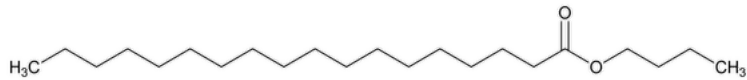


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Butyl Stearate



$C_{22}H_{44}O_2$ 340.59
Octadecanoic acid, butyl ester;
Butyl octadecanoate CAS RN[®]: 123-95-5.

DEFINITION

Butyl Stearate consists of the esters of butyl alcohol and fatty acids composed chiefly of stearic acid ($C_{18}H_{36}O_2$) and a minor amount of palmitic acid ($C_{16}H_{32}O_2$). It contains NLT 90.0% of butyl stearate [$C_{22}H_{44}O_2$ (M_w 340.59)], and the total of butyl stearate ($C_{22}H_{44}O_2$) and butyl palmitate [$C_{20}H_{40}O_2$ (M_w 312.53)] is NLT 96.0%.

IDENTIFICATION

- **A.** It meets the requirements of the test for *Content of Butyl Palmitate and Butyl Stearate*.

ASSAY

• **CONTENT OF BUTYL PALMITATE AND BUTYL STEARATE**

Standard solution A: 2.0 mg/mL of [USP Butyl Stearate RS](#) in chloroform
Standard solution B: 0.2 mg/mL of [USP Butyl Palmitate RS](#) in chloroform
System suitability solution: 1.4 µg/mL of [USP Butyl Stearate RS](#) and 1.0 µg/mL of [USP Butyl Palmitate RS](#) in chloroform, prepared from *Standard solution A*, *Standard solution B*, and chloroform
Sample solution: 2.0 mg/mL of Butyl Stearate in chloroform
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)

Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 30-m capillary; bonded with a 0.25-µm layer of thickness of phase G27
Temperatures
Detector: 280°
Injection port: 280°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	—	60	2
60	4	250	20.5

Carrier gas: Helium
Flow rate: 1.4 mL/min
Injection volume: 1 µL
Injection type: Split injection, split ratio is 5:1.

System suitability

Samples: *System suitability solution* and *Standard solution A*
[NOTE—The relative retention times for butyl palmitate and butyl stearate are 0.91 and 1.00, respectively.]

System suitability requirements

Resolution: NLT 20 between butyl palmitate and butyl stearate, *System suitability solution*

Tailing factor: NMT 2.0 for the butyl stearate peak, *System suitability solution*

Relative standard deviation: NMT 3.0% for the butyl stearate peak, *Standard solution A*

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Identify the butyl palmitate and butyl stearate peaks in the *Sample solution* based on those in *Standard solution A* and *Standard solution B*.

Calculate the percentage of butyl palmitate or butyl stearate in the portion of Butyl Stearate taken:

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

r_U = peak response of butyl palmitate or butyl stearate from the *Sample solution*

r_S = peak response of butyl palmitate from *Standard solution B* or peak response of butyl stearate from *Standard solution A*

C_S = concentration of [USP Butyl Palmitate RS](#) in *Standard solution B* or concentration of [USP Butyl Stearate RS](#) in *Standard solution A*

C_U = concentration of Butyl Stearate in the *Sample solution*

Acceptance criteria: NLT 90.0% of butyl stearate and NLT 96.0% for the sum of butyl stearate and butyl palmitate

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE, Class II\(741\)](#): 19°–24°
- [FATS AND FIXED OILS, Acid Value\(401\)](#): NMT 0.5
- [FATS AND FIXED OILS, Iodine Value\(401\)](#): NMT 1.0
- [FATS AND FIXED OILS, Saponification Value\(401\)](#): 165–180
- [WATER DETERMINATION, Method Ia\(921\)](#): NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at room temperature. Keep away from heat and sources of ignition.
- [USP REFERENCE STANDARDS \(11\)](#)
 - [USP Butyl Palmitate RS](#)
 - [USP Butyl Stearate RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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