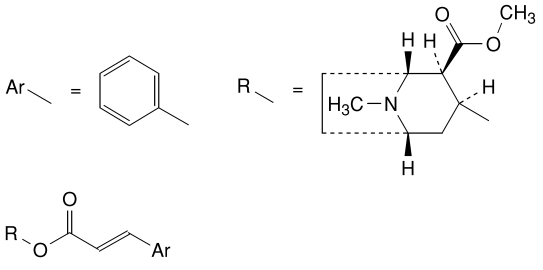
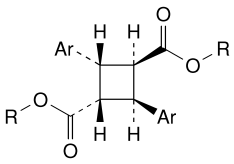
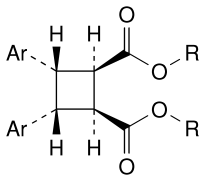
IMPURITIES



A. methyl (1*R*,2*R*,3*S*,5*S*)-8-methyl-3-[[(*E*)-3-phenylpropenoyl]oxy]-8-azabicyclo[3.2.1]octane-2-carboxylate (cinnamoylcocaine),



B. bis[(1*R*,2*R*,3*S*,5*S*)-2-(methoxycarbonyl)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl] (1*r*,2*c*,3*t*,4*t*)-2,4-diphenylcyclobutane-1,3-dicarboxylate (α-truxilline),



C. bis[(1*R*,2*R*,3*S*,5*S*)-2-(methoxycarbonyl)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl] (1*r*,2*c*,3*t*,4*t*)-3,4-diphenylcyclobutane-1,2-dicarboxylate (β-truxilline).

01/2008:1410

COCONUT OIL, REFINED

Cocois oleum raffinatum

[8001-31-8]

DEFINITION

Refined coconut oil is the fatty oil obtained from the dried, solid part of the endosperm of *Cocos nucifera* L., then refined.

CHARACTERS

A white or almost white, unctuous mass, practically insoluble in water, freely soluble in methylene chloride and in light petroleum (bp: 65 °C to 70 °C), very slightly soluble in alcohol.

The refractive index is about 1.449, determined at 40 °C.

IDENTIFICATION

A. It complies with the test for melting point (see Tests).

B. It complies with the test for composition of fatty acids (see Tests).

TESTS

Melting point (*2.2.14*): 23 °C to 26 °C.

Acid value (*2.5.1*). Not more than 0.5, determined on 20.0 g.

Peroxide value (*2.5.5*). Not more than 5.0.

Unsaponifiable matter (*2.5.7*). Not more than 1.0 per cent, determined on 5.0 g.

Alkaline impurities in fatty oils (*2.4.19*). It complies with the test for alkaline impurities in fatty oils.

Composition of fatty acids (*2.4.22, Method B*). Coconut oil is melted under gentle heating to a homogeneous liquid prior to sampling.

Reference solution. Dissolve 15.0 mg of *tricaproin CRS*, 80.0 mg of *tristearin CRS*, 0.150 g of *tricaprin CRS*, 0.200 g of *tricaprylin CRS*, 0.450 g of *trimyristin CRS* and 1.25 g of *trilaurin CRS* in a mixture of 2 volumes of *methylene chloride R* and 8 volumes of *heptane R* and dilute to 50 ml with the same mixture of solvents heating at 45 °C to 50 °C. Transfer 2 ml to a 10 ml centrifuge tube with a screw cap and evaporate the solvent in a current of *nitrogen R*. Dissolve with 1 ml of *heptane R* and 1 ml of *dimethyl carbonate R* and mix vigorously under gentle heating (50 °C to 60 °C). Add, while still warm, 1 ml of a 12 g/l solution of *sodium R* in *anhydrous methanol R*, prepared with the necessary precautions and mix vigorously for about 5 min. Add 3 ml of *distilled water R* and mix vigorously for about 30 s. Centrifuge for 15 min at 1500 *g*. Inject 1 µl of the organic phase.

Calculate the percentage content of each fatty acid using the following expression:

$$\frac{A_{\mathrm{x,s,c}}}{\sum A_{\mathrm{x,s,c}}} \times 100 \text{ per cent } m/m$$

$A_{x,s,c}$ is the corrected peak area of each fatty acid in the test solution:

$$A_{x,s,c} = A_{x,s} \times R_c$$

R_c is the relative correction factor:

$$R_c = \frac{m_{x,r} \times A_{1,r}}{A_{x,r} \times m_{1,r}}$$

for the peaks corresponding to caproic, caprylic, capric, lauric and myristic acid methyl esters.

$m_{x,r}$ = mass of tricaproin, tricaprylin, tricaprin, trilaurin or trimyristin in the reference solution, in milligrams,

$m_{1,r}$ = mass of tristearin in the reference solution, in milligrams,

$A_{x,r}$ = area of the peaks corresponding to caproic, caprylic, capric, lauric and myristic acid methyl esters in the reference solution,

$A_{1,r}$ = area of the peak corresponding to stearic acid methyl ester in the reference solution,

$A_{x,s}$ = area of peaks corresponding to any specified or unspecified fatty acid methyl esters,

R_c = 1 for peaks corresponding to each of the remaining specified fatty acid methyl esters or any unspecified fatty acid methyl ester.

