

CNS disease have also occurred after occupational exposure to toluene.

Some studies have noted an excess mortality from motor neuron diseases among leather workers,<sup>4</sup> although this has not been confirmed by others.<sup>5</sup> Occupational exposure to solvents has been postulated as the cause.<sup>4</sup> Of the many agents currently used in leather work, those with known or probable neurotoxic effects are *n*-hexane, methyl butyl ketone, toluene, and methyl ethyl ketone. Ethyl acetate is commonly used but has no recognised neurological adverse effects.<sup>4</sup> A Swedish study of workers in a range of occupations has found some support for an increased risk of amyotrophic lateral sclerosis after occupational exposure to solvents, probably toluene and petrol.<sup>6</sup> Another Swedish study found an association between multiple sclerosis and occupational exposure to solvents, especially white spirit and petrol.<sup>6</sup>

1. Marjot R, McLeod AA. Chronic non-neurological toxicity from volatile substance abuse. *Hum Toxicol* 1989; **8**: 301–6.
2. Lolin Y. Chronic neurological toxicity associated with exposure to volatile substances. *Hum Toxicol* 1989; **8**: 293–300.
3. Filley CM, et al. The effects of toluene on the central nervous system. *J Neuropathol Exp Neurol* 2004; **63**: 1–12.
4. Hawkes CH, et al. Motoneuron disease: a disorder secondary to solvent exposure? *Lancet* 1989; **i**: 73–6.
5. Martyn CN. Motoneuron disease and exposure to solvents. *Lancet* 1989; **i**: 394.
6. Gunnarsson L-G, Lindberg G. Amyotrophic lateral sclerosis in Sweden 1970–83 and solvent exposure. *Lancet* 1989; **i**: 958.

**Handling.** Suitable precautions should be taken to avoid skin contact with toluene as it can penetrate skin and produce systemic toxicity.

**Pregnancy.** Retrospective surveys of pregnancies in mothers with a history of solvent abuse suggested that toluene abuse during pregnancy can cause preterm delivery and perinatal death. It was suggested that toluene may be teratogenic as intra-uterine exposure was associated with prenatal and postnatal growth retardation, microcephaly, impairment of mental development, and facial dysmorphism.<sup>1–3</sup> It is uncertain if these results can be extrapolated to cover occupational exposure. Although some studies of occupational exposure to solvents during pregnancy have suggested an association,<sup>4,5</sup> exposure is usually to a number of solvents<sup>2</sup> and there is little consistent evidence to link exposure to any particular one with spontaneous abortion, retarded fetal development, still-birth, or congenital malformation.<sup>6</sup>

1. Wilkins-Haug L, Gabow PA. Toluene abuse during pregnancy: obstetric complications and perinatal outcomes. *Obstet Gynecol* 1991; **77**: 504–9.
2. Pearson MA, et al. Toluene embryopathy: delineation of the phenotype and comparison with fetal alcohol syndrome. *Pediatrics* 1994; **93**: 211–15.
3. Arnold GL, et al. Toluene embryopathy: clinical delineation and developmental follow-up. *Pediatrics* 1994; **93**: 216–20.
4. McDonald JC, et al. Chemical exposures at work in early pregnancy and congenital defect: a case-referent study. *Br J Ind Med* 1987; **44**: 527–33.
5. Khattak S, et al. Pregnancy outcome following gestational exposure to organic solvents: a prospective controlled study. *JAMA* 1999; **281**: 1106–9.
6. Scott A. *BMJ* 1992; **304**: 369.

#### Pharmacokinetics

Toluene is absorbed after inhalation and ingestion, and to some extent through the skin. It is rapidly metabolised mainly by oxidation to benzoic acid which is excreted in the urine largely as the glycine conjugate hippuric acid; *o*-, *m*-, and *p*-cresol are minor urinary metabolites. Some unchanged toluene is excreted through the lungs.

#### Uses

Toluene is widely used as an industrial solvent.

