

# Paraffin

## 1 Nonproprietary Names

BP: Hard paraffin  
JP: Paraffin  
PhEur: Paraffinum solidum  
USPNF: Paraffin

## 2 Synonyms

905 (mineral hydrocarbons); hard wax; paraffinum durum; paraffin wax.

## 3 Chemical Name and CAS Registry Number

Paraffin [8002-74-2]

## 4 Empirical Formula      Molecular Weight

Paraffin is a purified mixture of solid saturated hydrocarbons having the general formula  $C_nH_{2n+2}$ , and is obtained from petroleum or shale oil.

## 5 Structural Formula

See Section 4.

## 6 Functional Category

Ointment base; stiffening agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Paraffin is mainly used in topical pharmaceutical formulations as a component of creams and ointments. In ointments, it may be used to increase the melting point of a formulation or to add stiffness. Paraffin is additionally used as a coating agent for capsules and tablets, and is used in some food applications. Paraffin coatings can also be used to affect the release of drug from ion-exchange resin beads.<sup>(1)</sup>

## 8 Description

Paraffin is an odorless and tasteless, translucent, colorless, or white solid. It feels slightly greasy to the touch and may show a brittle fracture. Microscopically, it is a mixture of bundles of microcrystals. Paraffin burns with a luminous, sooty flame. When melted, paraffin is essentially without fluorescence in daylight; a slight odor may be apparent.

## 9 Pharmacopeial Specifications

See Table I.

**Table I:** Pharmacopeial specifications for paraffin.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	+	+	+
Characters	—	+	—
Congealing range	50–75°C	—	47–65°C
Reaction	—	—	+
Heavy metals	≤ 10 ppm	—	—
Arsenic	≤ 2 ppm	—	—
Sulfates	+	+	—
Polycyclic aromatic hydrocarbons	—	+	—
Readily carbonizable substances	+	—	+
Acidity or alkalinity	+	+	—

## 10 Typical Properties

Density:  $\approx 0.84\text{--}0.89\text{ g/cm}^3$  at 20°C

Melting point: various grades with different specified melting ranges are commercially available.

Solubility: soluble in chloroform, ether, volatile oils, and most warm fixed oils; slightly soluble in ethanol; practically insoluble in acetone, ethanol (95%), and water. Paraffin can be mixed with most waxes if melted and cooled.

## 11 Stability and Storage Conditions

Paraffin is stable, although repeated melting and congealing may alter its physical properties. Paraffin should be stored at a temperature not exceeding 40°C in a well-closed container.

## 12 Incompatibilities

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## 13 Method of Manufacture

Paraffin is manufactured by the distillation of crude petroleum or shale oil, followed by purification by acid treatment and filtration. Paraffins with different properties may be produced by controlling the distillation and subsequent congealing conditions.

Synthetic paraffin, synthesized from carbon monoxide and hydrogen is also available; see Section 17.

## 14 Safety

Paraffin is generally regarded as an essentially nontoxic and nonirritant material when used in topical ointments and as a coating agent for tablets and capsules. However, granulomatous reactions (paraffinomas) may occur following injection of paraffin into tissue for cosmetic purposes or to relieve pain. Long-term inhalation of aerosolized paraffin may lead to interstitial pulmonary disease. Ingestion of a substantial amount of white soft paraffin has led to intestinal obstruction in one instance.<sup>(2–6)</sup>

See also Mineral Oil for further information.

**15 Handling Precautions**

Observe normal precautions appropriate to the circumstances and quantity of material handled. In the UK, the recommended occupational exposure limits for paraffin wax fumes are 2 mg/m<sup>3</sup> long-term (8-hour TWA) and 6 mg/m<sup>3</sup> short-term.<sup>(7)</sup>

**16 Regulatory Status**

Accepted in the UK for use in certain food applications. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets, topical emulsions, and ointments). Included in nonparenteral medicines licensed in the UK.

**17 Related Substances**

Light mineral oil; microcrystalline wax; petrolatum; synthetic paraffin.

**Synthetic paraffin**

**Molecular weight:** 400–1400

**Appearance:** a hard, odorless, white wax consisting of a mixture of mostly long-chain, unbranched, saturated hydrocarbons along with a small amount of branched hydrocarbons.

**Melting point:** 96–105°C

**Viscosity (dynamic):** 5–15 mPa s (5–15 cP) at 135°C.

**Comments:** the USPNF 20 states that synthetic paraffin is synthesized by the Fischer–Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. The lower molecular weight fractions are removed by distillation and the residue is hydrogenated and further treated by percolation through activated charcoal. This mixture may be fractionated into its components by a solvent-separation method. Synthetic paraffin may contain not more than 0.005% w/w of a suitable antioxidant.

**18 Comments**

The more highly purified waxes are used in preference to paraffin in many applications because of their specifically controlled physical properties such as hardness, malleability, and melting range. The EINECS numbers for paraffin are 232-315-6 and 265-154-5.

**19 Specific References**

- 1 Motyckas S, Nairn J. Influence of wax coatings on release rate of anions from ion-exchange resin beads. *J Pharm Sci* 1978; **67**: 500–503.
- 2 Crosbie RB, Kaufman HD. Self-inflicted oleogranuloma of breast. *Br Med J* 1967; **3**: 840–841.
- 3 Bloem JJ, van der Waal I. Paraffinoma of the face: a diagnostic and therapeutic problem. *Oral Surg* 1974; **38**: 675–680.
- 4 Greaney MG, Jackson PR. Oleogranuloma of the rectum produced by Lasonil ointment. *Br Med J* 1977; **2**: 997–998.
- 5 Pujol J, Barneon G, Bousquet J, *et al.* Interstitial pulmonary disease induced by occupation exposure to paraffin. *Chest* 1990; **97**: 234–236.
- 6 Goh D, Buick R. Intestinal obstruction due to ingested Vaseline. *Arch Dis Child* 1987; **62**: 1167–1168.
- 7 Health and Safety Executive. *EH40/2002: Occupational Exposure Limits 2002*. Sudbury: Health and Safety Executive, 2002.

**20 General References**

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**21 Author**

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**22 Date of Revision**

30 August 2002.