V_S = volume of *Titrant* consumed by the *Sample* (mL)
V_B = volume of *Titrant* consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 144.1 mg/mEq
W = weight of the *Sample* (mg)

Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES

• **HEAVY METALS** ⟨**231**⟩
Test preparation: 4.0 g in 40 mL of water
Analysis: To the *Test preparation* add dropwise with vigorous stirring 10 mL of 3 N hydrochloric acid, and filter. Use 25 mL of the filtrate.
Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS

• **WATER DETERMINATION,** *Method I* ⟨**921**⟩**:** NMT 1.5%
• **ALKALINITY**
Sample solution: 2 g in 20 mL of hot water
Analysis: To the *Sample solution* add 2 drops of phenolphthalein TS.
Acceptance criteria: The pink color produced, if any, is discharged by the addition of 0.20 mL of 0.10 N sulfuric acid.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.
• **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Sodium Benzoate RS

Sodium Bicarbonate—*see Sodium Bicarbonate General Monographs*

Sodium Borate

$Na_2B_4O_7 \cdot 10H_2O$ 381.37
$Na_2B_4O_7$ 201.22
Borax [1303-96-4].
Anhydrous [1330-43-4].

DEFINITION

Sodium Borate contains an amount of $Na_2B_4O_7$ equivalent to NLT 99.0% and NMT 105.0% of $Na_2B_4O_7 \cdot 10H_2O$.

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL,** *Sodium* ⟨**191**⟩
Sample solution: 1 in 20
Acceptance criteria: Meets the requirements
• **B. IDENTIFICATION TESTS—GENERAL,** *Borate* ⟨**191**⟩
Sample solution: 1 in 20
Acceptance criteria: Meets the requirements

ASSAY

• **PROCEDURE**
Sample: 3 g of Sodium Borate
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.5 N hydrochloric acid VS
Blank: 50 mL of water
Endpoint detection: Visual
Analysis: Dissolve the *Sample* in 50 mL of water, add methyl red TS, and titrate with 0.5 N hydrochloric acid VS. [NOTE—Heating on a steam bath may be required initially to effect solution.]

Calculate the percentage of sodium borate ($Na_2B_4O_7 \cdot 10H_2O$) in the *Sample* taken:

$$\text{Result} = [(V - B) \times N \times F] \times 100/W$$

V = volume of *Titrant* consumed by the *Sample* (mL)
B = volume of *Titrant* consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 190.7 mg/mEq
W = weight of the *Sample* (mg)

Acceptance criteria: 99.0%–105.0%

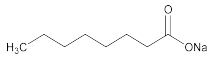
IMPURITIES

• **HEAVY METALS** ⟨**231**⟩
Test preparation: Dissolve 1 g in 16 mL of water and 6 mL of 1 N hydrochloric acid. Dilute with water to 25 mL.
Acceptance criteria: NMT 20 ppm
• **CARBONATE AND BICARBONATE**
Sample solution: To 5 mL of a solution (1 in 20), contained in a test tube, add 1 mL of 3 N hydrochloric acid.
Acceptance criteria: No effervescence is observed.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

Sodium Caprylate



$C_8H_{15}NaO_2$ 166.20
Sodium octanoate [1984-06-1].

» Sodium Caprylate contains not less than 99.0 percent and not more than 101.0 percent of $C_8H_{15}NaO_2$, calculated on the anhydrous basis.

USP Reference standards ⟨11⟩**—**
USP Caprylic Acid RS

Appearance of solution—Dissolve 2.5 g of Sodium Caprylate in 25.0 mL of freshly boiled and cooled water: the resulting solution is clear and colorless, and if not, not more intensely colored than a reference solution prepared as follows:

Reference stock solution—Pipet 30.0 mL of ferric chloride CS, 30.0 mL of cobaltous chloride CS, and 24.0 mL of cupric sulfate CS into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume, and mix.

Reference solution—Pipet 1.0 mL of the *Reference stock solution* into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume, and mix.

Identification—

A: The retention time of the major peak in the chromatogram of *Test solution 1* corresponds to that in the chromatogram of the *Reference solution,* as obtained in the test for *Chromatographic purity.*

B: Proceed as directed below.

Methoxyphenylacetic reagent—Dissolve 2.7 g of methoxyphenylacetic acid in 6 mL of 10% tetramethylammonium hydroxide solution in methanol, and add 20 mL of alcohol. Store in a polyethylene container.

Procedure—Dissolve about 20 mg of Sodium Caprylate in 0.5 mL of water, add 1.5 mL of *Methoxyphenylacetic reagent,* and cool in ice water for 30 minutes. A voluminous, white, crystalline precipitate is formed. Place in water at 20°, and stir for 5 minutes. The precipitate does not disappear. Add 1 mL of ammonia TS. The precipitate dissolves completely. Add 1 mL of ammonium carbonate solution (16 in 100): no precipitate is formed.

pH ⟨791⟩**:** between 8.0 and 10.5, in a solution obtained in the test for *Appearance of solution.*

Water, *Method I* ⟨921⟩**:** not more than 3.0%.

