LABELLING STANDARD

DENTAL AND ORAL CARE PRODUCTS FOR PROFESSIONAL USE

I) Description:

This labelling standard applies to single and combination ingredient products for dental and oral care which are for "Professional Use Only".

Fluoride dental products included in this standard exceed the acceptable limits set for over-the-counter fluoride dental products. Formulations appropriate for this category include: dentifrices, treatment gels/rinses, varnishes, cavity and crown drug preparations as well as hemostatic agents.

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) Pharmacopoeial standards (Schedule B) for formulated preparations are shown in Appendix I. Note that this list is intended only as a guide and is not necessarily current or all inclusive.

ii) Finished product specifications for fluoride-containing treatment gels and rinses should include tests for identification and an assay with suitable limits for the medicinal ingredient(s). 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. Antimicrobial preservative effectiveness should be determined in order to establish that the product is capable of resisting microbial contamination.

III) **Ingredients:**

a) **Single Medicinal ingredients:**

Fluoride-General (anticarie, etc)

Sodium Fluoride

i)dentifrice: >0.27%
-Max 2.74% (1.24% fluoride ion equivalent)

ii)treatment gel: >0.02% (twice daily use)
>0.05% (once daily use)
-Max 2.74% (1.24% fluoride ion equivalent)

iii)treatment rinse: >0.02% (twice daily use)
>0.05% (once daily use)
>0.2% (once weekly use)
-Max 2.74% (1.24% fluoride ion equivalent)

Stannous Fluoride

i) treatment gel: >0.6% (Max 1.64%, 0.4% fluoride ion equivalent)

ii) treatment rinse: >0.1% (Max 1.64%, 0.4% fluoride ion equivalent)

A stannous fluoride gel/rinse may be sold in a more concentrated form, provided the product is labelled with adequate directions for diluting with water before use to obtain a 1.64% (or less) preparation.

Acidulated Phosphate Fluoride

Derived from sodium fluoride ≤ 2.74% (alone or in combination with hydrogen fluoride ≤ 0.49%) acidulated with a mixture of sodium phosphate, dibasic or monobasic and phosphoric/orthophosphoric acid to a level of 0.1 molar phosphate to yield a pH of 3.0 to 4.5). Hydrofluoric acid (from hydrogen fluoride and phosphoric acid) is also considered acceptable.

i) treatment rinse/gel: >0.02% (200ppm fluoride ion)
(maximum 12,400 ppm, 1.24% fluoride ion equivalent)

For these products, the acidifying agent (acid) and the sodium/hydrogen fluoride are considered to be medicinal ingredients. These ingredients should be declared in the quantitative declaration.

eg. sodium fluoride....._____ %
hydrogen fluoride....._____ %
phosphoric acid....._____ %
orthophosphoric acid.._____ %
hydrofluoric acid....._____ %

Fluoride-Varnish

These formulations have been accepted on the Canadian market and for the purpose of this labelling standard are considered acceptable.

i) Sodium fluoride liquid 5% (2.26% fluoride ion equivalent)

ii) Difluorosilane (fluor silane) liquid 5% (0.76% fluoride ion equivalent)

Hemostatic Agents

Racemic Epinephrine Hydrochloride

i)	strip (cord)	≤ 0.78 mg/cm
ii)	coil (cotton)	≤ 1.18 mg/cm
ii)	liquid	≤ 8% Used to saturate cord, pellet, etc.
iii)	pellet	≤ 1.15 mg

Aluminum Potassium Sulfate (Alum)

i)	strip (cord)	≤ 0.68 mg/cm

Aluminum Chloride

i)	strip (cord)	≤ 0.79 mg/cm
ii)	Coil (cotton)	≤ 1.97 mg/cm
iii)	liquid	≤ 25% (used to saturate cord, coil, pellets, etc.)

iv) pellet ≤ 2 mg

Aluminum Sulfate

i) strip (cord) ≤ 0.57 mg/cm

ii) liquid ≤ 25% (used to saturate cord, pellets, etc.)

iii) pellet ≤ 2.5mg

b) **Combinations of Medicinal Ingredients:**

The following combination products have been accepted in Canada and are considered acceptable for the purpose of this labelling standard:

Fluoride

i) Sodium Fluoride (0.69%-acidulated) and Stannous fluoride (1.64%) treatment rinse.

ii) Sodium Fluoride (acidulated) and Stannous Fluoride Gel cavity and crown preparation (0.72% fluoride ion equivalent)

iii) Sodium Fluoride 0.42% and Strontium Chloride 3.96%

iv) Sodium fluoride 1.09%, stannous fluoride 0.40% and hydrogen fluoride 0.14%

For all multi-ingredient products, the concentration of fluoride should not exceed the maximum single ingredient concentration of 0.49% hydrogen fluoride, 2.74% Sodium Fluoride or 1.64% Stannous Fluoride. In addition, the final concentration of any multi-ingredient product is limited to a maximum 1.24% fluoride ion equivalent.

