

Pharmacopoeia compilations

European Pharmacopoeia Paraffin, White Soft

Vaselineum album - 07/2009 : 1799

DEFINITION

Purified and wholly or nearly decolorised mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant. White soft paraffin described in this monograph is not suitable for oral use.

CHARACTERS

Appearance : white or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted.

Solubility : practically insoluble in water, slightly soluble in methylene chloride, practically insoluble in ethanol at 96 per cent and in glycerol.

IDENTIFICATION

First identification : A, B, D
Second identification : A, C, D

A. The drop point is between 35°C and 70°C and does not differ by more than 5°C from the value stated on the label, according to method (2.2.17) with the following modification to fill the cup : heat the substance to be examined at a temperature not exceeding 80°C, with stirring to ensure uniformity. Warm the metal cup at a temperature not exceeding 80°C in an oven, remove it from the oven, place on a clean plate or ceramic tile and pour a sufficient quantity of the melted sample into the cup to fill it completely. Allow the filled cup to cool for 30 min on the plate or the ceramic tile and place it in a water bath at 24 - 26°C for 30 - 40 mn. Level the surface of the sample with a single stroke of a knife or razor blade, avoiding compression of the sample.

B. Infrared absorption spectrophotometry (2.2.24)

Preparation: place about 2 mg of white soft paraffin on a plate of sodium chloride R. Spread the substance to be examined between two plates and then take off one of the plates. Comparison : the same operations with white soft paraffin SCR.

C. Melt 2 g and when a homogeneous phase is

obtained, add 2 ml of water R and 0.2 ml of 0.05 M iodine. Shake. Allow to cool. The solid upper layer is violet-pink or brown.

D. Appearance (see tests).

TESTS

Appearance

The substance is white. Melt 12 g on a water-bath. The melted mass is not more intensely coloured than a mixture of 1 volume of yellow primary solution and 9 volumes of a 1 per cent m/V solution of hydrochloric acid R at 10 g/l (2.2.2, Method II)

Acidity or alkalinity

To 10 g add 20 ml of boiling water R and shake vigorously for 1 min. Allow to cool and decant. To 10 ml of the aqueous layer add 0.1 ml of phenolphthalein solution R. The solution is colourless. Not more than 0.5 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to red.

Consistency (2.9.9) : 60 to 300 Polycyclic aromatic hydrocarbons

Use reagents for ultraviolet spectrophotometry. Dissolve 1.0 g in 50 ml of hexane R which has been previously shaken twice with 10 ml of dimethyl sulphoxide R. Transfer the solution to a 125 ml separating funnel with unlubricated ground-glass parts (stopper, stopcock). Add 20 ml of dimethyl sulphoxide R. Shake vigorously for 1 min and allow to stand until 2 clear layers are formed. Transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 ml of dimethyl sulphoxide R. Shake vigorously the combined lower layers with 20 ml of hexane R for 1 min. Allow to stand until 2 clear layers are formed.

Separate the lower layer and dilute to 50.0 ml with dimethyl sulphoxide R. Measure the absorbance (2.2.25) over the range 260 nm to 420 nm using a path length of 4 cm and as compensation liquid the clear lower layer obtained by vigorously shaking 10 ml of dimethylsulfoxide R with 25 ml of hexane R for 1 min. Prepare a reference solution in dimethyl sulfoxide R containing

6.0 mg of naphthalene R per litre and measure the absorbance of the solution at the maximum at 278 nm using a path length of 4 cm and dimethyl sulphoxide R as compensation liquid. At no wavelength in the range 260 nm to 420 nm does the absorbance of the test solution exceed that of the reference solution at 278 nm.

Sulphuric ashes (2.4.14)

Maximum 0.05 per cent, determined on 2.0 g.

STORAGE

Protected from light.

LABELLING

The label states:

- the nominal drop point,
- where applicable, the name and concentration of any added antioxidant.

European Pharmacopoeia Paraffin, Yellow Soft

Vaselineum flavum - 07/2008 : 1554

DEFINITION

Yellow soft paraffin is a purified mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant.

CHARACTERS

A yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted, practically insoluble in water, soluble in methylene chloride, practically insoluble in ethanol at 96 per cent and in glycerol.

