Reference solution (a). Dilute 0.5 ml of *2-butanol R1* and 0.5 ml of *propanol R* to 50.0 ml with test solution (a). Dilute 5.0 ml of the solution to 50.0 ml with test solution (a).

Reference solution (b). Dilute 100 µl of *benzene R* to 100.0 ml with test solution (a). Dilute 0.20 ml of the solution to 100.0 ml with test solution (a).

Column:

– *material*: fused silica,

– *size*: *l* = 30 m, Ø = 0.32 mm,

– *stationary phase*: *poly[(cyanopropyl)(phenyl)][dimethyl]siloxane R* (film thickness 1.8 µm).

Carrier gas: *helium for chromatography R.*

Auxiliary gas: *nitrogen for chromatography R* or *helium for chromatography R.*

Linear velocity: 35 cm/s.

Split ratio: 1:5.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 12	40
	12 - 32	40 → 240
	32 - 42	240
Injection port		280
Detector		280

Detection: flame ionisation.

Injection: 1 µl.

Retention time: benzene = about 10 min.

System suitability: reference solution (a):

– *resolution*: minimum of 10 between the first peak (propanol) and the second peak (2-butanol).

Limits:

– *benzene* (test solution (a)): not more than half of the area of the corresponding peak in the chromatogram obtained with reference solution (b) (2 ppm), after the sensitivity has been adjusted so that the height of the peak due to benzene in the chromatogram obtained with reference solution (b) represents at least 10 per cent of the full scale of the recorder.

– *total of impurities apart from 2-butanol* (test solution (b)): not more than 3 times the area of the peak due to 2-butanol in the chromatogram obtained with test solution (b) (0.3 per cent), after the sensitivity has been adjusted so that the height of the 2 peaks following the principal peak in the chromatogram obtained with reference solution (a) represents at least 50 per cent of the full scale of the recorder.

Peroxides. In a 12 ml test-tube with a ground-glass stopper and a diameter of about 15 mm, introduce 8 ml of *potassium iodide and starch solution R*. Fill completely with the substance to be examined. Shake vigorously and allow to stand protected from light for 30 min. No colour develops.

Non-volatile substances: maximum 20 ppm.

Evaporate 100 g to dryness on a water-bath *after having verified that it complies with the test for peroxides* and dry in an oven at 100-105 °C. The residue weighs a maximum of 2 mg.

Water (*2.5.12*): maximum 0.5 per cent, determined on 5.0 g.

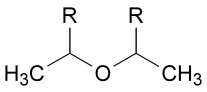
STORAGE

Protected from light.

IMPURITIES

A. acetone,

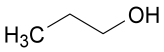
B. benzene,



C. R = CH_3: 2-(1-methylethoxy)propane (diisopropyl ether),

D. R = H: ethoxyethane (diethyl ether),

E. CH_3-OH: methanol,

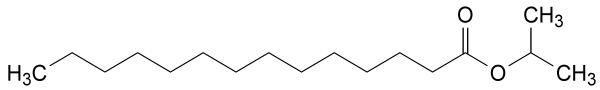


F. propan-1-ol (*n*-propanol).

01/2008:0725

ISOPROPYL MYRISTATE

Isopropylis myristas



$C_{17}H_{34}O_2$ M_r 270.5

DEFINITION

1-Methylethyl tetradecanoate together with variable amounts of other fatty acid isopropyl esters.

Content: minimum 90.0 per cent of $C_{17}H_{34}O_2$.

CHARACTERS

Appearance: clear, colourless, oily liquid.

Solubility: immiscible with water, miscible with ethanol (96 per cent), with methylene chloride, with fatty oils and with liquid paraffin.

Relative density: about 0.853.

IDENTIFICATION

First identification: B.

Second identification: A, C.

A. It complies with the test for saponification value (see Tests).

B. Examine the chromatograms obtained in the assay.

Results: the principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution.

C. Superpose 2 ml of a 1 g/l solution in *ethanol (96 per cent) R* on a freshly prepared solution of 20 mg of *dimethylaminobenzaldehyde R* in 2 ml of *sulphuric acid R*. After 2 min, a yellowish-red colour appears at the junction of the 2 liquids and gradually becomes red.

TESTS

Appearance of solution. The solution is clear (*2.2.1*) and not more intensely coloured than reference solution Y_7 (*2.2.2, Method II*).