Please note that combination products consisting of stannous fluoride and/or sodium fluoride and a local anesthestic such as benzocaine or tetracaine are beyond the scope of this labelling standard.

Hemostatic

i) Racemic Epinephrine Hydrochloride ≤ 0.67 mg/cm (strip)
Aluminum Potassium Sulfate ≤ 0.37 mg/cm

ii) Aluminum Potassium Sulfate ≤ 0.68 mg/cm (strip)
Racemic Epinephrine Hydrochloride ≤ 0.36 mg/cm

iii) Racemic Epinephrine Hydrochloride ≤ 0.36 mg/cm (strip)
Zinc Chloride ≤ 0.22 mg/cm

iv) Zinc Phenolsulphonate ≤ 0.57 mg/cm (strip)
Racemic Epinephrine Hydrochloride ≤ 0.06 mg/cm

c) **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.

Herbal ingredients are not permitted except as fragrance or flavour components.

IV) **Labelling:**

a) This labelling standard 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:** Therapeutic indications for professional use products that are not clearly stated on the label should be implied by the name of the product and formulation. There would be no objection to one or more of the following:

Fluoride Products (General)

- dental prophylaxis
- anti-cavity, anti-caries

Hemostatic Agents

- local dental hemostasis

ii) **Dosage Directions:**

Appropriate dosage directions should appear on the label.

The potency of the product *i.e.* **concentration/unit**, must be clearly indicated. If the product is to be diluted before use, the appropriate dilution directions must be present, and the potency of the product after dilution clearly indicated.

iii) **Warnings**

The following warnings should appear on "professional use only" products:

1. All products--label

   (a) "For Professional Use only"

   (b) "Keep out of the reach of children" *****

   (c) The presence of a package insert where one exists

   ***** Not applicable to products intended solely for use in a dentists` office, or packaged for hospital use only. (C.01.031.2 (3)(c))

2. Rinses and gargles

   (a) "Do Not Swallow" or "Not to be taken internally"

   (b) Not recommended for use by children under 6 years of age

3. Hemostatic agents--label or insert

(a) Use in only one quadrant of the mouth at a time

(b) Contraindicated in patients with cardiovascular disease, diabetes, hyperthyroidism, hypertension, glaucoma, or difficulty in urination due to an enlargement of the prostate gland, or who are epinephrine sensitive.**

(c) Avoid use on exposed bone or where heavy bleeding is present.**

** Products containing epinephrine

V) **REFERENCES**

1) Barceloux, D.G. and Ellenhorn, M.J., **Medical Toxicology**, Elsevier Science Publishing Co. Inc., 1988.

2) Canadian Medical Association, **Guide to Prescription and Over the Counter Drugs**,1990.

3) Gennaro, A.R. (Ed.), **Remington's Pharmaceutical Sciences, 18th Ed.**. Mack Publishing Co., 1990.

4) **Nutrition Recommendations:** The Report of the Scientific Review Committee, Health and Welfare, 1990.

5) **Preventive Dental Services, 2nd Edition**, Health and Welfare Canada, 1988.

6) Reynolds, J.E.F.(Ed.), **Martindale: The Extra Pharmacopoeia 30th Ed.,** The Pharmaceutical Press, 1993.

7) **Anticaries Drug Products for Over-the-Counter Human Use, Notice of Proposed Rulemaking**. United States Federal Register 60, No. 194, 1995: pp. 52474-52508.

8) American Dental Association, **Accepted Dental Therapeutics** 40th ed., 1984

APPENDIX I: FORMULATED PREPARATIONS

FORMULATED PREPARATIONS	U.S.P. XXIII (1995)	B.P. (1993)	Pharmaceutical Codex (1994)
Stannous Fluoride Gel	X		

Sodium Fluoride and Phosphoric Acid Gel	X		
Sodium Fluoride and Phosphoric Acid Topical Solution	X		
Aluminum Chloride Solution		X	