IDENTIFICATION

First identification : A, B, D.
Second identification : A, C, D

A. The drop point (2.2.17) is 40°C to 60°C and does not differ by more than 5°C from the value stated on the label, with the following modification to fill the cup : heat the substance to be examined at 118°C to 122°C, with stirring to ensure uniformity, then cool to 100°C to 107°C. Warm the metal cup at 103°C to 107°C in an oven, remove it from the oven, place on a clean plate or ceramic tile and pour a sufficient quantity of the melted sample into the cup to fill it completely. Allow the filled cup to cool for 30 min. on the ceramic tile and place it in a water-bath at 24°C to 26°C for a further 30 - 40 min. Level the surface of the sample with a single stroke of a knife or razor, avoiding compression of the sample.

B. Infrared absorption spectrophotometry (2.2.24). Preparation: place about 2 mg of yellow soft paraffin on a plate of sodium chloride R. Spread the substance to be examined between two plates and then take off one of the plates. Comparison: the same operations with white soft paraffin SCR.

C. Melt 2 g and when a homogenous phase is obtained, add 2 ml of water R and 0.2 ml of 0.05 M iodine. Shake. Allow to cool. The solid upper layer is violet-pink or brown.

D. Appearance (see tests).

TESTS

Appearance

The substance is yellow. Melt 12 g on a water-bath. The melted mass is not more intensely coloured than a mixture of 7.6 volumes of yellow primary solution and 2.4 volumes of red primary solution (2.2.2, Method II).

Acidity or alkalinity

To 10 g of yellow soft paraffin, add 20 ml of boiling water R and shake vigorously for 1 min. Allow to cool and decant. To 10 ml of the aqueous layer add 0.1 ml of phenolphthalein solution R. The solution is colourless. Not more than 0.5 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to red.

Consistency (2.9.9)

The consistency is 100 to 300.

Polycyclic aromatic hydrocarbons

Use reagents for ultraviolet absorption spectrophotometry. Dissolve 1.0 g in 50 ml of hexane R which has been previously shaken twice with one-fifth its volume of dimethyl sulphoxide R. Transfer the solution to a 125 ml separating funnel with unlubricated groundglass parts (stopper, stopcock). Add 20 ml of dimethyl sulphoxide R. Shake vigorously for 1 min and allow to stand until two clear layers are formed. Transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 ml of dimethyl sulphoxide R. Shake vigorously the combined lower layers with 20 ml of hexane R for 1 min. Allow to stand until two clear layers are formed.

Separate the lower layer and dilute to 50.0 ml with dimethyl sulphoxide R. Measure the absorbance (2.2.25) between 260 nm and 420 nm using a path length of 4 cm and using as the compen-

sation liquid the clear lower layer obtained by vigorously shaking 10 ml of dimethyl sulphoxide R with 25 ml of hexane R for 1 min. Prepare a 9.0 mg/L reference solution of naphthalene R in dimethyl sulphoxide R and measure the absorbance of this solution at the maximum at 278 nm using a path length of 4 cm and using dimethyl sulphoxide R as the compensation liquid. At no wavelength in the range of 260 nm to 420 nm does the absorbance of the test solution exceed that of the reference solution at 278 nm.

Sulphuric ashes (2.4.14)

Not more than 0.05 per cent, determined on 2.0 g.

STORAGE

Store protected from light.

LABELLING

The label states the nominal drop point.

French Pharmacopoeia Codex

White Petroleum Jelly (Codex*) 2004

DEFINITION

White Soft Paraffin is a mixture of purified hydrocarbons obtained from heavy fractions of some petroleum. White Soft Paraffin described in this monograph is particularly suitable for oral use

CHARACTERISTICS

Aspect

Soft unctuous mass, of variable consistency according to the uses it is intended for, of whitish colour, translucent in fine layers, slightly fluorescent in daylight when melted.

Solubility: insoluble in water, When melted, White Soft Paraffin is soluble, in all proportions, in methylene chloride.

White Soft Paraffin, when allowed to cool can show a slight deposit.

F:36 °C to 60 °C.

White Soft Paraffin is more or less fibrous. It is practically anhydrous.

IDENTIFICATION

A. Spectrophotometry absorption by infrared (2.2.24)

The spectrum obtained shows maximum absorption at 2950 cm⁻¹, 2920 cm⁻¹, 2850 cm⁻¹, 1460 cm⁻¹, 1375 cm⁻¹, 725 cm⁻¹ and 715 cm⁻¹. To measure, it is necessary to realize a film on the halide plate surface in a way that the transmission measured at 2915 cm⁻¹ was about 5 %.

Preparation: the substance spread out as a film on a halide plate.

B. Melt 2 g of White Soft Paraffin and when a uniform phase is obtained, add 2 ml of water and 0.2 ml of 0.1 M iodine. Heat until two liquid layers are formed. Shake. Allow to cool, the solid upper layer is violet-pink.

