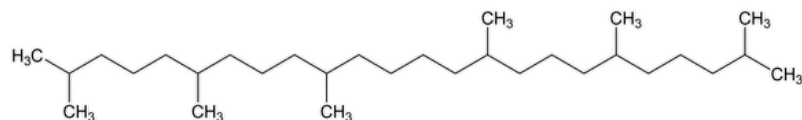


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Squalane



$C_{30}H_{62}$ 422.81

Tetracosane, 2,6,10,15,19,23-hexamethyl-;

2,6,10,15,19,23-Hexamethyltetracosane CAS RN®: 111-01-3.

DEFINITION

Squalane is a saturated hydrocarbon that contains NLT 97.0% and NMT 102.0% of 2,6,10,15,19,23-hexamethyltetracosane ($C_{30}H_{62}$). It is obtained either by hydrogenation of squalene, an aliphatic triterpene derived from certain fish oils, particularly shark liver oil, or from β -farnesene, a fermentation product of plant sugars.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F ▲](#) (CN 1-MAY-2020)

Sample: Undried specimen

Acceptance criteria: Meets the requirements

- **B. CHROMATOGRAPHIC IDENTITY**

Analysis: Proceed as directed in the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution*, excluding the solvent peak, corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**

Diluent: [n-Heptane](#)

System suitability solution: 4 mg/mL of [USP Squalane RS](#) and 4 μ L/mL of [methyl erucate](#) in *Diluent*

Standard solution: 4 mg/mL of [USP Squalane RS](#) in *Diluent*

Sample solution: 4 mg/mL of Squalane in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: GC

Detector: Flame ionization

Column: 0.32-mm $\times$ 30-m fused silica capillary; coated with a 1- μ m film of phase [G2](#)

Temperatures

Injection port: 275°

Detector: 300°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	5.9	290	11

Carrier gas: Helium

Flow rate: 1.7 mL/min

Injection volume: 1 µL

Injection type: Split; split ratio, 12:1

Liner: General purpose split/splitless liner with deactivated wool

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for methyl erucate and squalane are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5 between the peaks due to methyl erucate and squalane, *System suitability solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of squalane ($C_{30}H_{62}$) in the portion of Squalane taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of [USP Squalane RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Squalane in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0%

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#): 0.807–0.810 at 20°
- [FATS AND FIXED OILS \(401\), Procedures, Acid Value](#): NMT 0.2
- [FATS AND FIXED OILS, Iodine Value \(401\)](#): NMT 4
- [FATS AND FIXED OILS, Saponification Value \(401\)](#): NMT 2
- [REFRACTIVE INDEX \(831\)](#): 1.4510–1.4525 at 20°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label to indicate whether it is derived from animal or plant sources.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Squalane RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SQUALANE	Documentary Standards Support	CE2020 Complex Excipients