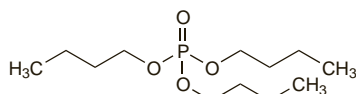
### Tri-*n*-butyl Phosphate

Fosfato de tributilo; Tributyl Phosphate; Tributyl-fosfát; Tributylis Phosphas; Tri-*n*-butylis Phosphas; Tri(*n*-butyl)phosphate; Tri-*n*-butilo fosfat; Tri-*n*-butyle, phosphate de; Tri-*n*-butylfosfat; Tri-*n*-butylis phosphas; Tri-*n*-butylifosfaatti. Phosphoric acid tributyl ester.

Три-*n*-бутилфосфат

C<sub>12</sub>H<sub>27</sub>O<sub>4</sub>P = 266.3.

CAS — 126-73-8.



**Pharmacopoeias.** In *Eur.* (see p.vii).

**Ph. Eur. 6.2** (Tri-*n*-butyl Phosphate; Tributyl Phosphate BP 2008). A clear, colourless to pale yellow liquid. Slightly soluble in water; miscible with alcohol. Protect from light.

#### Profile

Tri-*n*-butyl phosphate is an organophosphate that is used as a solvent and plasticiser.

#### References.

1. WHO. Tri-*n*-butyl phosphate. *Environmental Health Criteria* 112. Geneva: WHO, 1991. Available at: <http://www.inchem.org/documents/ehc/ehc/ehc112.htm> (accessed 29/06/04)

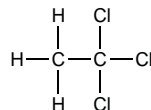
### Trichloroethane

Methylchloroform;  $\alpha$ -Trichloroethane; Trichloroetano. 1,1,1-Trichloroethane.

Трихлорэтан

C<sub>2</sub>H<sub>3</sub>Cl<sub>3</sub> = 133.4.

CAS — 71-55-6.



**Description.** Trichloroethane is a colourless, slightly hygroscopic liquid. Sp. gr. about 1.31. B.p. about 74°. Practically insoluble in water; miscible with alcohol, with chloroform, and with ether. Non-flammable. Store in airtight containers.

#### Adverse Effects and Treatment

Acute intoxication with trichloroethane may result in initial excitement followed by CNS depression with dizziness, drowsiness, headache, lightheadedness, and ataxia, progressing to coma and death from respiratory depression in severe cases. Death may also occur from ventricular arrhythmias. Fatalities have occurred after accidental exposure to high concentrations of trichloroethane in confined spaces. Trichloroethane is commonly used in dry cleaning, type correction fluids, and as a solvent for plaster removal and is frequently implicated in volatile substance abuse (p.2019).

Nausea, vomiting, and diarrhoea have been reported after ingestion. Trichloroethane is a mild irritant.

Treatment of adverse effects consists of removal from exposure and general supportive and symptomatic measures. Activated charcoal is unlikely to be of benefit after ingestion and gastric lavage is contra-indicated. Adrenaline and other sympathomimetics should be avoided because of the risk of precipitating cardiac arrhythmias.

#### References.

1. Health and Safety Executive. 1,1,1-Trichloroethane. *Toxicity Review* 9. London: HMSO, 1984.
2. WHO. 1,1,1-Trichloroethane. *Environmental Health Criteria* 136. Geneva: WHO, 1992. Available at: <http://www.inchem.org/documents/ehc/ehc/ehc136.htm> (accessed 30/06/04)

**Effects on the heart.** Effects on the heart of trichloroethane abuse were considered usually to be acute, and sudden death from ventricular arrhythmias had occurred in abusers. There have, however, been a few cases of chronic cardiac toxicity after both abuse and occupational exposure.<sup>1</sup>

1. Marjot R, McLeod AA. Chronic non-neurological toxicity from volatile substance abuse. *Hum Toxicol* 1989; **8**: 301–6.