TESTS

Homogeneity

When kept during 1 hour at a temperature of 20°C below its melting point, White Soft Paraffin remains homogenous.

Acidity

To 10 g of White Soft Paraffin add 20 ml of boiling R water, shake vigorously for 1 minute, cool, allow to separate. To 10 ml of the aqueous layer add 0.1 ml of phenolphthalein solution R. The solution is colourless and not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour of the solution to pink.

Carbonisable substances

To a graduated test tube introduce 0.5 g of White Soft Paraffin. Add 20.0 ml of sulphuric acid R. Maintain in a water-bath during 10 min. shaking for 5 sec. every 2 min. Cool and transfer the tube content to a perfectly dry separating funnel. Allow to stand during 10 min. Collect the lower layer, filter if necessary on fritted glass (4). Examine the solution over the range 400 nm to 450 nm (2.2.25) using sulphuric acid R as a compensation liquid. Absorbance does not exceed 0.40.

Absorbance (2.2.25)

- Maximum of 0.20 examined from 250 nm to 275 nm.

- Maximum of 0.05 examined from 300 nm to 350 nm.

Dissolve 0.100 g of White Soft Paraffin in hexane R and add the same solvent until 200.0 ml.

Saponification number. (2.5.6).

Maximum of 2, tested on 2.00 g of White Soft Paraffin.

Sulphated ashes. (2.4.14).

Maximum of 0.03%, tested on 4.0 g of White Soft Paraffin.

* French Pharmacopoeia Codex Issue NR 11

German Pharmacopoeia D.A.B. 10

White Soft Paraffin Vaselinum album

DEFINITION

White Soft Paraffin is a mixture of purified, bleached, for the most part saturated hydrocarbons.

CHARACTERS

White colour or greenish glint, pasty substance, practically odourless and slightly fluorescent in daylight.

PURITY TEST

Colour

Melted on a water-bath, White Soft Paraffin is not more intensely coloured (V.6.2 Method II) than a mixture of 1 volume of yellow primary solution and 9 volumes of a 1 per cent solution of hydrochloric acid RN.

Acidity or alkalinity

To 5 ml of White Soft Paraffin on a water-bath add 20 ml of water at 90-95°C and shake vigorously for 1 minute. Separate the aqueous layer which should not change the colour to red after 0.1 ml of phenolphthalein solution R1 has been added. Not more than 0.5 ml of 0.01 N sodium hydroxide is required to change the colour of the indicator to red.

Congelling temperature at rotary thermometer (V.6.12 N1) : 38 to 56°C

Polycyclic aromatic hydrocarbons

Introduce 1.0 g previously dissolved in 25 ml of hexane for spectrophotometry RN (1) into a 100 ml separating funnel with unlubricated ground-glass parts (stopper, stopcock). Add 5 ml of dimethyl sulphoxide R for spectrophotometry. Shake vigorously for 1 minute and allow to stand until two clear layers are formed. Transfer the lower layer to a second separating funnel. Add 2 ml of hexane RN (1) for spectrophotometry and shake vigorously for 1 minute.

Allow to stand until two clear layers are formed. The absorption (V.6.19) of the lower layer is measured between 260 nm and 420 nm using as a compensation liquid the inferior liquid layer obtained by vigorously shaking for 1 minute 5.0 ml of dimethyl sulphoxide R for spectrophotometry with 25 ml of hexane for

spectrophotometry RN (1). The cloudy compensation liquid can be withdrawn either by centrifuging or by heating of the solution at max. 40°C. At no wavelength in the range 350 to 400 nm does the absorbance of the solution exceed 0.05 ; 0.32 between 270 and 279 nm ; 0.27 between 280 and 289 nm ; 0.24 between 290 and 299 nm and 0.21 between 300 and 310 nm.

High polymer additives

Spread out regularly 3 to 5 g of White Soft Paraffin inside of hands. No thread should be detached when you clap the hands.

Sulphuric acid resistance

Introduce 5 ml of liquid White Soft Paraffin and 5 ml of sulphuric acid 90% RN in a test tube (description in Heavy Paraffin) and heat during 10 minutes on a water-bath at 70 +/- 1°C.

After 5, 6 and 8 mn draw the tube from the bath and shake vigorously 3 times in the longitudinal direction of the tube for 3 seconds. At latest 5 minutes after the heating is stopped, White Soft Paraffin and the sulphuric acid are so well separated that the colour comparison is possible. At the light, the sulphuric acid layer is not more intensely coloured (V.6.2 Method I) than a mixture of 0.5 ml of blue primary solution, 1.5 ml of red primary solution, 3.0 ml of yellow primary solution.

