

Table 4 (Continued)

Name	Acceptance Criteria, NMT (%)
(R)-(+)-Limonene	2.0–15.0
Eucalyptol	70.0–95.0
Camphor	0.1

Percentage of γ -terpinene: 0.1%–6.0%

Percentage of *p*-cymene: 0.5%–15.0%

Total percentage of all identified aroma substances [(+)- α -pinene, β -pinene, sabinene, (R)-(-)- α -phellandrene, (R)-(+)-limonene, eucalyptol, camphor, β -myrcene, γ -terpinene, *p*-cymene, terpinen-4-ol, and α -terpineol]: NLT 98.0%

IMPURITIES

• TEST FOR ALDEHYDE

Alcoholic hydroxylamine solution: Dissolve 3.5 g of hydroxylamine hydrochloride in 95 mL of 60% alcohol (v/v) and add 0.5 mL of a 2-mg/mL solution of methyl orange in 60% alcohol (v/v) and sufficient 0.5 M potassium hydroxide in 60% alcohol (v/v) to give a pure yellow color. Dilute with 60% alcohol (v/v) to 100 mL.

Analysis: In a ground-glass-stoppered tube, 25 mm in diameter and 150 mm long, add 10 mL of Eucalyptus Oil. Then add 5 mL of toluene and 4 mL of *Alcoholic hydroxylamine solution*. Shake vigorously, and titrate immediately with 0.5 M potassium hydroxide in 60% alcohol (v/v) until the red color changes to yellow. Continue the titration with shaking; the endpoint is reached when the pure yellow color of the indicator is permanent in the lower layer after shaking vigorously for 2 min and allowing separation to take place. The reaction is complete in about 15 min.

Repeat the titration using a further 10 mL of Eucalyptus Oil and, as a reference solution for the endpoint, the titrated liquid from the first determination, to which has been added 0.5 mL of 0.5 M potassium hydroxide in 60% alcohol (v/v).

Acceptance criteria: NMT 2.0 mL of 0.5 M potassium hydroxide in 60% alcohol (v/v) is required in the second titration.

SPECIFIC TESTS

- **SPECIFIC GRAVITY** <841>: 0.906–0.927, at 20°
- **REFRACTIVE INDEX** <831>: 1.450–1.470, at 20°
- **OPTICAL ROTATION** <781>: 0°–10°, at 20°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. Do not store above 25°.
- **USP REFERENCE STANDARDS** <11>
 - USP Camphor RS
 - USP Eucalyptol RS
 - USP Eucalyptus Oil RS

▲NF35

Hard Fat

DEFINITION

Hard Fat is a mixture of glycerides of saturated fatty acids.

IMPURITIES

- **RESIDUE ON IGNITION** <281>: NMT 0.05%

• ALKALINE IMPURITIES

Sample: 2.0 g

Analysis: Dissolve the *Sample* in a mixture of 1.5 mL of alcohol and 3.0 mL of ether. Add 0.05 mL of bromophenol blue TS, and titrate with 0.01 N hydrochloric acid to a yellow endpoint.

Acceptance criteria: NMT 0.15 mL of 0.01 N hydrochloric acid

SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE**, *Class II* <741>: The melting temperature does not differ by more than 2° from the nominal value given in *Labeling*.
- **FATS AND FIXED OILS**, *Acid Value* <401>: NMT 1.0
- **FATS AND FIXED OILS**, *Hydroxyl Value* <401>: NMT 70
- **FATS AND FIXED OILS**, *Iodine Value* <401>: NMT 7.0
- **FATS AND FIXED OILS**, *Saponification Value* <401>: 215–255
- **FATS AND FIXED OILS**, *Unsaponifiable Matter* <401>: NMT 3.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers at a temperature that is 5° or more below the melting range stated in the labeling.
- **LABELING:** The labeling includes the nominal melting temperature, which is 27°–44°.

Fennel Oil

DEFINITION

Fennel Oil is the volatile oil distilled with steam from the dried, ripe fruit of *Foeniculum vulgare* Mill. (Fam. Apiaceae).

[NOTE—If solid material has separated, carefully warm the Fennel Oil until it is completely liquefied, and mix before using.]

IMPURITIES

Delete the following:

- **HEAVY METALS**, *Method II* <231>: NMT 40 $\mu\text{g/g}$ • (Official 1-Jan-2018)

SPECIFIC TESTS

- **SPECIFIC GRAVITY** <841>: 0.953–0.973
- **CONGEALING TEMPERATURE** <651>: NLT 3°
- **OPTICAL ROTATION**, *Angular Rotation* <781A>: +12° to +24°
- **REFRACTIVE INDEX** <831>: 1.528–1.538 at 20°
- **SOLUBILITY IN 90% ALCOHOL:** 1 volume dissolves in 1 volume of 90% alcohol.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** The label states the Latin binomial and, following the official name, the part of the plant source from which the article was derived. The label also states that if solid material has separated, carefully warm Oil until it is completely liquefied, and mix before using.

Ferric Oxide

DEFINITION

Ferric Oxide contains NLT 97.0% and NMT 100.5% of ferric oxide (Fe_2O_3), calculated on the ignited basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL**, *Iron* <191>

Sample solution: Dissolve 0.5 g in 50 mL of hydrochloric acid, and dilute with water to 200 mL.

Acceptance criteria: Meets the requirements of the test for *Ferric Salts*