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20 General References

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- Schiffman SS, *et al.* Effect of temperature, pH, and ions on sweet taste. *Physiol Behav* 2000; 68(4): 469–481.

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21 Author

PL Goggin.

22 Date of Revision

4 May 2017.

Sodium Formaldehyde Sulfoxylate

1 Nonproprietary Names

USP–NF: Sodium Formaldehyde Sulfoxylate

2 Synonyms

Formaldehyde hydrosulfite; formaldehyde sodium sulfoxylate; formaldehydesulfoxylic acid sodium salt; methanesulfinic acid, hydroxy-, monosodium salt; monosodium hydroxymethane sulfinate; *Rongalite*; sodium hydroxymethane sulfinate; sodium hydroxymethylsulfinate; sodium methanalsulfoxylate; sodium sulfinomethanolate.

3 Chemical Name and CAS Registry Number

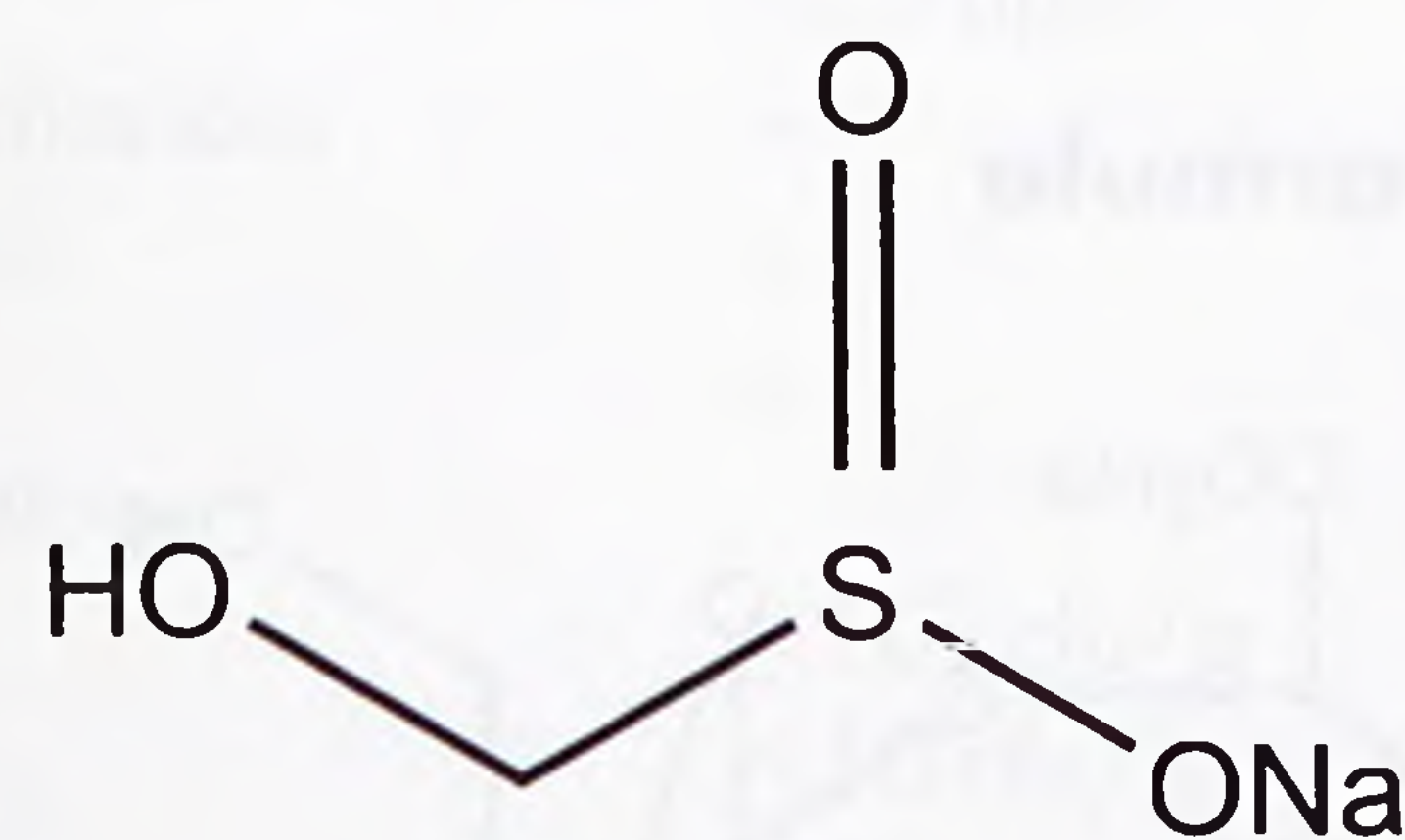
Sodium formaldehyde sulfoxylate [149-44-0]

Sodium formaldehyde sulfoxylate dihydrate [6035-47-8]

4 Empirical Formula and Molecular Weight

CH₃NaO₃S 118.09
CH₃NaO₃S·2H₂O 154.11

5 Structural Formula



6 Functional Category

Antioxidant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium formaldehyde sulfoxylate is a water-soluble antioxidant and is generally used as the dihydrate. It is used in the formulation of injection products at a level of up to 0.1% w/v in the final preparation administered to the patient.

8 Description

When freshly prepared, sodium formaldehyde sulfoxylate occurs as white, odorless crystals, which quickly develop a characteristic garlic odor on standing.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for sodium formaldehyde sulfoxylate.

| Test | USP 40–NF 35 S1 |
|-------------------------------|-----------------|
| Identification | + |
| Clarity and color of solution | + |
| Alkalinity | + |
| pH (1 in 50 solution) | 9.5–10.5 |
| Loss on drying | ≤27.0% |
| Sulfide | + |
| Iron | + |
| Sodium sulfite | ≤5.0% |
| Assay (as sulfur dioxide) | 45.5–54.5% |

Note: USP 40–NF 35 S1 also states that sodium formaldehyde sulfoxylate may contain a suitable stabilizer such as sodium carbonate.

10 Typical Properties

Acidity/alkalinity pH = 9.5–10.5 (2% w/v aqueous solution)

Melting point 64–68°C (dihydrate)

Solubility Freely soluble in water; slightly soluble in ethanol, chloroform, ether and benzene.

11 Stability and Storage Conditions

Store in well-closed, light-resistant containers at controlled room temperature (15–30°C).

12 Incompatibilities

Sodium formaldehyde sulfoxylate is incompatible with strong oxidizing agents; it is decomposed by dilute acid.

13 Method of Manufacture

Sodium formaldehyde sulfoxylate is manufactured from sodium dithionate and formaldehyde in water.

14 Safety

The toxicological properties of sodium formaldehyde sulfoxylate have not been fully investigated. However, it is used in the formulation of injection products at a level to 0.1% w/v in the final preparation administered to the patient.

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