Ashes (V.3.2.16)

Determined on 2.0 g not more than 0.05%

STORAGE

Protect from light

LABELLING

Oil index following the method V.5.N1 can be mentioned on the container.

REMARK

Use White Soft Paraffin if no other Soft Paraffin is recommended.

White Soft Paraffins with a congelling temperature of 60°C can also be used in a manufacture of special medicines at the condition that all other characters are respected.

(1) Before using the hexane for spectrophotometry RN, shake 1/5 of its volume of dimethyl sulphoxide R for spectrophotometry.

British Pharmacopoeia B.P. 2001

White Soft Paraffin

DEFINITION

White Soft Paraffin is a semi-solid mixture of hydrocarbons obtained from petroleum and bleached.

CHARACTERS

A white, translucent, soft unctuous mass, retaining these characteristics on storage and when melted and allowed to cool without stirring; not more than slightly fluorescent by daylight, even when melted ; odourless when rubbed on the skin.

Practically insoluble in water; soluble in chloroform, in ether and in petroleum spirit (boiling range, 40° to 60°), the solutions sometimes showing a slight opalescence; practically insoluble in ethanol (96%).

Acidity or alkalinity

To 10 g add 20 ml of boiling water, shake vigorously for 1 minute, cool, allow to separate and filter the aqueous layer. To 10 ml of the filtrate add 0.1 ml of phenolphthalein solution. The solution is colourless and not more than 0.1 ml of 0.1 M sodium hydroxide VS is required to change the colour of the solution to pink.

Light absorption

Absorbance of a 0.05 % w/v solution in 2,2,4-trimethylpentane at 290 nm, not more than 0.5, Appendix II B.

Drop point

42° to 60°, when determined by the following method and using an Ubbelohde apparatus complying with British Standard 894: 1956 (Specification for Ubbelohde apparatus for flow and drop points). Heat the substance being examined, with stirring, to 118° to 122°, to ensure uniformity, and then cool to 103° to 107°.

Warm the metal cup to 103° to 107° in an oven, remove it from the oven, place on a clean plate or ceramic tile and pour sufficient of the melted sample into the cup to fill it completely. Allow the filled cup to cool for 30 minutes on the tile and then place it in a water bath at 24° to 26° for a further 30 to 40 minutes. Level the surface of the sample with a single stroke of a knife or razor blade, avoiding any "working" of the sample. Push the cup, without lateral movement, into the metal case as far as the rim stop and wipe away the excess of the substance that is squeezed out of the bottom of the tube, ensuring that the air vents are not blocked. Fit the thermometer, with the cup attached, through

the bored cork to the boiling tube such that the bottom of the cup is 24 to 26 mm above the bottom of the boiling tube.

Fix the boiling tube vertically within the beaker so that at least two thirds of its length is immersed in the liquid contained in the beaker.

Adjust the temperature of the outer bath so that the temperature of the substance rises at the rate of 1° per minute. The temperature at which the first drop of melted liquid falls from the metal cup is regarded as the drop point of the substance.

Carry out not fewer than three determinations, each time with a fresh sample of the substance being examined.

The difference between the readings must not exceed 3°. The mean of three readings is taken as the drop point of the substance.

Polycyclic aromatic hydrocarbons

To 1.0 g of the substance being examined in a separating funnel add 50 ml of hexane and shake to dissolve, warming gently if necessary.

Shake the solution with 20 ml of dimethyl sulphoxide for 1 minute, allow to stand until two clear layers are produced and transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 ml of dimethyl sulphoxide. Add 20 ml of hexane to the combined extracts, shake for 1 minute, allow to stand until two clear layers are produced, discard the upper layer and dilute the washed, lower layer to 50 ml with dimethyl sulphoxide (solution A).

Measure the light absorption of a 4 cm layer of solution A in the range 265 nm to 420 nm, Appendix II B, using in the reference cell the clear lower layer obtained by shaking 10 ml of dimethyl sulphoxide with 25 ml of hexane for 1 minute. Measure the absorbance of a 4 cm layer of a solution containing 6.0 ug per ml of naphthalene in dimethyl sulphoxide at 278 nm, Appendix II B, using dimethyl sulphoxide in the reference cell. The absorbance of solution A at all wavelengths in the range 265 to 420 nm is not more than that of the naphthalene solution at 278 nm

Foreign organic matter

Heat 1 g until fumes appear. No acrid odour is evolved.