The fatty acid fraction of the oil has the following composition:

– *caproic acid (R_{Rt} 0.11)*: not more than 1.5 per cent,

– *caprylic acid (R_{Rt} 0.23)*: 5.0 per cent to 11.0 per cent,

– *capric acid (R_{Rt} 0.56)*: 4.0 per cent to 9.0 per cent,

– *lauric acid (R_{Rt} 0.75)*: 40.0 per cent to 50.0 per cent,

– *myristic acid (R_{Rt} 0.85)*: 15.0 per cent to 20.0 per cent,

– *palmitic acid (R_{Rt} 0.93)*: 7.0 per cent to 12.0 per cent,

- *stearic acid (R_{Rt} 1.00)*: 1.5 per cent to 5.0 per cent,
- *oleic acid and isomers (R_{Rt} 1.01)*: 4.0 per cent to 10.0 per cent,
- *linoleic acid (R_{Rt} 1.03)*: 1.0 per cent to 3.0 per cent,
- *linolenic acid (R_{Rt} 1.06)*: not more than 0.2 per cent,
- *arachidic acid (R_{Rt} 1.10)*: not more than 0.2 per cent,
- *eicosenoic acid (R_{Rt} 1.11)*: not more than 0.2 per cent.

STORAGE

Store in a well-filled container, protected from light.

01/2008:1411

COCOYL CAPRYLOCAPRATE

Cocoylis caprylocapras

DEFINITION

Mixture of esters of saturated C_{12} - C_{18} alcohols with caprylic (octanoic) and capric (decanoic) acids obtained by the reaction of these acids with vegetable saturated fatty alcohols.

CHARACTERS

Appearance: slightly yellowish liquid.

Solubility: practically insoluble in water, miscible with ethanol (96 per cent) and with liquid paraffin.

Relative density: about 0.86.

Refractive index: about 1.445.

Viscosity: about 11 mPa·s.

IDENTIFICATION

A. Freezing point (*2.2.18*): maximum 15 °C.

B. Infrared absorption spectrophotometry (*2.2.24*).

Comparison: *cocoyl caprylocaprate CRS*.

C. Composition of fatty acids and fatty alcohols (see Tests).

TESTS

Appearance. The substance to be examined is not more intensely coloured than reference solution Y_5 (*2.2.2, Method I*).

Acid value (*2.5.1*): maximum 0.5, determined on 5.00 g.

Hydroxyl value (*2.5.3, Method A*): maximum 5.0.

Iodine value (*2.5.4, Method A*): maximum 1.0.

Saponification value (*2.5.6*): 160 to 173.

Composition of fatty acids and fatty alcohols (*2.4.22, Method C*). Use the chromatogram obtained with the following reference solution for identification of the peaks due to the fatty alcohols.

Reference solution. Dissolve the amounts of the substances listed in the following table in 10 ml of *heptane R*.

Substance	Amount (mg)
Methyl caproate R	10
Methyl caprylate R	90
Methyl caprate R	50
Methyl laurate R	20
Methyl myristate R	10
Methyl palmitate R	10
Methyl stearate R	10
Capric alcohol R	10
Lauryl alcohol R	100
Myristyl alcohol R	40
Cetyl alcohol CRS	30
Stearyl alcohol CRS	20

Consider the sum of the areas of the peaks due to the fatty acids listed below to be equal to 100 and the sum of the areas of the peaks due to the fatty alcohols listed below to be equal to 100.

Composition of the fatty acid fraction of the substance:

- *caproic acid*: maximum 2.0 per cent,
- *caprylic acid*: 50.0 per cent to 80.0 per cent,
- *capric acid*: 20.0 per cent to 50.0 per cent,
- *lauric acid*: maximum 3.0 per cent,
- *myristic acid*: maximum 2.0 per cent.

Composition of the fatty alcohol fraction of the substance:

- *capric alcohol*: maximum 3.0 per cent,
- *lauryl alcohol*: 48.0 per cent to 63.0 per cent,
- *myristyl alcohol*: 18.0 per cent to 27.0 per cent,
- *cetyl alcohol*: 6.0 per cent to 13.0 per cent,
- *stearyl alcohol*: 9.0 per cent to 16.0 per cent.

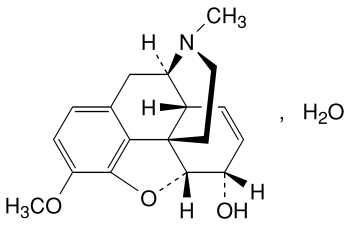
Water (*2.5.12*): maximum 0.1 per cent, determined on 5.00 g.

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

01/2008:0076
corrected 6.0

CODEINE

Codeinum



$C_{18}H_{21}NO_3,H_2O$ M_r 317.4

DEFINITION

7,8-Didehydro-4,5α-epoxy-3-methoxy-17-methylmorphinan-6α-ol.

Content: 99.0 per cent to 101.0 per cent (dried substance).