories. They may act as inert carriers for drugs or have emulsifying and emollient properties. Some are also used to improve the texture, stability, or water repellent properties of the final preparation. The bases discussed include petroleum hydrocarbons, animal fats and waxes, vegetable oils, and silicones. Other substances used in the preparation of bases can be found in Soaps and other Anionic Surfactants (p.2138) and in Nonionic Surfactants (p.1914).

Alkyl Benzoate

Alkyl (C₁₂-15) Benzoate; Benzoato de alquilo.

Алкил Бензоат

CAS — 68411-27-8 (C₁₂-C₁₅ alkyl ester).

Pharmacopoeias. In *USNF*.

USNF 26 (Alkyl (C₁₂-15) Benzoate). It consists of esters of a mixture of C₁₂ to C₁₅ primary and branched alcohols and benzoic acid (average molecular formula C₂₀H₃₂O₂ = 304.5). It is a clear, practically colourless, oily liquid. Insoluble in water, in glycerol, and in propylene glycol; soluble in alcohol, in acetone, in ethyl acetate, in isopropyl alcohol, in isopropyl myristate, in isopropyl palmitate, in liquid paraffin, in vegetable oils, in volatile silicones, and in wool fat. Store in airtight containers. Protect from light.

Profile

Alkyl benzoate has emollient properties. It may be used as an oily vehicle.

White Beeswax

Baltasis vaškas; Bleached Wax; Cera alba; Cera Blanca; Cera Branca; Cera de abejas; Cire Blanche; Cire d'abeille blanche; E901; Fehér viasz; Gebleichtes Wachs; Valkovaha; Vax, vitt; Vosk bílý; White Wax; Wosk biały.

Осветлённый Пчелиный Воск

CAS — 8012-89-3.

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

Ph. Eur. 6.2 (Beeswax, White). It is bleached yellow beeswax. It occurs as white or yellowish-white pieces or plates, translucent when thin, with an odour similar to that of yellow beeswax, though fainter and never rancid, and with a fine-grained, matt and non-crystalline fracture, becoming soft and malleable when warmed in the hand. Drop point 61° to 66°. Practically insoluble in water; partially soluble in hot alcohol; completely soluble in fatty and essential oils.

USNF 26 (White Wax). It is bleached and purified yellow beeswax. A yellowish-white solid, somewhat translucent in thin layers. It has a faint characteristic odour and is free from rancidity. M.p. 62° to 65°. Insoluble in water; sparingly soluble in cold alcohol; boiling alcohol dissolves the cerotic acid and a portion of the myricin that are constituents of the wax; completely soluble in chloroform, in ether, in fixed oils, and in volatile oils; partly soluble in cold benzene and in cold carbon disulfide; completely soluble in these liquids at about 30°.

Yellow Beeswax

Cêra Amarela; Cera Amarilla; Cera de abejas amarilla; Cera flava; Cire d'abeille jaune; Cire Jaune; E901; Gelbes Wachs; Geltonasis vaškas; Keltavaha; Refined Wax; Sárga viasz; Vax, gult; Vosk žltý; Wosk żółty; Yellow Wax.

Жёлтый Пчелиный Воск

CAS — 8012-89-3.

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

Ph. Eur. 6.2 (Beeswax, Yellow). The wax obtained by melting with hot water the walls of the honeycomb of the bee, *Apis mellifera*, and removing the foreign matter. It occurs as yellow or light brown pieces or plates with a faint and characteristic odour of honey, and with a fine-grained, matt and non-crystalline fracture, becoming soft and malleable when warmed in the hand. Drop point 61° to 66°. Practically insoluble in water; partially soluble in hot alcohol; completely soluble in fatty and essential oils.

USNF 26 (Yellow Wax). The purified wax from the honeycomb of the bee, *Apis mellifera* (Apidae). It is a solid, varying in colour from yellow to greyish-brown with an agreeable honey-like odour, somewhat brittle when cold, pliable when warmed in the hand, and presenting a dull, granular, noncrystalline fracture when broken. M.p. 62° to 65°. Insoluble in water; sparingly sol-

uble in cold alcohol; boiling alcohol dissolves the cerotic acid and a portion of the myricin that are constituents of the wax; completely soluble in chloroform, in ether, in fixed oils, and in volatile oils; partly soluble in cold benzene and in cold carbon disulfide; completely soluble in these liquids at about 30°.

Profile

Yellow beeswax is used as a stiffening agent in ointments and creams, and enables water to be incorporated to produce water-in-oil emulsions. It is also used as a coating in the manufacture of modified-release oral preparations. White beeswax has similar uses; it is occasionally used to adjust the melting-point of suppositories.