**Effects on the liver.** According to a brief review of non-neurological toxicity from volatile substance abuse,<sup>1</sup> there were no reports of damage to the liver after the abuse of trichloroethane. There was a report of hepatotoxicity after acute occupational exposure, but this might have been a hypersensitivity reaction. There was another report<sup>2</sup> of fatty liver disease in 4 patients with a history of occupational exposure to trichloroethane although there has been some debate over the validity of the association for 2 of these cases.<sup>3,4</sup> Chronic active hepatitis associated with trichloroethane exposure has since been reported.<sup>5</sup>

1. Marjot R, McLeod AA. Chronic non-neurological toxicity from volatile substance abuse. *Hum Toxicol* 1989; **8**: 301–6.
2. Hodgson MJ, et al. Liver disease associated with exposure to 1,1,1-trichloroethane. *Arch Intern Med* 1989; **149**: 1793–8.
3. Guzelian PS. 1,1,1-Trichloroethane and the liver. *Arch Intern Med* 1991; **151**: 2321–2.
4. Hodgson MJ, Vanthiel DH. 1,1,1-Trichloroethane and the liver. *Arch Intern Med* 1991; **151**: 2322 and 2325–6.
5. Croquet V, et al. Hépatite chronique active probablement induite par le 1,1, 1-trichloroéthane. *Gastroenterol Clin Biol* 2003; **27**: 120–2.

**Effects on the skin.** Scleroderma has been reported<sup>1</sup> in 3 patients occupationally exposed to trichloroethylene and, in 2 cases, also to trichloroethane.

1. Flindt-Hansen H, Isager H. Scleroderma after occupational exposure to trichloroethylene and trichloroethane. *Acta Derm Venereol (Stockh)* 1987; **67**: 263–4.

#### Pharmacokinetics

Trichloroethane is absorbed after inhalation and ingestion, and through intact skin. Small amounts are metabolised to trichloroethanol and trichloroacetic acid and excreted in the urine, but it is largely excreted unchanged through the lungs over a period of days.

#### Uses

Trichloroethane has wide applications as an industrial solvent. It is commonly used in dry cleaning, typewriter correction fluids, and as a solvent for plaster removal.

### White Spirit

Stoddard Solvent; Trementina.

Уайтспирит

CAS — 64742-82-1 (white spirit type 1); 64741-92-0 (white spirit type 2); 64742-48-9 (white spirit type 3); 64742-88-7 (white spirit type 0); 8052-41-3 (Stoddard solvent).

**Description.** White spirit is a mixture of hydrocarbons available as a colourless liquid. Store in airtight containers.

#### Adverse Effects and Treatment

As for Kerosene, p.2024.

#### References to the toxicity of white spirit.<sup>1</sup>

For discussion of neurotoxicity after occupational exposure to solvents including white spirit, see under Toluene, p.2026.

1. WHO. Selected petroleum products. *Environmental Health Criteria* 20. Geneva: WHO, 1982. Available at: <http://www.inchem.org/documents/ehc/ehc/ehc20.htm> (accessed 30/06/04)

#### Uses

White spirit is used as an industrial solvent. It is available in various grades. One grade available in the USA is known as Stoddard solvent.

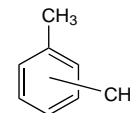
### Xylene

Dimethylbenzene; Ksilen; Xileno; Xylo; Xylole.

Ксилол

C<sub>8</sub>H<sub>10</sub> = 106.2.

CAS — 1330-20-7; 108-38-3 (*m*-xylene); 95-47-6 (*o*-xylene); 106-42-3 (*p*-xylene).



**Description.** Xylene is a mixture of the *o*-, *m*-, and *p*-isomers in which the *m*-isomer predominates. It is a colourless, volatile, flammable liquid. Wt per mL about 0.86 g. B.p. about 138° to 142°. Store in airtight containers.

#### Adverse Effects, Treatment, and Precautions

The acute toxicity of xylene is similar to that of benzene (p.2020) but is less marked. Adverse effects are treated similarly to benzene.

Xylene has been implicated in volatile substance abuse (p.2019). Commercial xylene may contain benzene, and this may perhaps influence the pattern of adverse effects.

Xylene should not be used to dissolve ear wax if the tympanic membrane is perforated.