Sulphuric ashes

Not more than 0.1 %, Appendix IX A.

STORAGE

White Soft Paraffin should be protected from light.

American Pharmacopoeia U.S.P. XXIV

Petrolatum

DEFINITION

Petrolatum is a purified mixture of semisolid hydrocarbons obtained from petroleum. It may contain a suitable stabilizer.

Packaging and storage

Preserve in well-closed containers. Labelling – Label it to indicate the name and proportion of any added stabilizer.

Color

Melt about 10 g on a steam bath, and pour about 5 mL of the liquid into a clear-glass 15- X 150- mm test tube, keeping the petrolatum melted. The petrolatum is not darker than a solution made by mixing 3.8 mL of ferric chloride CS and 1.2 ml of cobaltous chloride CS in a similar tube, the comparison of the two being made in reflected light against a white background, the petrolatum tube being held directly against the background at such an angle that there is no fluorescence.

Specific gravity (841)

Between 0.815 and 0.880 at 60°.

Melting range, class III (741)

between 38° and 60°.

Consistency - Apparatus

Determine the consistency of Petrolatum by means of a penetrometer fitted with a polished cone-shaped metal plunger weighing 150 g, having a detachable steel tip of the following dimensions: the tip of the cone has an angle of 30°, the point being truncated to a diameter of 0.381 +/- 0.025 mm, the base of the tip is 8.38 +/- 0.05 mm in diameter, and the length of the tip is 14.94 +/- 0.05 mm. The remaining portion of the cone has an angle of 90°, is about 28 mm in height and has a maximum diameter at the base of about 65 mm. The containers for the test are flat-bottom metal cylinders that are 100 +/- 6 mm in diameter and not less than 65 mm in height. They are constructed of at least 1.6 mm (16-gauge) metal, and are provided with well-fitting, water-tight covers.

Procedure

Place the required number of containers in an oven, and bring them and a quantity of Petrolatum to a temperature of 82 +/- 2.5°, pour

the Petrolatum into one or more of the containers, filling to within 6 mm of the rim.

Cool to 25 +/- 2.5° over a period of not less than 16 hours, protected from drafts. Two hours before the test, place the containers in a water bath at 25 +/- 0.5°. If the room temperature is below 23.5° or above 26.5°, adjust the temperature of the cone to 25 +/- 0.5° by placing it in the water bath.

Without disturbing the surface of the substance under test, place the container on the penetrometer table, and lower the cone until the tip just touches the top surface of the test substance at a spot 25 mm to 38 mm from the edge of the container.

Adjust the zero setting and quickly release the plunger, then hold it free for 5 seconds. Secure the plunger, and read the total penetration from the scale. Make three or more trials, each so spaced that there is no overlapping of the areas of penetration. Where the penetration exceeds 20 mm, use a separate container of the test substance for each trial. Read the penetration to the nearest 0.1 mm. Calculate the average of the three or more readings, and conduct further trials to a total of 10 if the individual results differ from the average by more than +/- 3 %; the final average of the trials is not less than 10.0 mm and not more than 30.0 mm, indicating a consistency value between 100 and 300.

Acidity

If the addition of phenolphthalein TS in the test for Alkalinity produces no pink color, add 0.1 ml of methyl orange TS : no red or pink color is produced.

Alkalinity

Introduce 35 g into a suitable beaker, add 100 ml of boiling water, cover, and place on a stirring hot-plate maintained at the boiling point of water. After 5 minutes, allow the phases to separate. Draw off the separated water into a casserole, wash the petrolatum further with two 50-mL portions of boiling water, and add the washings to the casserole. To the pooled washings add 1 drop of phenolphthalein TS, and boil : the solution does not acquire a pink color.

Residue on ignition (281)

Heat 2 g in an open porcelain or platinum dish over a Bunsen flame : it volatilizes without emitting an acrid odor and on ignition yields not more than 0.1 % of residue.

Organic acids

Weigh 20.0 g add 100 mL of a 1 in 2 mixture of neutralized alcohol and water, agitate thoroughly, and heat to boiling.

Add 1 mL of phenolphthalein TS, and titrate rapidly with 0.1 N sodium hydroxide VS, with vigorous agitation to the production of a sharp pink endpoint, noting the color change in the

alcohol-waterlayer : not more than 400 µl of 0.100 N sodium hydroxide is required.

Fixed oils, fats and rosin

Digest 10g with 50 mL of 5 N sodium hydroxide at 100° for 30 minutes. Separate the water layer, and acidify it with 5 N sulfuric acid : no oily or solid matter separates.

(*)American pharmacopoeiaXXIII

European Pharmacopoeia

Liquid Paraffin (Paraffinum Liquidum) 01/2008: 0239

DEFINITION

Liquid paraffin is a purified mixture of liquid saturated hydrocarbons obtained from petroleum.

CHARACTERS

Oily liquid, colourless, transparent, free from fluorescence in daylight, practically insoluble in water, sparingly soluble in ethanol at 96 per cent, soluble in hydrocarbons.

IDENTIFICATION

First identification: A,C.

Second identification: B,C.

A. Examine the liquid paraffin by absorption spectrophotometry in infrared (2.2.24), in comparison with the reference spectre of solid paraffin of European pharmacopoeia.

B. In a glass tube, boil cautiously 1 ml of liquid paraffin and 1 ml of sodium hydroxyde 0.1 M. Shake during about 30 s. Cool at room temperature. The two phases are separated. Add 0.1 ml phenolphthaleine R to the aqueous phase. The solution colour becomes red.

C. The liquid paraffin is conform to viscosity test (see test).

TESTS

Acidity or alkalinity

To 10 ml add 20 ml of boiling R water and shake

vigorously for 1 min. Separate the aqueous layer and filter. To 10 ml of the filtrate, add 0.1 ml of phenolphthalein solution R. The solution is colourless. Not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour to pink.

Relative density. (2.2.5)

0.827 to 0.890

Viscosity. (2.2.9)

110 mPa.s to 230 mPa.s.

Polycyclic aromatic hydrocarbons

Use solvents for spectrophotometry. Introduce 25.0 ml of liquid paraffin into a 125 ml separating funnel with unlubricated ground joint-glass parts (stopper, stopcock). Add 25 ml of hexane R preliminary cleaned by shaking with 2 times the fifth of its volume of dimethyl sulphoxide R. Mix and add 5.0 ml of dimethyl sulphoxide R. Shake vigorously for 1 min. and allow to stand until two clear layers are formed. Transfer the lower layer to a second separating funnel, add 2 ml of hexane R and shake the mixture vigorously. Allow to stand until two clear layers are formed. Separate the lower layer and measure its absorbance (2.2.25) over the range 260 nm to 420 using as compensation liquid the clear lower layer obtained by vigorously shaking 5.0 ml of dimethyl sulphoxide R with 25 ml of hexane R. Prepare a reference solution in trimethylpentane R containing 7.0 mg of naphthalene R per litre and measure the absorbance of that solution at the maximum at 275 nm using trimethylpentane R as compensation liquid. At no wavelength in the range 260 nm to 420 nm does the absorbance of the test solution exceed one-third that of the reference solution at 275 nm.

Readily carbonisable substances

Use a ground-glass-stoppered tube about 125 mm long and 18 mm in internal diameter, graduated at 5 ml and 10 ml ; preliminary washed with warm R water (temperature at 60°C minimum), with R acetone, then R heptane and finally with R acetone and dried at 100-110°C and cooled in a desiccator.

Introduce 5 ml of the substance to be examined and add 5 ml of nitrogen-free sulphuric acid R1. Insert the stopper and shake as vigorously as possible, in the longitudinal direction of the tube, for 5 s. Loosen the stopper and place immediately the tube in a water-bath, avoiding contact of the tube with the bottom or side of the bath, and heat for 10 min. After 2 min., 4 min., 6 min. and 8 min., remove the tube from the bath and shake as vigorously as possible, in the longitudinal direction of the tube for 5 s. At the end of 10 min. of heating, remove the tube from the water-bath and allow to stand for 10 min. Centrifuge during 5 min. at 2000 g. The lower layer is not more intensely coloured (2.2.2, Procédé I) than a mixture of 0.5 ml of blue primary solution, 1.5 ml of red primary solution, 3.0 ml of yellow primary solution and 2 ml of hydrochloric acid R (10 g/l).

Solid paraffins

Dry a suitable quantity of the substance to be examined by heating at 100°C for 2 h. and cool in a desiccator over sulphuric acid R. Place in a glass tube with an internal diameter of about 25 mm, close the tube and immerse in a bath of iced water. After 4 h., the liquid is sufficiently clear for a black line 0.5 mm wide against a white background held vertically behind the tube to be easily seen.

STORAGE

Store protected from light.

Light Liquid Paraffin (Paraffinum Perliquidum) 01/2008: 0240

DEFINITION

Light liquid paraffin is a purified mixture of liquid saturated hydrocarbons obtained from petrol.