A sterile preparation of white beeswax, hard paraffin, and isopropyl palmitate (Sterile Surgical Bone Wax) is used to control bleeding from damaged bone during surgery. It should not be confused with Aseptic Surgical Wax (BPC 1949), also known as Horsley's Wax, which contained yellow beeswax, olive oil, and phenol in a mercuric chloride solution and was used to control haemorrhage in bone or cranial surgery.

Beeswaxes are also used in foods and cosmetics.

Hypersensitivity to beeswax has been reported.

Granuloma formation. Use of surgical bone wax has been associated with an inflammatory response in some patients. Formation of granuloma tissue at the site of application to the orbit,¹ foot,² and sternum³ has been reported. Seven patients developed local pain and tenderness after use of bone wax in foot surgery; further surgery to remove granulomatous tissue 4 to 52 months later resolved pain in 5 patients.² In an autopsy study of 18 cadavers with evidence of sternotomy, 17 of which had macroscopic evidence of bone wax use, signs of inflammation or granuloma formation were found in all but one. The authors concluded that bone wax is non-resorbable and can cause chronic inflammation up to 10 years after application.³

1. Katz SE, Rootman J. Adverse effects of bone wax in surgery of the orbit. *Ophthalm Plast Reconstr Surg* 1996; **12**: 121-6.
2. Anfinson O-G, et al. Complications secondary to the use of standard bone wax in seven patients. *J Foot Ankle Surg* 1993; **32**: 505-8.
3. Sudmann B, et al. Histologically verified bone wax (beeswax) granuloma after median sternotomy in 17 of 18 autopsy cases. *Pathology* 2006; **38**: 138-41.

Hypersensitivity. Sensitivity reactions to topical beeswax products have been reported rarely. Contact dermatitis from use of a beeswax-based nipple protector has been reported,¹ and cheilitis from a beeswax lip product has also occurred.²

1. Garcia M, et al. Allergic contact dermatitis from a beeswax nipple-protective. *Contact Dermatitis* 1995; **33**: 440-1.
2. Lucente P, et al. Contact cheilitis due to beeswax. *Contact Dermatitis* 1996; **35**: 258.

Preparations

BP 2008: Paraffin Ointment;

USP 31: Rose Water Ointment; White Ointment; Yellow Ointment.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Arg.:** Aqualane; Cold Cream Naturel; Zoodermina Cream; **Austria:** Tiroler Steinol; **Braz.:** Balmex; **Chile:** Cold Cream Avenue; **Fr.:** Cerat; Inalterable; Cold Cream Naturel; **USA:** Paladin.

Candelilla Wax

E902.

Канделильский Воск

CAS — 8006-44-8.

Pharmacopoeias. In *USNF*.

USNF 26 (Candelilla Wax). The purified wax from the leaves of the plant *Euphorbia antisiphilitica*. It is a hard, yellowish-brown, opaque to translucent wax. M.p. between 68.5° and 72.5°. Insoluble in water; soluble in chloroform and in toluene.

Profile

Candelilla wax is used as a pharmaceutical excipient and in the food industry.

Cetostearyl Alcohol

Alcohol cetostearyllico; Alcohol cetyllicus et stearyllicus; Alcohol Cetylstearyllicus; Alcool Cetostearyllico; Alkohol cetostearyllicus; Cetylalcohol; Cetyl-sztearyl-alkohol; Cetostearylalkohol; Cetostearylalk; Cetostearylalkohol; Cétostéarylique alcool; Cétostéarylique, alcool; Cetylstearylalkohol; Setostearylialkoholi.

Цетостеариловый Спирт

CAS — 8005-44-5; 67762-27-0.

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

Ph. Eur. 6.2 (Cetostearyl Alcohol). A mixture of solid aliphatic alcohols, mainly stearyl alcohol and cetyl alcohol. It contains not less than 90% of stearyl plus cetyl alcohols and not less than 40% of stearyl alcohol. A white or pale yellow wax-like mass, plates, flakes, or granules. M.p. 49° to 56°. Practically insoluble in water; soluble in alcohol and in petroleum spirit. When melted, it is

miscible with fatty oils, with liquid paraffin, and with melted wool fat.

