

# EFU Investigation of Natural Fluoride Mouthwashes vs. ADA Accepted Mouthwashes



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## ABSTRACT

### Objectives:

- 1) Evaluate the efficacy of two all-natural anticavity mouthwashes and two commercially available American Dental Association® Accepted anticavity mouthwashes using enamel fluoride uptake (EFU), and
- 2) Investigate fluoride mouthwash efficacy as a function of pH.

**Methods:** Product efficacy was evaluated using an EFU method identical to the one identified as Method 40 in the FDA Monograph, with the following exception: lesions were formed using a solution of 0.1M lactic acid/0.2% Carbopol 907 50% saturated with HAP at pH 5.0. Fluoride analyses were performed with a fluoride ion specific electrode and pH analyzer. Samples and standards were prepared by aqueous dilution mixed with an equal volume of TISAB II.

**Results:** Measured ionic fluoride and pH levels were as follows: Johnson & Johnson Cinnamon Act® Anticavity Fluoride Rinse (234ppm/6.3), natural pH 7.2 mouthwash (211ppm), natural lemon-lime mouthwash (206ppm/4.1), natural spearmint mouthwash (200ppm/4.2), Colgate® Phos-Flur Anti-Cavity Fluoride Rinse (200ppm/4.1), and natural non-fluoride mouthwash (<2ppm/3.0). Increases in incipient lesion enamel fluoride content were as follows: natural lemon-lime (3807±152ppm), natural spearmint (3524±81ppm), Colgate (3323±89ppm), Act (1659±68ppm), natural pH 7.2 mouthwash (1210±41ppm), and natural non-fluoride (512±24ppm).

**Conclusions:** The non-fluoride mouthwash was not as effective in promoting enamel fluoride uptake as any of the other mouthwashes. The natural experimental mouthwash (pH 7.2) was significantly more effective than placebo but less effective than the other fluoride mouthwashes with regard to promoting incipient lesion enamel fluoride uptake. Tom's of Maine Natural Spearmint Anticavity Fluoride Mouthwash was not significantly different from the Colgate rinse. Tom's of Maine Natural Lemon-Lime Anticavity Fluoride Mouthwash for a Dry Mouth was significantly more effective than any of the other mouthwashes. Fluoride uptake increases significantly with decreasing mouthwash pH.

## INTRODUCTION

The anticaries monograph mandates five types of formulations for fluoride treatment rinses. Antimicrobial preservation is always an important consideration in formulating mouthwashes that do not contain alcohol or artificial preservatives. Mouthwashes formulated around pH 7 can be highly susceptible to microbial growth. Tom's of Maine fluoride mouthwashes were formulated as "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 - 4.5 and which yields an effective fluoride ion concentration of 0.02 percent."<sup>1</sup> Colgate Phos-Flur Anti-Cavity Fluoride Rinse also appears to be formulated in this manner. Act Anticavity Fluoride Rinse appears to be formulated as "sodium fluoride 0.05 percent aqueous solution with a pH of approximately 7."<sup>2</sup> It is of interest to note that the monograph allows a 226ppm ionic fluoride concentration at pH 7, but requires only a 200ppm ionic fluoride concentration at the lower pH range (13% less fluoride).

## OBJECTIVES

The objectives of this study were two-fold. The first was to evaluate the efficacy (enamel fluoride uptake) of two new anticavity mouthwashes vs. two commercially available, ADA accepted anticavity mouthwashes. The second objective was to evaluate efficacy (again, fluoride uptake into incipient enamel lesions) as a function of mouthwash pH.

## MATERIALS & METHODS

**Materials:** The Act (Lot 1643ND2/May 2006) and Colgate (Lot 211017/November 2004) rinses were purchased at a local Kennebunk market, while the Tom's of Maine anticavity mouthwashes were the initial plant-manufactured commercial production runs (Spearmint-Lot FW1001/ June 2006; Lemon-Lime-Lot FW1003/June 2006). To understand efficacy as a function of pH, an eight ounce (237mL) bottle of Tom's Spearmint Anticavity Fluoride Mouthwash was brought to pH 7.19 with 1.7mL of 10N NaOH. The dilution necessary for the pH adjustment was less than 1% of the total volume.

