PARAFFIN, HARD
Paraffinum solidum

DEFINITION
Hard paraffin is a purified mixture of solid saturated hydrocarbons generally obtained from petroleum. It may contain a suitable antioxidant.

CHARACTERS
A colourless or white mass, practically insoluble in water, freely soluble in methylene chloride, practically insoluble in alcohol. The melted substance is free from fluorescence in daylight.

IDENTIFICATION
First identification: A, C.
Second identification: B, C.
A. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the Ph. Eur. reference spectrum of hard paraffin.
B. It complies with the test for acidity or alkalinity (see Tests).
C. Melting point (2.2.16): 50 °C to 61 °C.

TESTS
Acidity or alkalinity. To 15 g add 30 ml of boiling water R and shake vigorously for 1 min. Allow to cool and to separate. To 10 ml of the aqueous layer add 0.1 ml of phenolphthalein solution R. The solution is colourless. Not more than 1.0 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to red. To a further 10 ml of the aqueous layer add 0.1 ml of methyl red solution R. The solution is yellow. Not more than 0.5 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.

Polycyclic aromatic hydrocarbons. Use reagents for ultraviolet absorption spectrophotometry. Dissolve 0.50 g in 25 ml of heptane R and place in a 125 ml separating funnel with unlubricated ground-glass parts (stopper, stopcock). 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 heptane 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) between 265 nm and 420 nm using as the compensation liquid the clear lower layer obtained by vigorously shaking 5.0 ml of dimethyl sulphoxide R with 25 ml of heptane R for 1 min. Prepare a 7.0 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 dimethyl sulphoxide R as the compensation liquid. At wavelengths from 265 nm to 420 nm, the absorbance of the test solution is not greater than one-third that of the reference solution at 278 nm.

Sulphates (2.4.13). Introduce 2.0 g of the melted substance to be examined into a 50 ml ground-glass-stoppered separating funnel. Add 30 ml of boiling distilled water R and shake vigorously for 1 min. Filter. 15 ml of the filtrate complies with the limit test for sulphates (150 ppm).

STORAGE
Store protected from light.

LABELLING
The label states, where applicable, the name and concentration of any added antioxidant.

PARAFFIN, LIGHT LIQUID
Paraffinum perliquidum

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

CHARACTERS
A colourless, transparent, oily liquid, free from fluorescence in daylight. Practically insoluble in water, slightly soluble in ethanol (96 per cent), miscible with hydrocarbons.

IDENTIFICATION
First identification: A, C.
Second identification: B, C.
A. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the Ph. Eur. reference spectrum of liquid paraffin.
B. In a test tube cautiously boil 1 ml with 1 ml of 0.1 M sodium hydroxide, with continuous shaking, for about 30 s. On cooling to room temperature, 2 phases separate. To the aqueous phase add 0.1 ml of phenolphthalein solution R. The colour turns to red.
C. It complies with the test for viscosity (see Tests).

TESTS
Acidity or alkalinity. To 10 ml add 20 ml of boiling water R 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 of the indicator to pink.

Relative density (2.2.5): 0.810 to 0.875.

Viscosity (2.2.9): 25 mPas to 80 mPas.

Polycyclic aromatic hydrocarbons. Use reagents for ultraviolet spectrophotometry. Introduce 25.0 ml into a 125 ml separating funnel with unlubricated ground-glass parts (stopper, stopcock). Add 25 ml of hexane R which has been previously shaken twice with one-fifth 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 2 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 2 clear layers are formed. Separate the lower layer and measure its absorbance (2.2.25) between 260 nm and 420 nm, using as the compensation liquid the clear lower layer obtained by vigorously shaking 5.0 ml of dimethyl sulphoxide R with 25 ml of hexane R for 1 min. Prepare a 7.0 mg/l reference solution of naphthalene R in trimethylpentane R and measure the absorbance of the solution at the maximum at 275 nm, using trimethylpentane R as the compensation liquid. At no wavelength between 260 nm and 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; wash with hot water R (temperature at least 60 °C), acetone R, heptane R and finally with acetone R, dry at 100-110 °C. Cool 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, immediately place 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 at 2000 g for 5 min. The lower layer is not more intensely coloured (2.2.2, 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 and 2 ml of a 10 g/l solution of hydrochloric acid R.

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, to be easily seen against a white background held vertically behind the tube.

STORAGE
Protected from light.

01/2005:0239

PARAFFIN, LIQUID
Paraffinum liquidum

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

CHARACTERS
A colourless, transparent, oily liquid, free from fluorescence in daylight. Practically insoluble in water, slightly soluble in ethanol (96 per cent), miscible with hydrocarbons.

IDENTIFICATION
First identification: A, C.
Second identification: B, C.
A. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the Ph. Eur. reference spectrum of liquid paraffin.
B. In a test tube cautiously boil 1 ml with 1 ml of 0.1 M sodium hydroxide, with continuous shaking, for about 30 s. On cooling to room temperature, 2 phases separate. To the aqueous phase add 0.1 ml of phenolphthalein solution R. The colour turns to red.
C. It complies with the test for viscosity (see Tests).

TESTS
Acidity or alkalinity. To 10 ml add 20 ml of boiling water R 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 of the indicator to pink.
Relative density (2.2.5): 0.827 to 0.890.
Viscosity (2.2.9): 110 mPa.s to 230 mPa.s.
Polymeric aromatic hydrocarbons. Use reagents for ultraviolet spectrophotometry.
Introduce 25.0 ml into a 125 ml separating funnel with un lubricated ground-glass parts (stopper, stopcock). Add 25 ml of hexane R which has been previously shaken twice with one-fifth 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 2 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 2 clear layers are formed. Separate the lower layer and measure its absorbance (2.2.25) between 260 nm and 420 nm, using as the compensation liquid the clear lower layer obtained by vigorously shaking 5.0 ml of dimethyl sulphoxide R with 25 ml of hexane R for 1 min. Prepare a 7.0 mg/l reference solution of naphthalene R in trimethylpentane R and measure the absorbance of the solution at the maximum at 275 nm, using trimethylpentane R as the compensation liquid. At no wavelength between 260 nm and 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; wash with hot water R (temperature at least 60 °C), acetone R, heptane R and finally with acetone R, dry at 100-110 °C. Cool 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, immediately place 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 at 2000 g for 5 min. The lower layer is not more intensely coloured (2.2.2, 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 and 2 ml of a 10 g/l solution of hydrochloric acid R.

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, to be easily seen against a white background held vertically behind the tube.

STORAGE
Protected from light.

01/2005:1799

PARAFFIN, WHITE SOFT
Vaselinum album

DEFINITION
Purified and wholly or nearly decolourised 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, soluble in methylene chloride, practically insoluble in alcohol and in glycerol.

General Notices (1) apply to all monographs and other texts