Ph. Eur. 6.2 (Cetostearyl Alcohol (Type A), Emulsifying; Alcohol Cetyllicus et Stearyllicus Emulsificans A). A mixture containing not less than 80% cetostearyl alcohol and not less than 7% sodium cetostearyl sulfate, both calculated with reference to the anhydrous substance. A suitable buffer may be added. White or pale yellow, wax-like mass, plates, flakes, or granules. Soluble in hot water giving an opalescent solution; practically insoluble in cold water; slightly soluble in alcohol.

Ph. Eur. 6.2 (Cetostearyl Alcohol (Type B), Emulsifying; Alcohol Cetyllicus et Stearyllicus Emulsificans B). A mixture containing not less than 80% cetostearyl alcohol and not less than 7% sodium laurilsulfate, both calculated with reference to the anhydrous substance. A suitable buffer may be added. White or pale yellow, wax-like mass, plates, flakes, or granules. Soluble in hot water giving an opalescent solution; practically insoluble in cold water; slightly soluble in alcohol.

USNF 26 (Cetostearyl Alcohol). It contains not less than 40% of stearyl alcohol (C₁₈H₃₈O = 270.5) and the sum of the stearyl alcohol content and the cetyl alcohol (C₁₆H₃₄O = 242.4) content is not less than 90%. Unctuous, white flakes or granules, having a faint, characteristic odour. M.p. 48° to 55°. Insoluble in water; soluble in alcohol and in ether.

Profile

Cetostearyl alcohol is used in creams, ointments, and other topical preparations as a stiffening agent and emulsion stabiliser. Used with suitable hydrophilic substances, as in Emulsifying Wax, it produces oil-in-water emulsions that are stable over a wide pH range. It is also used to improve the emollient properties of paraffin ointments. It is used in the formulation of modified-release oral preparations.

Cetostearyl alcohol can cause hypersensitivity.

Hypersensitivity. Sensitivity reactions to cetostearyl alcohol in topical preparations have been reported rarely.^{1,3}

1. Pecegueiro M, et al. Contact dermatitis to Hirudoid cream. *Contact Dermatitis* 1987; **17**: 290-3.
2. Marston S. Contact dermatitis from cetostearyl alcohol in hydrocortisone butyrate lipocream, and from lanolin. *Contact Dermatitis* 1991; **24**: 372.
3. Rademaker M, et al. Contact dermatitis from cetostearyl alcohol. *Australas J Dermatol* 1997; **38**: 220-1.

Preparations

BP 2008: Cetomacrogol Emulsifying Wax; Cetrimide Emulsifying Ointment; Emulsifying Wax;

USNF 26: Emulsifying Wax.

Cetyl Alcohol

Alcohol cetílico; Alcohol cetyllicus; Alcohol Hexadecílico; Álcool Cetílico; Alkohol cetyllicus; Cetanol; Cetyl-alkohol; Cetylalkohol; Cetylalkohol; Cetyllicque, alcool; Ethal; Ethol; 1-Hexadecanol; Hexadecan-1-ol; Hexadecyl Alcohol; n-Hexadecyl Alcohol; Palmityl Alcohol; Setylialkoholi.

Цетиловый Спирт

C₁₆H₃₄O = 242.4.

CAS — 36653-82-4; 124-29-8.

HO-CH₂(CH₂)₁₄-CH₃

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

Ph. Eur. 6.2 (Cetyl Alcohol). A mixture of solid alcohols, mainly cetyl alcohol, of animal or vegetable origin. It occurs as a white or almost white, unctuous mass, powder, flakes, or granules. M.p. 46° to 52°. Practically insoluble in water; freely to sparingly soluble in alcohol; miscible when melted with animal and vegetable oils, with liquid paraffin, and with melted wool fat.

USNF 26 (Cetyl Alcohol). A mixture containing not less than 90% of cetyl alcohol the remainder consisting chiefly of related alcohols. White unctuous flakes, cubes, granules, or castings, with a faint characteristic odour. M.p. 45° to 50°. Insoluble in water; soluble in alcohol and in ether, the solubility increasing with increasing temperature.

Profile

Cetyl alcohol is used in topical preparations for its emollient, water absorbent, stiffening, and weak emulsifying properties. It may be incorporated into suppositories to raise the melting-point and may be used in the coating of modified-release solid dose forms. It is also used in cosmetics.

Cetyl alcohol can cause hypersensitivity.

Hypersensitivity. Hypersensitivity reactions have occasionally been attributed to the presence of cetyl alcohol in topical preparations.^{1,4} One report suggested that minor impurities in the cetyl alcohol may be responsible.⁴

1. Komamura H, et al. A case of contact dermatitis due to impurities of cetyl alcohol. *Contact Dermatitis* 1997; **36**: 44-6.