Dissolve 2.0 g in *methanol R* and dilute to 20 ml with the same solvent.

Refractive index (*2.2.6*): 1.434 to 1.437.

Viscosity (*2.2.9*): 5 mPa·s to 6 mPa·s.

Acid value (*2.5.1*): maximum 1.0.

Iodine value (*2.5.4*): maximum 1.0.

Saponification value (*2.5.6*): 202 to 212.

Water (*2.5.12*): maximum 0.1 per cent, determined on 5.0 g.

Total ash (*2.4.16*): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Gas chromatography (*2.2.28*).

Internal standard solution. Dissolve 50.0 mg of *tricosane R* in *heptane R* and dilute to 250.0 ml with the same solvent.

Test solution. Dissolve 20.0 mg of the substance to be examined in the internal standard solution and dilute to 100.0 ml with the same solution.

Reference solution. Dissolve 20.0 mg of *isopropyl tetradecanoate CRS* in the internal standard solution and dilute to 100.0 ml with the same solution.

Column:

- *material*: fused silica,
- *size*: *l* = 50 m, Ø = 0.2 mm,
- *stationary phase*: *poly(cyanopropyl)siloxane R* (film thickness 0.2 µm).

Carrier gas: *helium for chromatography R*.

Flow rate: 1 ml/min.

Split ratio: 1:40.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 6	125 → 185
	6 - 16	185
Injection port		250
Detector		250

Detection: flame ionisation.

Injection: 2 µl.

Calculate the percentage content of $C_{17}H_{34}O_2$ in the substance to be examined.

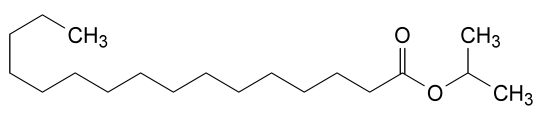
STORAGE

Protected from light.

01/2008:0839

ISOPROPYL PALMITATE

Isopropylis palmitas



$C_{19}H_{38}O_2$ M_r 298.5

DEFINITION

1-Methylethyl hexadecanoate together with varying amounts of other fatty acid isopropyl esters.

Content: minimum 90.0 per cent of $C_{19}H_{38}O_2$.

CHARACTERS

Appearance: clear, colourless, oily liquid.

Solubility: immiscible with water, miscible with ethanol (96 per cent), with methylene chloride, with fatty oils and with liquid paraffin.

Relative density: about 0.854.

IDENTIFICATION

First identification: B.

Second identification: A, C.

A. It complies with the test for saponification value (see Tests).

B. Examine the chromatograms obtained in the assay.

Results: the principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution.

C. Superpose 2 ml of a 1 g/l solution in *ethanol (96 per cent) R* on a freshly prepared solution of 20 mg of *dimethylaminobenzaldehyde R* in 2 ml of *sulphuric acid R*. After 2 min, a yellowish-red colour appears at the junction of the 2 liquids which gradually becomes red.

TESTS

Appearance of solution. The solution is clear (*2.2.1*) and not more intensely coloured than reference solution Y_7 (*2.2.2, Method II*).

Dissolve 2.0 g in *methanol R* and dilute to 20 ml with the same solvent.

Refractive index (*2.2.6*): 1.436 to 1.440.

Viscosity (*2.2.9*): 5 mPa·s to 10 mPa·s.

Acid value (*2.5.1*): maximum 1.0.

Iodine value (*2.5.4*): maximum 1.0.

Saponification value (*2.5.6*): 183 to 193.

Water (*2.5.12*): maximum 0.1 per cent, determined on 5.0 g.

Total ash (*2.4.16*): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Gas chromatography (*2.2.28*).

Internal standard solution. Dissolve 50.0 mg of *tricosane R* in *heptane R* and dilute to 250.0 ml with the same solvent.

Test solution. Dissolve 20.0 mg of the substance to be examined in the internal standard solution and dilute to 100.0 ml with the same solution.

Reference solution. Dissolve 20.0 mg of *isopropyl hexadecanoate CRS* in the internal standard solution and dilute to 100.0 ml with the same solution.

Column:

- *material*: fused silica,
- *size*: *l* = 50 m, Ø = 0.2 mm,
- *stationary phase*: *poly(cyanopropyl)siloxane R* (film thickness 0.2 µm).

Carrier gas: *helium for chromatography R*.

Flow rate: 1 ml/min.

Split ratio: 1:40.