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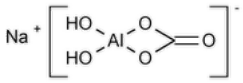
Dihydroxyaluminum Sodium Carbonate



$NaAl(OH)_2CO_3$ 143.99

Aluminum, [carbonato(1-)-*O*]dihydroxy-, monosodium salt;

Sodium (*T*-4)-[carbonato(2-)-*O*,*O*']dihydroxyaluminate(1-);

Sodium (carbonato)dihydroxyaluminate(1-) CAS RN®: 539-68-4; .16482-55-6.

DEFINITION

Dihydroxyaluminum Sodium Carbonate contains NLT 98.3% and NMT 107.9% of dihydroxyaluminum sodium carbonate [$NaAl(OH)_2CO_3$], calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample solution: Combine 1 g with 20 mL of 3 N hydrochloric acid.

Acceptance criteria: The sample dissolves with effervescence.

• **B.** **Identification Tests—General, *Aluminum* ⟨191⟩**

Sample: *Sample solution* prepared in *Identification* test *A*

Acceptance criteria: Meets the requirements

• **C.** The *Sample solution*, prepared and tested as directed in the test for *Sodium Content*, exhibits a significant absorption at the sodium emission line at 589.0 nm.

ASSAY

• **Procedure**

Edetate disodium titrant: Dissolve 18.6 g of edetate disodium in water to make 500 mL, and standardize as directed in *Reagents, Volumetric Solutions, Edetate Disodium, Twentieth-Molar (0.05 M)*.

Sample: 300 mg undried

Analysis: Transfer the *Sample* to a 250-mL beaker, add 10 mL of 2 N sulfuric acid, cover the beaker, heat to 80° for 5 min, and boil for 1 min. Add 30.0 mL of 0.1 M edetate disodium VS, again boil for 1 min, cool, and then add 10 mL of acetic acid–ammonium acetate buffer TS, 50 mL of acetone, and 2 mL of dithizone TS. Using a pH meter, adjust with the addition of ammonium hydroxide or dilute sulfuric acid to a pH of 4.5. Titrate with 0.05 M zinc sulfate VS, maintaining the pH of 4.5 by the addition of ammonium hydroxide as necessary, to an orange-pink color. Perform a blank determination, and make any necessary correction. Each mL of 0.1 M *Edetate disodium titrant* is equivalent to 14.40 mg of dihydroxyaluminum sodium carbonate [$NaAl(OH)_2CO_3$].

Acceptance criteria: 98.3%–107.9% on the dried basis

IMPURITIES

Change to read:

• ▲**Mercury ⟨261⟩, *Procedures, Procedure 2*▲** (CN 1-Jun-2023)

Sample solution: 2.0 g in 35 mL of 1 N sulfuric acid

Acceptance criteria: NMT 1 ppm

• **Isopropyl Alcohol**

Isopropyl alcohol-free dihydroxyaluminum sodium carbonate: Use a portion of Dihydroxyaluminum Sodium Carbonate that has been previously tested as directed in this section and found to be free of isopropyl alcohol.

Sodium chloride solution: 0.2 g/mL in water

Standard stock solution: 20 mg/mL of isopropyl alcohol in *Sodium chloride solution*

Standard solution A: 0.4 mg/mL of isopropyl alcohol in *Sodium chloride solution* from *Standard stock solution*

Standard solution B: 0.8 mg/mL of isopropyl alcohol in *Sodium chloride solution* from *Standard stock solution*

Standard solution C: 1.0 mg/mL of isopropyl alcohol in *Sodium chloride solution* from *Standard stock solution*

Standard solution D: 1.2 mg/mL of isopropyl alcohol in *Sodium chloride solution* from *Standard stock solution*

Headspace containers: Use suitable 20-mL containers capable of being tightly closed with an inert septum and a metallic crimp cap.

Standard preparations: To four separate 20-mL *Headspace containers*, add 1.0 g of *Isopropyl alcohol-free dihydroxyaluminum sodium carbonate*. To the containers add, respectively, 10.0 mL of the appropriate *Standard solution*. These containers contain about 4, 8, 10, and 12 mg of isopropyl alcohol, respectively. [Note—Keep the containers cool until sealed.] Seal the containers, place in a water bath maintained at 70°, and allow to stand for 1 h.

Sample preparation: Transfer 1.0 g of the Dihydroxyaluminum Sodium Carbonate to a *Headspace container*, and add 10.0 mL of *Sodium chloride solution*. [Note—Keep the container cool until sealed.] Seal the container, place in a water bath maintained at 70°, and allow to stand for 1 h.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.9-m × 3-mm; packed with support S3

Temperatures

Column: 180°

Injection port: 200°

Detector: 250°

Injection volume: 1 mL of gaseous phase

System suitability

Samples: *Standard preparations* containing 10 mg per container

Suitability requirements

Relative standard deviation: NMT 4% for replicate injections

Analysis

Samples: *Standard preparations* and *Sample preparation*

[Note—Use peak areas where peak responses are indicated.]

Using a gas-tight syringe, separately inject equal volumes of the gaseous headspace of the *Standard preparations* and the *Sample preparation* into the gas chromatograph. Record the chromatograms, and measure the peak responses. Determine, based on a retention time comparison, if isopropyl alcohol is detected in the *Sample preparation*. Plot the responses of the *Standard preparations* versus the content, in mg, of isopropyl alcohol in each container, draw the straight line best fitting the plotted points, and calculate the correlation coefficient for the line. A suitable system is one that yields a line having a correlation coefficient of NLT 0.99. From the graph, determine the total amount, T_U, in mg, of isopropyl alcohol in the *Sample preparation*.

Calculate the percentage of isopropyl alcohol in the Dihydroxyaluminum Sodium Carbonate taken:

$$\text{Result} = 0.1 \times (T_U / W_U)$$

T_U = total amount of isopropyl alcohol in the *Sample preparation* (mg)

W_U = weight of the Dihydroxyaluminum Sodium Carbonate taken (g)

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

- **Sodium Content**

Potassium chloride solution: 38 mg/mL of potassium chloride in water

Sodium chloride stock solution: 25.42 µg/mL of sodium chloride in water (10.0 µg/mL of sodium) from sodium chloride previously dried at 105° for 2 h

Standard solution A: 0.5 µg/mL of sodium from *Sodium chloride stock solution* prepared as follows. On the day of use, transfer 4.0 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* to a 100-mL volumetric flask. Add 5.0 mL of *Sodium chloride stock solution* and dilute with water to volume.

Standard solution B: 1.0 µg/mL of sodium from *Sodium chloride stock solution* prepared as follows. On the day of use, transfer 4.0 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* to a 100-mL volumetric flask. Add 10.0 mL *Sodium chloride stock solution* and dilute with water to volume.

Sample solution: Transfer 250 mg of Dihydroxyaluminum Sodium Carbonate, previously dried, to a 200-mL volumetric flask. Add 40 mL of 1 N hydrochloric acid, and boil for 1 min. Cool, and dilute with water to volume. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, and dilute with water to volume. Transfer 5.0 mL of this solution to a 100-mL volumetric flask containing 4.0 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution*, and dilute with water to volume.

Blank solution: Pipet 4 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* into a 100-mL volumetric flask, and dilute with water to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Analytical wavelength: Sodium emission line at 589.0 nm

Lamp: Sodium hollow-cathode

Flame: Air–acetylene

Blank: *Blank solution*

Analysis

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

Plot the absorbances of the *Standard solutions* versus the concentrations, in µg/mL of sodium, and draw a straight line between the plotted points. From the graph so obtained, determine the concentration, *C*, in µg/mL of sodium in the *Sample solution*.

Calculate the percentage of sodium in the portion of Dihydroxyaluminum Sodium Carbonate taken:

$$\text{Result} = 4000 \times (C/W)$$

C = concentration of sodium in the *Sample solution* (µg/mL)

W = weight of Dihydroxyaluminum Sodium Carbonate taken (mg)

Acceptance criteria: 15.2%–16.8%

- **Acid-Neutralizing Capacity** ⟨301⟩

Sample: 425 mg of undried material

Analysis: Proceed as directed using the *Sample*. Each mg of dihydroxyaluminum sodium carbonate [$NaAl(OH)_2CO_3$] has an expected acid-neutralizing capacity of 0.0278 mEq.

Acceptance criteria: NLT 75.0% of the expected mEq value, calculated in relation to the results of the *Assay*

- **pH** ⟨791⟩**:** 9.9–10.2 in a suspension (1 in 25)
- **Loss on Drying** ⟨731⟩

Sample: Dry at 130° to constant weight.

Acceptance criteria: NMT 14.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DIHYDROXYALUMINUM SODIUM CARBONATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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