#### References.

1. WHO. Recommended health-based limits in occupational exposure to selected organic solvents. *WHO Tech Rep Ser* 664 1981. Available at: [http://libdoc.who.int/trs/WHO\\_TRS\\_664.pdf](http://libdoc.who.int/trs/WHO_TRS_664.pdf) (accessed 03/09/08)
2. Health and Safety Executive. Xylenes. *Toxicity Review* 26. London: HMSO, 1992.
3. WHO. Xylenes. *Environmental Health Criteria* 190. Geneva: WHO, 1997. Available at: <http://www.inchem.org/documents/ehc/ehc/ehc190.htm> (accessed 30/06/04)

**Effects on the eyes.** Eye injuries due to accidental contact with paints containing xylene have been reported.<sup>1</sup> The injuries resembled alkali burns and were treated in a similar manner. Xylene-induced keratopathy has been reviewed.<sup>2</sup>

1. Ansari EA. Ocular injury with xylene - a report of two cases. *Hum Exp Toxicol* 1997; **16**: 273–5.
2. Trajillo F, et al. Xylene keratopathy: a case report and review of the literature. *Cornea* 2003; **22**: 88–90.

**Effects on the nervous system.** References to the adverse effects of xylene on the nervous system.

1. Arthur LJH, Curmoock DA. Xylene-induced epilepsy following innocent glue sniffing. *BMJ* 1982; **284**: 1787.
2. Roberts FP, et al. Near-pure xylene causing reversible neuropsychiatric disturbance. *Lancet* 1988; **ii**: 273.

**Handling.** Suitable precautions should be taken to avoid skin contact with xylene as it can penetrate skin and produce systemic toxicity.

#### Pharmacokinetics

Xylene is absorbed after inhalation, ingestion, and to some extent through the skin. It is rapidly metabolised by oxidation to the corresponding *o*-, *m*-, or *p*-methylbenzoic (toluic) acids and excreted in the urine largely as the glycine conjugate, methylhippuric acid (toluic acid). Xylenols are minor metabolites and are excreted in the urine as the glucuronide and sulfate conjugates. Some unchanged xylene is excreted through the lungs.

#### Uses

Xylene is used as an industrial and pharmaceutical solvent and in preparations to dissolve ear wax.

# 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 (C<sub>12</sub>-15) Benzoate; Benzoato de alquilo.

Алкил Бензоат

CAS — 68411-27-8 (C<sub>12</sub>-C<sub>15</sub> alkyl ester).

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Alkyl (C<sub>12</sub>-15) Benzoate). It consists of esters of a mixture of C<sub>12</sub> to C<sub>15</sub> primary and branched alcohols and benzoic acid (average molecular formula C<sub>20</sub>H<sub>32</sub>O<sub>2</sub> = 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,<sup>1</sup> foot,<sup>2</sup> and sternum<sup>3</sup> 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.<sup>2</sup> 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.<sup>3</sup>

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,<sup>1</sup> and cheilitis from a beeswax lip product has also occurred.<sup>2</sup>

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 Steinöl; 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 cetostearylowy; Cetearyl Alcohol; Cetyl-sztearyl-alkohol; Cetostearylalkohol; Cetostearyl Alc.; 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 laurylsulfate, 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 (C<sub>18</sub>H<sub>38</sub>O = 270.5) and the sum of the stearyl alcohol content and the cetyl alcohol (C<sub>16</sub>H<sub>34</sub>O = 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.<sup>1,3</sup>

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 cetyllovy; Cetanol; Cetyl-alkohol; Cetyllo alkohol; Cetylalkohol; Cetyllique, alcool; Ethal; Ethol; 1-Hexadecanol; Hexadecan-1-ol; Hexadecyl Alcohol; n-Hexadecyl Alcohol; Palmityl Alcohol; Setylialkoholi.

Цетиловый Спирт

C<sub>16</sub>H<sub>34</sub>O = 242.4.

CAS — 36653-82-4; 124-29-8.

**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.<sup>1,4</sup> One report suggested that minor impurities in the cetyl alcohol may be responsible.<sup>4</sup>

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