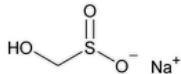


Status: Currently Official on 16-Feb-2025  
Official Date: Official Prior to 2013  
Document Type: NF Monographs  
DocId: GUID-572CC41B-54EF-4D1C-BD61-096C69EFA69D\_1\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M76590\\_01\\_01](https://doi.org/10.31003/USPNF_M76590_01_01)  
DOI Ref: lk7ph

© 2025 USPC  
Do not distribute

## Sodium Formaldehyde Sulfoxylate



$\text{CH}_3\text{NaO}_3\text{S}$  118.09

$\text{CH}_3\text{NaO}_3\text{S} \cdot 2\text{H}_2\text{O}$  154.11

Methanesulfinic acid, hydroxy-, monosodium salt;

Monosodium hydroxymethanesulfinate CAS RN®: 149-44-0.

Dihydrate CAS RN®: 6035-47-8.

### DEFINITION

Sodium Formaldehyde Sulfoxylate contains an amount of sodium formaldehyde sulfoxylate ( $\text{CH}_3\text{NaO}_3\text{S}$ ) equivalent to NLT 45.5% and NMT 54.5% of  $\text{SO}_2$ , calculated on the dried basis. It may contain a suitable stabilizer, such as sodium carbonate.

### IDENTIFICATION

• A.

**Sample solution:** Dissolve 4 g in 10 mL of water in a test tube.

**Analysis:** To the *Sample solution* add 1 mL of silver–ammonia–nitrate TS.

**Acceptance criteria:** Metallic silver is produced, either as a finely divided, gray precipitate or as a bright metallic mirror on the inner surface of the tube.

• B.

**Sample solution:** Dissolve 40 mg of salicylic acid in 5 mL of sulfuric acid, and add 50 mg of Sodium Formaldehyde Sulfoxylate.

**Analysis:** Warm very gently.

**Acceptance criteria:** A permanent, deep red color appears.

### ASSAY

• PROCEDURE

**Sample:** 1 g

**Titrimetric system**

(See [Titrimetry \(541\)](#).)

**Mode:** Direct titration

**Titrant:** 0.1 N iodine VS. [NOTE—Prepare an adequate amount for both the Assay and the test for *Sodium Sulfite*.]

**Endpoint detection:** Visual

**Analysis:** Transfer the *Sample* to a 50-mL volumetric flask, dissolve in 25 mL of water, and dilute with water to volume. Reserve a portion of this solution for the test for *Sodium Sulfite*. Transfer 4.0 mL of the remaining solution to a conical flask containing 100 mL of water. Titrate with *Titrant*, adding 3 mL of starch TS as the endpoint is approached. Each mL of 0.1 N iodine is equivalent to 1.602 mg of  $\text{SO}_2$ .

**Acceptance criteria:** 45.5%–54.5% of  $\text{SO}_2$  on the dried basis

### IMPURITIES

• SULFIDE

**Analysis:** Dissolve 6 g in 14 mL of water in a test tube, and wet a strip of lead acetate test paper with the clear solution.

**Acceptance criteria:** No discoloration is evident within 5 min.

• IRON

**Standard solution:** Dissolve 43.2 mg of ferric ammonium sulfate in 10 mL of 2 N sulfuric acid, and add water to make 1000 mL, each mL representing 5  $\mu\text{g}$  of Fe.

**Sample solution:** Transfer 1.0 g of Sodium Formaldehyde Sulfoxylate to a suitable crucible, and carefully ignite, initially at a low temperature until thoroughly charred, and finally, preferably in a muffle furnace, at 500°–600° until the carbon is all burned off. Cool, dissolve the residue in 2 mL of hydrochloric acid, and dilute with water to 50 mL.

**Analysis:** To 5.0 mL of the *Standard solution* and 50 mL of the *Sample solution* add 50 mg of ammonium persulfate and 5 mL of ammonium thiocyanate TS, and transfer each to a separate color comparison tube.

**Acceptance criteria:** 0.0025%; the color of the *Sample* is not deeper than that of the *Standard solution*.

• **SODIUM SULFITE**

**Sample solution:** 4.0 mL of the solution prepared for the Assay in a conical flask containing 100 mL of water

**Titrimetric system**

(See [Titrimetry \(541\)](#).)

**Mode:** Direct titration

**Titrant:** 0.1 N iodine VS, prepared in the Assay

**Endpoint detection:** Visual

**Analysis:** Add 2 mL of formaldehyde TS to the *Sample solution*, and titrate with the *Titrant*, adding 3 mL of starch TS as the endpoint is approached.

Calculate the percentage of sodium sulfite ( $\text{Na}_2\text{SO}_3$ ) in the Sodium Formaldehyde Sulfoxylate taken:

$$\text{Result} = (V_2 - V_1) \times (N/W) \times (F \times 1.25)$$

$V_2$  = volume of 0.1 N iodine VS consumed in the titration performed in the Assay (mL)

$V_1$  = volume of 0.1 N iodine VS consumed in this titration (mL)

$N$  = actual normality of the *Titrant* (mEq/mL)

$W$  = weight of the *Sample* in the Assay (g)

$F$  = equivalency weight of sodium sulfite, 63.02 mg/mEq

**Acceptance criteria:** NMT 5.0% on the dried basis

**SPECIFIC TESTS**

• [pH \(791\)](#)

**Sample solution:** 20 mg/mL

**Acceptance criteria:** 9.5–10.5

• [Loss on Drying \(731\)](#)

**Analysis:** Dry at 105° for 3 h.

**Acceptance criteria:** NMT 27.0%

• **ALKALINITY**

**Sample solution:** 1.0 g of Sodium Formaldehyde Sulfoxylate in 50 mL of water

**Analysis:** To the *Sample solution* add phenolphthalein TS, and titrate with 0.10 N sulfuric acid.

**Acceptance criteria:** NMT 3.5 mL is required for neutralization.

• **CLARITY AND COLOR OF SOLUTION**

**Sample solution:** 1 g of Sodium Formaldehyde Sulfoxylate in 20 mL of water

**Analysis:** Transfer 10 mL of the *Sample solution* to a 20- × 150-mm test tube. Compare with water in a similar test tube.

**Acceptance criteria:** The *Sample solution* and the water are equally clear and, when viewed transversely by transmitted light, exhibit no apparent difference in color.

**ADDITIONAL REQUIREMENTS**

• **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers, and store at controlled room temperature.

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

Topic/Question	Contact	Expert Committee
SODIUM FORMALDEHYDE SULFOXYLATE	<a href="#">Documentary Standards Support</a>	SE2020 Simple Excipients

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SE2020 Simple Excipients

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

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. Information currently unavailable

**Current DocID: GUID-572CC41B-54EF-4D1C-BD61-096C69EFA69D\_1\_en-US**

**DOI:** [https://doi.org/10.31003/USPNF\\_M76590\\_01\\_01](https://doi.org/10.31003/USPNF_M76590_01_01)

**DOI ref:** [Jk7ph](#)

OFFICIAL