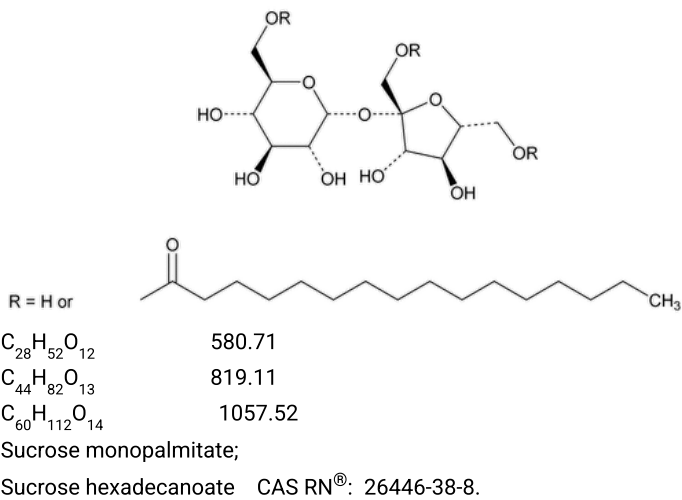


Sucrose Palmitate



DEFINITION

Sucrose Palmitate is a mixture of sucrose monoesters, mainly sucrose monopalmitate, obtained by transesterification of palmitic acid methyl esters of vegetable origin with sucrose. The manufacture of the fatty acid methyl esters includes a distillation step. It contains variable quantities of mono- and diesters as set forth in the following table:

Content of Monoesters (%)	Content of Diesters (%)	Sum of Triesters and Polyesters (%)
NLT 55.0	NMT 40.0	NMT 20.0

IDENTIFICATION

- **A.** It meets the requirements of the *Fatty Acid Composition* test.
- **B.** It meets the requirements of the *Content of Monesters, Diesters, Triesters, and Polyesters*.

ASSAY

• **CONTENT OF MONOESTERS, DIESTERS, TRIESTERS, AND POLYESTERS**

Mobile phase: Tetrahydrofuran
Sample solution: 15 mg/mL of Sucrose Palmitate in tetrahydrofuran
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC, size-exclusion
Detector: Differential refractometer
Column: 7-mm × 60-cm; packing L21, 100 Å
[NOTE—Two 7-mm × 30-cm L21 columns may be used in place of one 60-cm column, provided system suitability requirements are met.]
Flow rate: 1.2 mL/min
Injection size: 20 µL
Analysis
Sample: Sample solution

[NOTE—The relative retention time with reference to the monoester peak (retention time is approximately 10 min) is about 0.92 for diesters, and about 0.90 for triesters and polyesters.]

[NOTE—Disregard solvent peaks and peaks having a signal-to-noise ratio less than 10.]

Calculate the percentage of monoesters in the portion of Sucrose Palmitate taken:

$$\text{Result} = A \times (100 - D - S - E)/100$$

A = percentage of monoesters determined by peak normalization

D = percentage of free fatty acids, using the following formula:

$$\text{Result} = AV \times 256/561.1$$

AV = acid value

S = percentage of free sucrose (see *Free Sucrose* in *Organic Impurities*)

E = percentage of water (see *Water Determination, Ia* in *Specific Tests*)

Calculate the percentage of diesters in the portion of Sucrose Palmitate taken:

$$\text{Result} = B \times (100 - D - S - E)/100$$

B = percentage of diesters determined by peak normalization

D = percentage of free fatty acids (above)

S = percentage of free sucrose (see *Free Sucrose* in *Organic Impurities*)

E = percentage of water (see *Water Determination, Ia* in *Specific Tests*)

Calculate the percentage of triesters and polyesters in the portion of Sucrose Palmitate taken:

$$\text{Result} = C \times (100 - D - S - E)/100$$

C = percentage of triesters and polyesters determined by peak normalization

D = percentage of free fatty acids (above)

S = percentage of free sucrose (see *Free Sucrose* in *Organic Impurities*)

E = percentage of water (see *Water Determination, Ia* in *Specific Tests*)

• **FATTY ACID COMPOSITION:** Sucrose Palmitate exhibits the following composition profiles of fatty acids, as determined under [Fats and Fixed Oils, Fatty Acid Composition \(401\)](#).

Fatty Acid	Percentage (%)
Lauric acid	NMT 3.0
Myristic acid	NMT 3.0
Palmitic acid	70.0–85.0
Stearic acid	10.0–25.0
Sum of the contents of palmitic acid and stearic acid	NLT 90.0

IMPURITIES

Change to read:

Inorganic Impurities

- **FATS AND FIXED OILS, Acid Value (401):** NMT 6.0 ▲ (ERR 1-May-2020), determined on a 3-g sample. Use a freshly neutralized mixture of 2-propanol and water (2:1), and gently heat.

Organic Impurities