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## Emulsifying Wax

### Add the following:

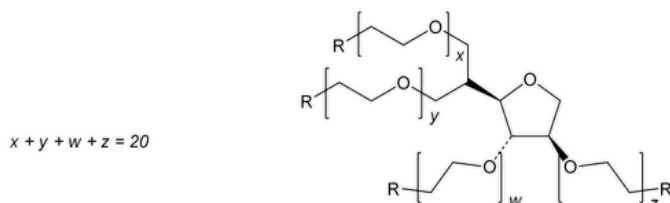
▲



▲ (NF 1-Aug-2023)

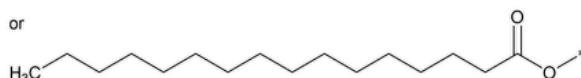


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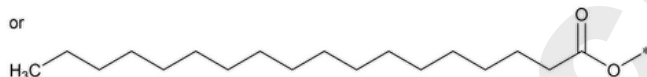


R = HO—\*

or



or



▲ (NF 1-Aug-2023)

### DEFINITION

Emulsifying Wax is a waxy solid prepared from cetostearyl alcohol containing a polyoxyethylene derivative of a fatty acid ester of sorbitan.

### Add the following:

#### IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197A or 197F

**Sample:** Use a thin film of melted test specimen when performing 197F.

**Acceptance criteria:** Meets the requirements

- **B.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils \(401\)](#), [Procedures, Fatty Acid Composition](#). ▲ (NF 1-Aug-2023)

### SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE** (741)

**Sample:** Emulsifying Wax

**Analysis:** Melt a quantity of the *Sample* slowly, while stirring, until it reaches a temperature of 90°–92°. Remove the source of the heat, and allow the molten substance to cool to a temperature of 8°–10° above the expected melting point. Chill the bulb of a suitable thermometer (see [General Notices, 6.80.30. Temperature Reading Devices](#)) to 5°, wipe it dry, and while it is still cold, dip it into the molten substance so that the bulb is completely covered. Withdraw it immediately, and hold it vertically away from the heat until the surface dulls. Fix the thermometer securely in a test tube so that the lower point is 15 mm from the bottom of the test tube. Place the test tube in a water bath at 10°–15°, and allow it to remain at that temperature for 30 min. Raise the temperature of the bath at the rate of 2°/min to 30°, then change to a rate of 1°/min, and note the temperature at which the first drop of melted substance leaves the thermometer. Repeat the determination twice on a freshly melted portion of the sample substance. If the variation of three determinations is less than 1°, take the average of the three as the melting point. Otherwise, make two additional determinations, and take the average of the five.

**Acceptance criteria:** 50°–54°

**Add the following:**

- ▲ [FATS AND FIXED OILS \(401\), Procedures, Fatty Acid Composition](#)

**Analysis**

Calculate the percentage of each fatty acid methyl ester component in the test specimen:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$  = peak area of each individual fatty acid ester component from the *Test solution* (see [Table 1](#))

$r_T$  = sum of the peak areas of the fatty acid methyl esters (methyl myristate, methyl palmitate, methyl stearate) in the chromatogram from the *Test solution*

**Table 1**

Component	Relative Retention Time
Methyl Myristate	0.9
Methyl Palmitate	1.0
Methyl Stearate	1.1

**Acceptance criteria**

**For stearic acid:** 40.0%–60.0%

**Sum of stearic acid and palmitic acid:** NLT 90.0%▲ (NF 1-Aug-2023)

- [FATS AND FIXED OILS \(401\), Procedures, Hydroxyl Value](#): 178–192
- [FATS AND FIXED OILS \(401\), Procedures, Iodine Value](#): NMT 3.5
- [FATS AND FIXED OILS \(401\), Procedures, Saponification Value](#): NMT 14
- [pH \(791\)](#)

**Sample dispersion:** Heat 3 g of Emulsifying Wax in 100 mL of water to 55°, with stirring, followed by cooling to 25°.

**Acceptance criteria:** 5.5–7.0

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

**Add the following:**

- ▲ [USP REFERENCE STANDARDS \(11\)](#)

[USP Emulsifying Wax RS](#)▲ (NF 1-Aug-2023)

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

Topic/Question	Contact	Expert Committee
EMULSIFYING WAX	<a href="#">Documentary Standards Support</a>	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	CE2020 Complex Excipients

**Chromatographic Database Information:** [Chromatographic Database](#)

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