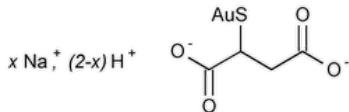


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## Gold Sodium Thiomalate



$C_4H_3AuNa_2O_4S$  plus  $C_4H_4AuNaO_4S$  368.09

Butanedioic acid, mercapto-, monogold(1+) sodium salt.

Mercaptosuccinic acid, monogold(1+) sodium salt CAS RN®: 12244-57-4; UNII: E4768ZY6GM.

» Gold Sodium Thiomalate is a mixture of the mono- and di-sodium salts of gold thiomalic acid. It contains not less than 44.8 percent and not more than 49.6 percent of Au. It contains not less than 49.0 percent and not more than 52.5 percent of Au on a dry, alcohol- and glycerin-free basis.

**Packaging and storage**—Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

### Identification—

**A:** To 2 mL of a solution (1 in 10) add 1 mL of calcium nitrate solution (1 in 10): a white precipitate is formed, and it dissolves in 2 N nitric acid and reappears upon the addition of ammonium acetate TS.

**B:** To 2 mL of a solution (1 in 10) add 4 mL of silver nitrate TS: a yellowish precipitate is formed, and it dissolves completely in an excess of 6 N ammonium hydroxide.

**C:** To 2 mL of a solution (1 in 10) add 1 mL of 6 N ammonium hydroxide and 1 mL of 30 percent hydrogen peroxide, evaporate in a porcelain dish, and ignite. Add 20 mL of water to the ignited residue, and filter: particles of gold remain on the filter. Separate portions of the filtrate meet the requirements of the tests for [Sodium \(191\)](#) and for [Sulfate \(191\)](#).

**pH (791):** between 5.8 and 6.5, in a solution (1 in 10).

**Loss on drying (731):**—Dry it at 60° and at a pressure not exceeding 5 mm of mercury for 2 hours: it loses not more than 8.0% of its weight.

### Limit of alcohol—

**Standard solution**—Transfer 50 mg of dehydrated alcohol to a 200-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL to a 50-mL volumetric flask, and dilute with water to volume. This solution contains about 0.025 mg of alcohol per mL.

**Test solution**—Transfer about 50 mg of Gold Sodium Thiomalate, accurately weighed, to a 10-mL volumetric flask, and dilute with water to volume.

**Chromatographic system** (see [CHROMATOGRAPHY \(621\)](#))—The gas chromatograph is equipped with a flame-ionization detector and a 0.53-mm × 30-m fused-silica capillary column coated with a 3.0-μm film of phase G43. The column temperature is maintained at 40° for 8.5 minutes, then the temperature is increased at 30° per minute to 240°. The total chromatographic time is about 15 minutes. The injection port and detector block temperatures are maintained at 150°. The carrier gas is helium, flowing at a rate of about 2 mL per minute, and the split flow rate is about 20 mL per minute. Chromatograph the **Standard solution**, and record the peak responses as directed for **Procedure**: the relative standard deviation for replicate injections is not more than 4.6%.

**Procedure**—Separately inject equal volumes (about 1 μL) of the **Standard solution** and the **Test solution** into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of alcohol ( $C_2H_5OH$ ) in the portion of Gold Sodium Thiomalate taken by the formula:

$$100(C_a/C_b)(r_u/r_s)$$

in which  $C_a$  is the concentration, in mg per mL, of  $C_2H_5OH$  in the **Standard solution**;  $C_b$  is the concentration, in mg per mL, of Gold Sodium Thiomalate in the **Test solution**; and  $r_u$  and  $r_s$  are the alcohol peak responses obtained from the **Test solution** and the **Standard solution**, respectively. Not more than 4.0% is found.

### Limit of glycerin—

**[NOTE—**This procedure is based on the absorption characteristics of a sodium–copper–glycerin complex. The stability of this complex prepared as directed herein is such that all measurements are to be taken within 1 hour. Thoroughly rinse all glassware used in this

procedure with water to avoid large blank errors.]

*Sodium hydroxide solution*—Dissolve 23.6 g of sodium hydroxide in water to obtain 100 mL of solution.

*Cupric chloride solution*—Dissolve 3.8 g of cupric chloride in water to obtain 100 mL of solution.

*Glycerin standard solutions*—Dissolve an accurately weighed quantity of glycerin in water to obtain a solution having a known concentration of about 8 mg per mL. Pipet 1.0, 2.0, and 3.0 mL of this solution into a series of 10-mL volumetric flasks, followed by 4.0, 3.0, and 2.0 mL of water, respectively.

*Reagent blank*—Pipet 5.0 mL of water into a 10-mL volumetric flask.

*Test solution*—Dissolve about 400 mg Gold Sodium Thiomalate, accurately weighed, in 5.0 mL of water in a 10-mL volumetric flask.

*Procedure*—To each of the *Glycerin standard solutions*, the *Reagent blank*, and the *Test solution* add 1.0 mL of *Sodium hydroxide solution*, and mix. With vigorous shaking, and in increments of 0.1 mL, add *Cupric chloride solution*, checking for turbidity after each addition. After the solutions turn slightly turbid, add an excess of 0.1 mL of *Cupric chloride solution*, insert the stopper, and shake for 1 minute. Dilute with water to volume, and mix. Centrifuge the solutions in tapered, graduated 15-mL centrifuge tubes. The presence of 1 mm to 4 mm of copper hydroxide precipitate is observed. Using a suitable spectrophotometer equipped with 1-cm cells, and using water as a reference, measure the absorbance of the clear supernatant at a wavelength of 635 nm. Subtract the absorbance value of the *Reagent blank*, which is 0.040 or less, from the absorbance values of the *Glycerin standard solutions* and the *Test solution*. Plot the corrected absorbance readings of the *Glycerin standard solutions* against the corresponding weight of glycerin. From the standard curve so obtained, and the corrected absorbance of the *Test solution*, determine the weight of glycerin in the test specimen: not more than 5.5% is found.

**Assay**—Dissolve about 600 mg of Gold Sodium Thiomalate, accurately weighed, in water in a 25-mL volumetric flask, dilute with water to volume, and mix. Pass the entire solution through a clean, dry 0.5-µm filter into a clean, dry receiver. Pipet 20.0 mL of the filtrate into a 300-mL Kjeldahl flask, add 20 mL of nitric acid, and mix. To this solution add 15 mL of sulfuric acid slowly, with mixing. Heat over a low flame, gently at first, and then increase the heat until fumes of sulfur trioxide are evolved. Allow the flask and contents to cool to room temperature, add 30 mL of water slowly, with mixing, and 20 mL of hydrogen peroxide TS, again heat to fumes of sulfur trioxide, cool, and dilute with 30 mL of water. Pass the mixture through an ignited, tared filtering crucible, wash with water, heat the crucible and contents over a low flame to dry the precipitate, and ignite at  $650 \pm 50^\circ$  to constant weight. The weight of the residue so obtained, multiplied by 1.25, is the weight of Au in the Gold Sodium Thiomalate taken.

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

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