

§ 355.10

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concentrated form to be mixed with water before using to result in the appropriate fluoride concentration specified in the monograph.

(1) *Treatment rinse effervescent tablets.* A fluoride treatment rinse prepared by adding an effervescent tablet (a concentrated solid dosage form) to water before using to result in the appropriate fluoride concentration specified in the monograph.

(m) *Treatment rinse powder.* A fluoride treatment rinse prepared by adding the powder (a concentrated solid dosage form) to water before using to result in the appropriate fluoride concentration specified in the monograph.

[60 FR 52507, Oct. 6, 1995, as amended at 61 FR 52286, Oct. 7, 1996]

Subpart B—Active Ingredients

§ 355.10 Anticaries active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration and dosage form established for each ingredient:

(a) *Sodium fluoride*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a gel or paste dosage form.* Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration \geq 650 parts per million (ppm).

(2) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a powdered dosage form.* Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration of \geq 850 ppm for products containing the abrasive sodium bicarbonate and a poured-bulk density of 1.0 to 1.2 grams per milliliter.

(3) *Treatment rinses.* (i) An aqueous solution of acidulated phosphate fluoride derived from sodium fluoride acidulated with a mixture of sodium phosphate, monobasic, and phosphoric acid to a level of 0.1 molar phosphate ion and a pH of 3.0 to 4.5 and which yields an effective fluoride ion concentration of 0.02 percent.

(ii) An aqueous solution of acidulated phosphate fluoride derived from sodium fluoride acidulated with a mixture of sodium phosphate, dibasic, and phosphoric acid to a pH of 3.5 and which yields an effective fluoride ion concentration of 0.01 percent.

(iii) Sodium fluoride 0.02 percent aqueous solution with a pH of approximately 7.

(iv) Sodium fluoride 0.05 percent aqueous solution with a pH of approximately 7.

(v) Sodium fluoride concentrate containing adequate directions for mixing with water before using to result in a 0.02-percent or 0.05-percent aqueous solution with a pH of approximately 7.

(b) *Sodium monofluorophosphate*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a gel or paste dosage form.* Sodium monofluorophosphate 0.654 to 0.884 percent with an available fluoride ion concentration (consisting of $\text{PO}_3 \text{F}^-$ and F^- combined) \geq 800 ppm.

(2) *Dentifrices containing 1,500 ppm theoretical total fluorine in a gel or paste dosage form.* Sodium monofluorophosphate 1.153 percent with an available fluoride ion concentration (consisting of $\text{PO}_3 \text{F}^-$ and F^- combined) \geq 1,275 ppm.

(c) *Stannous fluoride*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a gel or paste dosage form.* (i) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration \geq 700 ppm for products containing abrasives other than calcium pyrophosphate.

(ii) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration \geq 290 ppm for products containing the abrasive calcium pyrophosphate.

(2) *Preventive treatment gel.* Stannous fluoride 0.4 percent in an anhydrous glycerin gel, made from anhydrous glycerin and the addition of suitable thickening agents to adjust viscosity.

(3) *Treatment rinse.* Stannous fluoride concentrate marketed in a stable form and containing adequate directions for mixing with water immediately before using to result in a 0.1-percent aqueous solution.

[60 FR 52507, Oct. 6, 1995, as amended at 61 FR 52286, Oct. 7, 1996]

§ 355.20 Packaging conditions.

(a) *Package size limitation.* Due to the toxicity associated with fluoride active ingredients, the following package size limitations are required for anticaries drug products: