

**TRIETHANOLAMINE SALICYLATE (TROLAMINE)
LABELLING STANDARD**

I) **Description:**

This labelling standard applies to Triethanolamine Salicylate (TEAS) as a single medicinal ingredient in the form of a cream, gel, ointment, liquid roll-on, lotion, or stick, intended for use as a topical analgesic. Triethanolamine Salicylate (TEAS) must be identified on product labelling by the names given in this monograph.

II) **Pharmaceutical Quality:**

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the Food and Drugs Act, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

i) Finished product specifications should include tests for identification and an assay with suitable limits for Triethanolamine Salicylate (TEAS), including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. It is recommended that antimicrobial preservative effectiveness be determined in order to establish that the product is capable of resisting microbial contamination.

III) **Ingredients:**

a) Single Medicinal Ingredients:	Concentration:
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Triethanolamine Salicylate (TEAS)	10-20%
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b) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the bioavailability, therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives.

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September 13, 1995

Revisions after this date will be highlighted in **bold and larger print**

IV) Labelling:

a) This monograph describes those requirements that are specific to this class of drugs. Other requirements described in the Regulations to the Food and Drugs Act and in the Guide for the Labelling of Drugs for Human Use must also be met.

b) Directions for Use:**i) Indications**

The primary indication should be to the effect:

For the temporary relief of aches, and pains of muscles and joints associated with backache, lumbago, strains, bruises, sprains and arthritic or rheumatic pain, pain of tendons and ligaments.

ii) Unacceptable Claims

Any reference to warmth

iii) Dosage

Adults and children 2 years of age and older:

- 1) Apply to affected area not more than to 4 times daily.
- 2) If condition worsens, or if symptoms persists for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

Children under 2 years of age:

- 1) Consult your physician.

iv) Warnings

- 1) External use only
- 2) If rash or irritation occurs discontinue use.
- 3) Avoid contact with the eyes and mucous membranes.
- 4) Do not apply to wounds or damaged skin.
- 5) Do not use this product if you are allergic to salicylates or if you are taking anticoagulant medication.

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V) **REFERENCES:**

- (1) Self-Medication, Third Edition, 1988, Canadian Pharmaceutical Association.
- (2) Canadian Drug Identification Code 19th Ed., 1992, Minister of National Health and Welfare.
- (3) United States Federal Register, Vol. 48, No. 27, Feb. 8, 1983, Proposed Rules.
- (4) United States Federal Register, Vol. 44, No. 234, Dec. 4, 1979, Proposed Rules.
- (5) Canadian Food and Drug Regulations
- (6) American Handbook of Nonprescription Drugs, 8th Edition, 1986, American Pharmaceutical Association.
- (7) Martindale, The Extra Pharmacopoeia, 29th Edition, 1989, Philadelphia College of Pharmaceutical Sciences.
- (8) Compendium of Pharmaceutical Specialties, 26th Edition, 1991, Canadian Pharmaceutical Association.
- (9) USP DI, Drug Information For the Health Care Professional, Vol I, 1994, 14th Ed. The United States Pharmacopoeial Convention Inc.
- (10) United States Pharmacopoeia USP XXII National Formulary XVII, 22nd Revision, United States Pharmacopoeial Convention, Inc., 1990.
- (11) British Pharmacopoeia, Volume II, 1988, The British Pharmacopoeia Commission, London.

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