Heavy metals, *Method II* ⟨231⟩**—**Dissolve 2.0 g of Sodium Caprylate in 10 mL of glacial acetic acid, add 10 mL of alcohol, and use 12 mL of the solution obtained as the *Test Preparation.* Prepare the *Standard Preparation* using 1 mL of *Standard Lead Solution* and 9 mL of a mixture of glacial acetic acid and alcohol (1:1). The limit is 5 µg per g.

Chromatographic purity—

Reference solution—Transfer 10 mg of USP Caprylic Acid RS to a 10-mL volumetric flask, and dilute with ethyl acetate to volume.

Test solution 1—Dissolve 116 mg of Sodium Caprylate in 5 mL of water, add 1 mL of dilute sulfuric acid (1 in 35), and extract with 10 mL of ethyl acetate. Separate the organic layer, and dry it over anhydrous sodium sulfate.

Test solution 2—Dilute 1.0 mL of *Test solution 1* with ethyl acetate to 100 mL, transfer 5.0 mL of the solution obtained, and dilute with ethyl acetate to 50 mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector, a split injection system with a split ratio of about 1:100, and a 0.25-mm × 30-m fused silica column coated with a 0.25-µm layer of phase G25. The carrier gas is helium, flowing at a rate of 1.5 mL per minute. The chromatograph is programmed as follows. Initially the temperature of the column is equilibrated at 100°, then 1 minute after the injection, the temperature is increased at a rate of 5° per minute to 220°, and maintained at 220° for another 10 minutes. The injection port temperature and the detector temperature are maintained at 250°. Chromatograph *Test solution 2,* and record the peak responses as directed for *Procedure:* the signal-to-noise ratio of the principal peak is not less than 5.

Procedure—Separately inject equal volumes (about 1 µL) of the *Reference solution, Test solution 2,* and *Test solution 1* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Disregard any peaks with an area less than half of the area of the principal peak from *Test solution 2,* and any peak due to the solvent. Calculate the percentage of each impurity in the portion of Sodium Caprylate taken by the formula:

$$100(r_i / r_s)$$

in which r_i is the peak response of the individual impurity, and r_s is the sum of the responses of all the peaks: not more than 0.3% of any impurity is found, and the sum of all the impurities found is not greater than 0.5%.

Assay—Transfer an accurately weighed quantity of about 150 mg of Sodium Caprylate to a 125-mL volumetric flask, dissolve in 50 mL of glacial acetic acid, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 16.62 mg of $C_8H_{15}NaO_2$.

Sodium Carbonate

Na_2CO_3 (anhydrous) 105.99

$Na_2CO_3 \cdot H_2O$ 124.00

Carbonic acid, disodium salt;
Disodium carbonate [497-19-8].
Monohydrate [5968-11-6].

DEFINITION

Sodium Carbonate is anhydrous or contains one molecule of water of hydration. It contains NLT 99.5% and NMT 100.5% of Na_2CO_3, calculated on the anhydrous basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Sodium* ⟨**191**⟩**:** Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL,** *Carbonate* ⟨**191**⟩**:** Meets the requirements

ASSAY

- **PROCEDURE**

Sample: 2 g of Sodium Carbonate, previously dried, from the test for *Water Determination*

Blank: 50 mL of water

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 1 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a flask with the aid of 50 mL of water. Add methyl red TS, and titrate with 1 N sulfuric acid VS. Add the acid slowly, with constant stirring, until the solution becomes faintly pink. Heat the solution to boiling, cool, and continue the titration. Heat again to boiling, and titrate further as necessary until the faint pink color is no longer affected by continued boiling.

Calculate the percentage of sodium carbonate (Na_2CO_3) in the *Sample* taken.

$$\text{Result} = [(V - B) \times N \times F \times 100]/W$$

V = *Titrant* volume consumed by the *Sample* (mL)
B = *Titrant* volume consumed by the *Blank* (mL)
N = *Titrant* actual normality (mEq/mL)
F = equivalency factor, 52.99 mg/mEq
W = weight of the *Sample* (mg)

Acceptance criteria: 99.5%–100.5% on the anhydrous basis

IMPURITIES

- **HEAVY METALS** ⟨**231**⟩

Test preparation: Dissolve 2.0 g in 10 mL of water.

Analysis: Add 1 drop of phenolphthalein TS to the *Test preparation*, and neutralize the solution with hydrochloric acid, added dropwise. Heat the solution to boiling, and again neutralize by the dropwise addition of hydrochloric acid. Cool, and dilute with water to 25 mL. Proceed as directed in the chapter.

Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS

- **WATER DETERMINATION,** *Method III* ⟨**921**⟩

Sample: 2 g

Analysis: Dry the *Sample* at 105° for 4 h.

Acceptance criteria: The anhydrous form loses NMT 0.5% of its weight, and the hydrous form loses 12.0%–15.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label it to indicate whether it is anhydrous or hydrous.

Sodium Cetostearyl Sulfate

» Sodium Cetostearyl Sulfate is a mixture of sodium cetyl sulfate and sodium stearyl sulfate. It contains not less than 40.0 percent of sodium cetyl sulfate ($C_{16}H_{33}NaSO_4$), and the sum of the sodium cetyl sulfate content and sodium stearyl sulfate ($C_{18}H_{37}NaSO_4$) content is not less than 90.0 percent (both contents calculated on the anhydrous basis). It may contain a suitable buffer.