Table I

| Rinse                | Ionic Fluoride (ppm) | Label Copy                              | pH  |
|----------------------|----------------------|---|-----|
| Act                  | 234                  | 0.05% NaF<br>0.0226% w/v F <sup>-</sup> | 6.3 |
| Colgate              | 200                  | 4.4mg NaF in each 10ml                  | 4.1 |
| Tom's Lemon-Lime     | 206                  | 0.0442% NaF                             | 4.1 |
| Tom's Spearmint      | 200                  | 0.0442% NaF                             | 4.2 |
| Tom's Spearmint(7.2) | 211                  | ---                                     | 7.2 |
| Tom's Fluoride-Free  | <2                   | ---                                     | 3.0 |

Figure 1

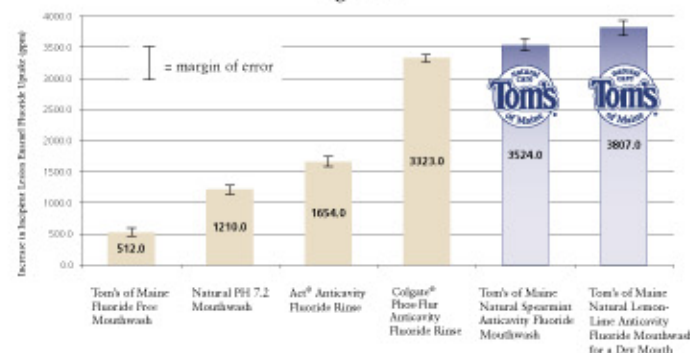


Figure 2



## Methods:

### Enamel Fluoride Uptake (FDA Method 40):

Sound, upper, central, human incisors were selected and a core of enamel 3mm in diameter was prepared from each tooth by cutting perpendicular to the labial surface with a hollow-core diamond drill bit. Each specimen was embedded in the end of a plexiglass rod (1/4" diameter x 2" long) using methylmethacrylate. The excess acrylic was cut away exposing the enamel surface. The enamel specimens were polished with 600 grit wet/dry paper and then with micro-fine Gamma Alumina. The resulting specimen was a 3mm disk of enamel with all but the exposed surface covered with acrylic. Each enamel specimen was then etched by immersion into 0.5mL of 1M HClO<sub>4</sub> for 15 seconds. A sample of each solution was then buffered with TISAB to a pH of 5.2 (0.25mL sample, 0.5mL TISAB and 0.25mL 1N NaOH) and the fluoride content determined by comparison to a similarly prepared standard curve (1mL std and 1 mL TISAB). These data represent the indigenous fluoride level of each specimen prior to treatment. The specimens were once again ground and polished as described above. An incipient lesion was formed in each enamel specimen by immersion into a 0.1M lactic acid/0.2% Carbopol 907 solution for 24 hours at room temperature. The treatments were then performed using undiluted mouthrinses as provided. The specimens were immersed into 25mL of their assigned rinse with constant stirring (350rpm) for 30 minutes. Following treatment, one layer of enamel was removed from each specimen and analyzed for fluoride as outlined above (i.e., 15 second etch). The pretreatment fluoride (indigenous) level of each specimen was then subtracted from the post-treatment value to determine the change in enamel fluoride due to the test treatment.

### Ionic Fluoride Analysis:

Fluoride analyses were performed with a fluoride ion specific electrode (Thermo Orion Model 96-09) and pH analyzer (Mettler-Toledo Model MA235). Samples and standards were prepared by aqueous dilution mixed with an equal volume of TISAB II.

## RESULTS

The increases in incipient lesion enamel fluoride content for each of the six rinses are displayed in Figure 1. Table I presents the results of the chemical (ionic fluoride & pH) analyses conducted on the mouthwashes, as well as label copy fluoride values. All pH values of the commercially available fluoride rinses were within mandated monograph limits, while all ionic fluoride levels were within ±10% of label copy and monograph targets. Altering the pH of the Tom's Spearmint rinse from 4.2 to 7.2 caused a 66% reduction in fluoride uptake.

## CONCLUSIONS

The non-fluoride mouthwash was not as effective in promoting enamel fluoride uptake as any of the other mouthwashes. The experimental mouthwash (Tom's pH 7.2) was significantly more effective than placebo but less effective than the other fluoride mouthwashes with regard to promoting incipient lesion enamel fluoride uptake. Tom's of Maine Natural Spearmint Anticavity Fluoride Mouthwash (Figure 2) was not significantly different from the Colgate rinse, while both of these rinses were statistically more effective than Act. Tom's of Maine Natural Lemon-Lime Anticavity Fluoride Mouthwash for a Dry Mouth (Figure 2) was significantly more effective than any of the other mouthwashes. Fluoride uptake increases significantly with decreasing mouthwash pH.

## REFERENCES

- <sup>1</sup> 21 CFR § 355.10[a][3][i].
- <sup>2</sup> 21 CFR § 355.10[a][3][iv].