CHARACTERS

Oily liquid, colourless, transparent, free from fluorescence in daylight, practically insoluble in water, sparingly soluble in ethanol at 96 per cent, soluble in hydrocarbons.

IDENTIFICATION

First identification: A,C.
Second identification: B,C.

A. Examine the light liquid paraffin by absorption spectrophotometry in infrared (2.2.24), in comparison with the reference spectrum of solid paraffin of European pharmacopoeia.

B. In a glass tube, bring cautiously to the boil 1 ml of liquid paraffin and 1 ml of sodium hydroxide 0.1 M. Shake during about 30 s. Cool at room temperature. The two phases are separated. Add 0.1 ml phenolphthalein R to the aqueous phase. The solution colour becomes red.

C. The light liquid paraffin is conform to viscosity test (see test).

TESTS

Light liquid paraffin complies with tests of the monograph Liquid Paraffin (0239) with the following modifications :

Relative density. (2.2.5)

0.810 to 0.875

Viscosity (2.2.9)

25 mPa.s to 80 mPa.s.

STORAGE

Store protected from light.

F.D.A. Regulation

PETROLATUM

Some synonyms

Petroleum jelly; Vaseline; White petrolatum; White petroleum jelly; White vaseline; Yellow petrolatum.

Current CAS number

8009-03-8

Other CAS number(s)

8027-32-5; 8038-17-3; 8040-87-7; 8044-44-8; 8044-45-9; 8044-46-0; 8057-56-5; 8063-27-2

Empirical formula

Unknown.

Functional use in foods

Release agent, lubricant, sealing agent, polishing agent, protective coating, defoaming agent.

Regulatory notes

§ 172.880 Petrolatum may be safely used in food, subject to the provisions of this section.

(a) Petrolatum complies with the specifications set forth in the USP XX (1980) for white petrolatum or in the NF XV (1980) for petrolatum.

(b) Petrolatum meets (certain) ultraviolet absorbance limits...

(c) Petrolatum is used or intended for use as follows:

Use Hydrocarbons that may be used in combination	Limitation (inclusive of all petrolatum with petrolatum)
In bakery products; as release agent and lubricant	With white mineral oil, not to exceed 0.15% of bakery product
In confectionery: as release agent and as sealing and polishing agent	Not to exceed 0.2% of confectionery
In dehydrated fruits and vegetables; as release agent	Not to exceed 0.02% of dehydrated fruits and vegetables
In eggs white solids; as release agent	Not to exceed 0.1% of egg white solids
On raw fruits and vegetables; as protective coating	In an amount not to exceed good manufacturing practice
In beet sugar and yeast; as defoaming agent	As described in § 173.340 of this chapter

(d) Petrolatum may contain any antioxidant permitted in food... in an amount not greater than that required to produce its intended effect. § 173.340 Defoaming agents (3) (This substance may be used) provided it is a component of defoaming agents limited to use in processing beet sugar and yeast, and subject to any limitation imposed. This substance must conform to the definition given in § 172.880 of this

chapter (b). This may not be added in an amount not in excess of that reasonably required to inhibit foaming. TSCA Definition 1990: A complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil.

It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25.

Regulatory Citations

Citation number / CFR part	Food category	Permitted functionality	Use limits
21 CFR 172.880 Food additives permitted for direct addition to food for human consumption. Subpart I – Multipurpose additives.	See above	See above	See above
21 CFR 173.340 Secondary direct food additives permitted in food for human consumption. Subpart D – Specific usage additives. Defoaming agents		(29) Surface-active agents	See above
21 CFR 573.720 Food additives permitted in feed and drinking water of animals. Petrolatum.			

MINERAL OIL, WHITE

Some synonyms

Liquid paraffin; Paraffin oil; White mineral oil; White oils.

Current CAS number

8012-95-1

Other CAS number(s)

8015-59-6; 8033-89-4; 8038-04-8; 8039-14-3 ; 8039-75-6; 8043-78-5; 37231-69-9; 37232-05-6; 37232-06-7; 37232-07- 8; 39290-23-8; 39355-35-6; 39464-77-2; 39464-78-3; 50935-85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 74870-90-9; 79956-36-8; 83046-05-3; 83046-05-3; 79956-36-8; 39355-35-6.

Description

A mixture of refined liquid hydrocarbons, essentially paraffinic and naphthenic in nature, obtained from petroleum. It occurs as a colorless, transparent, oily liquid, free or nearly free from fluorescence. It is odorless and tasteless when cold, and develops not more than a faint odor of petroleum when heated. It is insoluble in water and in an alcohol, is soluble in volatile oils, and is miscible with most fixed oils, but not with castor oil. It may contain any antioxidant permitted in food by the U.S. Food and Drug Administration, in an amount not greater than that required to produce its intended effect.

