Aluminum Chlorohydrex Propylene Glycol

$Al_y(OH)_{3y-z}Cl_z \cdot nH_2O \cdot mC_3H_8O_2$
$Al_2(H_2O)_{y-z}(OH)_{6-n}(Cl)_n(C_3H_8O_2)_z$
Aluminum chlorohydroxide, hydrate: propylene glycol complex (1:1).
Aluminum hydroxychloride, hydrate: propylene glycol complex (1:1) [53026-85-0].

» Aluminum Chlorohydrex Propylene Glycol is a complex of aluminum chlorohydrate and propylene glycol in which some of the waters of hydration of the aluminum chlorohydrate have been replaced by propylene glycol. It contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of anhydrous aluminum chlorohydrate.

Packaging and storage—Preserve in well-closed containers.

Labeling—The label states the content of anhydrous aluminum chlorohydrate.

Identification—

A: A solution (1 in 10) responds to the tests for *Aluminum* ⟨191⟩ and for *Chloride* ⟨191⟩.

B: *Infrared Absorption* ⟨197F⟩—

Test specimen—Dissolve 0.5 g in about 40 mL of water, and while mixing adjust with 2.5 N sodium hydroxide to a pH of 9.55 ± 0.05. Filter the suspension of precipitate thus obtained. Evaporate about 15 mL of the filtrate to about 1 mL on a hot plate. Deposit this solution on a silver chloride disk.

Standard specimen: a similar preparation of propylene glycol.

pH ⟨791⟩: between 3.0 and 5.0, in a solution [15 in 100 (w/w)].

Arsenic, *Method I* ⟨211⟩: 2 µg per g.

Delete the following:

•Heavy metals, *Method I* ⟨231⟩: 20 µg per g.• (Official 1-Jan-2018)

Limit of iron—Using Aluminum Chlorohydrex Propylene Glycol instead of Aluminum Chlorohydrate, proceed as directed in the test for *Limit of iron* under *Aluminum Chlorohydrate*. The limit is 150 µg per g.

Content of aluminum—

Edetate disodium titrant—Prepare and standardize as directed in the *Assay* under *Ammonium Alum*, except to use 37.2 g of edetate disodium instead of 18.6 g.

Test solution—Transfer about 1.6 g of Aluminum Chlorohydrex Propylene Glycol, accurately weighed, to a 100-mL beaker, add 15 to 20 mL of water and 5 to 6 mL of hydrochloric acid, and boil on a hot plate for 15 to 20 minutes. Cool the solution, and with the aid of water transfer to a 100-mL volumetric flask. Dilute with water to volume, and mix.

Procedure—Transfer 5.0 mL of the *Test solution* to a 250-mL beaker, add 10 to 15 mL of water, and adjust with 1 N sodium hydroxide to a pH of 1.5 ± 0.5. Add 10.0 mL of *Edetate disodium titrant*, and heat to boiling. Cool the solution and carefully introduce a magnetic stirring bar into the beaker. Add 10 to 15 mL of acetic acid–ammonium acetate buffer TS, 40 to 50 mL of alcohol, and while stirring adjust with glacial acetic acid to a pH of 4.6 ± 0.1. Add 1 to 2 mL of dithizone TS and 40 to 50 mL of alcohol, and titrate with 0.1 M zinc sulfate VS until the color changes from a green-violet to a rose-pink. Perform a blank titration, and make any necessary correction. Each mL of 0.1 M *Edetate disodium titrant* consumed is equivalent to 2.698 mg of aluminum (Al). Use the aluminum content thus obtained to calculate the *Aluminum/chloride atomic ratio*.

Content of chloride—Using Aluminum Chlorohydrex Propylene Glycol instead of Aluminum Chlorohydrate, proceed as directed in the test for *Content of chloride* under *Aluminum Chlorohydrate*. Use the chloride content thus obtained to calculate the *Aluminum/chloride atomic ratio*.

Aluminum/chloride atomic ratio—Divide the percentage of aluminum found in the *Assay* by the percentage of chloride found in the test for *Content of chloride*, and multiply by 35.453/26.98, in which 35.453 and 26.98 are the atomic weights of chlorine and aluminum, respectively: the ratio is between 1.91:1 and 2.1:1.

Assay—Calculate the percentage of anhydrous aluminum chlorohydrate in the Aluminum Chlorohydrex Propylene Glycol by the formula:

$$Al(\{26.98x + [17.01(3x - 1)] + 35.453\} / 26.98x)$$

in which *Al* is the percentage of aluminum found in the test for *Content of aluminum*, *x* is the aluminum/chloride atomic ratio, 26.98 is the atomic weight of aluminum, 17.01 is the molecular weight of the hydroxide ion (OH), and 35.453 is the atomic weight of chlorine (Cl).

Aluminum Dichlorohydrate

$Al_y(OH)_{3y-z}Cl_z \cdot nH_2O$
Aluminum chlorohydroxide;
Aluminum hydroxychloride.

DEFINITION

Aluminum Dichlorohydrate consists of complex basic aluminum chloride that is polymeric and loosely hydrated and encompasses a range of aluminum-to-chloride atomic ratios between 0.90: 1 and 1.25: 1. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of anhydrous aluminum dichlorohydrate [$Al_y(OH)_{3y-z}Cl_z$].

IDENTIFICATION

• **A. Identification Tests—General,** *Aluminum* ⟨191⟩ and *Chloride* ⟨191⟩
Sample solution: 100 mg/mL
Acceptance criteria: Meets the requirements

ASSAY

• **Procedure 1: Content of Chloride**
Sample: 700 mg
Titrimetric system
Mode: Direct titration
Titrant: 0.1 N silver nitrate VS
Electrode system: A glass silver–silver chloride electrode and a silver billet electrode system
Endpoint detection: Potentiometric
Analysis: Transfer the *Sample* to a 250-mL beaker, and add 100 mL of water and 10 mL of diluted nitric acid with stirring. Titrate with *Titrant*, and determine the endpoint potentiometrically. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride (Cl). Use the chloride content thus obtained to calculate the aluminum:chloride atomic ratio.

• **Procedure 2: Content of Aluminum**
Edetate disodium titrant: Prepare and standardize as directed in *Reagents, Volumetric Solutions, Edetate Disodium, Twentieth-Molar (0.05 M)*, except use 37.2 g of edetate disodium.
Sample solution: Transfer 200 mg of Aluminum Dichlorohydrate to a 250-mL beaker, add 20 mL of water and