Purity

Not available.

Specifications

Readily carbonizable substances: Passes test.
Specific gravity: Not less than that stated, or within the range claimed by the vendor.
Ultraviolet absorbance (polynuclear hydrocarbons): passes test.
Viscosity : Not less than that stated, or within the range claimed by the vendor*.

Functional use in foods

Binder, defoaming agent, fermentation aid, lubricant, release agent.

Regulatory notes

§ 172.878 White mineral oil may be safely used in food in accordance with the following conditions: (a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum, it is refined to meet the following specifications :

(1) It meets the test requirements of the USP XX for readily carbonizable substances.

(2) It meets the test requirements of USP XVII for sulfur compounds.

(3) It meets the specifications of the ... (AOAC)...

(b) White mineral oil may contain any antioxidant permitted in food by regulations... in an amount no greater than that required to produce its intended effect. (c) White mineral oil is used or intended for use as follows.

(*) National Academy of Sciences (1994). Draft monograph on mineral oil, white for inclusion into the Food Chemicals Codex. Submitted to the USFDA in partial fulfillment of contact number 223-92-2250. September 13, 1994.

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
As a release agent, binder and lubricant in or on capsules or tablets containing concentrates of flavouring, spices, condiments, and nutrients intended for addition to food, excluding confectionary.	Not to exceed 0.6% of the capsule or tablet
As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.	Not to exceed 0.6% of the capsule or tablet
As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation	In any amount not to exceed food manufacturing practice
As a deformer in food.	In accordance with 21 CFR 173-340
In bakery products, as a release agent and lubricant.	Not to exceed 0.15% of bakery product.
In dehydrated fruits and vegetables, as a release agent.	Not to exceed 0.02% of dehydrated fruits and vegetables.
In egg white solids, as a release agent.	Not to exceed 0.1% in egg white solids.
On raw fruits and vegetables, as a protective coating.	In an amount not to exceed good manufacturing practice.

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
In frozen meat, as a component of hot-melt coating.	Not to exceed 0.095% of meat.
As a protective float on brine used in the curing of pickles.	In an amount not to exceed good manufacturing practise.
In molding starch used in the manufacture of confectionery	Not to exceed 0.3% in the molding starch.
As a release agent, binder and lubricant in the manufacture of the yeast.	Not to exceed 0.15% of yeast
As an antidusting agent in sorbic acid for food use.	Not to exceed 0.25% in the sorbic acid.
As release agent and as sealing and polishing agent in the manufacture of confectionery	Not to exceed 0.2% of confectionery
As a dust control agent for wheat, corn, soybean, barley, rice, rye, oats and sorghum.	Applied at a level of no more than 0.02% by weight of grain.

§ 173.340 Defoaming agents (2) White mineral oil (conforming with § 172.878 of this chapter) may be used as a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008% of the wash water. (b) This may not be added in an amount not in excess of that reasonably required to inhibit foaming.

§ 175.230 Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section... (and include)... white mineral oil for use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with 21 CFR 172.878 .

§ 573.680 (b) [Mineral oil]... is used in animal feed for the following purposes:

(1) to reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralised salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(5) For the removal of water from substances intended as ingredients of animal feeds. (c) The quantity of mineral oil used in animal feed shall not exceed 3.0% in mineral supplements, nor shall it exceed 0.06% of the total ration when present in feed or feed concentrates.

Citation number / CFR part	Food category	Permitted functionality	Use limits
21 CFR 172.878 Food additives permitted for direct addition to food for human consumption. Subpart I – Multipurpose additives.	See above	See above	See above
21 CFR 173.340 Secondary direct food additives permitted in food for human consumption. Subpart D – Specific usage additives. Defoaming agents		{29} Surface-active agents	See above
21 CFR 175.230 indirect food additives: Adhesives and components of coatings. Subpart C – Substances for use as components of coatings. Hot-melt strippable food coatings.	See above	See above	See above
21 CFR 178-3570 Indirect food additives: adjuvants production aids and sanitizers. Subpart D – Certain adjuvants and production aids. Lubricants with accidental food contact.			
21 CFR 178-3620 Indirect food additives: adjuvants, production aids and sanitizers. Subpart D – certain adjuvants and production aids. Mineral oil.			
21 CFR 573.680 Food additives permitted in feed and drinking water of animals. Mineral oil.	See above	See above	See above