

TABLE 2.—ACCEPTABLE TEST VALUES FOR 1,000 PPM THEORETICAL TOTAL FLUORINE SODIUM MONOFLUOROPHOSPHATE DENTIFRICES IN A PASTE DOSAGE FORM

I. Soluble Fluoride Ions (PO<sub>3</sub>F<sup>=</sup> and F<sup>-</sup>)<sup>1</sup>

Abrasive	Ion	Fresh value <sup>2</sup>	Aged minimal value <sup>2,3</sup>	Test dilution (w/w)
Applicable to all abrasives	PO <sub>3</sub> F <sup>=</sup>	650 ppm <sup>4</sup>	Half total (PO <sub>3</sub> F <sup>=</sup> and F <sup>-</sup> ) value	1:10
	F <sup>-</sup>	10 to 150 ppm	10 ppm to PO <sub>3</sub> F <sup>=</sup> value	1:10
	Total (PO <sub>3</sub> F <sup>=</sup> and F <sup>-</sup> )	800 ppm	600 ppm	1:10

## II. Hydrogen Ion Concentration (pH)

Abrasive	Test value	Test dilution (w/w)
Alumina	6.4 to 9.0	1:10
Calcium carbonate	7.0 to 10.0	1:10
Calcium pyrophosphate	5.0 to 5.4	1:10
Dicalcium phosphate	6.3 to 7.6	1:10
Insoluble sodium metaphosphate	5.6 to 6.9	1:10
Silica	5.5 to 7.4	1:10

<sup>1</sup> For the compound sodium monofluorophosphate in a dentifrice formulation, fluoride ion exists as a combination of the ions PO<sub>3</sub>F<sup>=</sup> and F<sup>-</sup>. Values are given for each of these ions as well as the "Total": combination of PO<sub>3</sub>F<sup>=</sup> plus F<sup>-</sup>.

<sup>2</sup> Values listed are parts of the measured substance per million parts of the whole dentifrice.

<sup>3</sup> Values listed are intended for use in determining expiration dating for fluoride dentifrices covered by the final monograph. These values are not intended to be used to determine if a dentifrice meets monograph requirements, i.e., is safe and effective.

<sup>4</sup> Soluble PO<sub>3</sub> is derived either by direct analytical measurement or by subtracting soluble fluoride ion (F<sup>-</sup>) from total soluble available fluoride (PO<sub>3</sub>F<sup>=</sup> plus F<sup>-</sup>).

TABLE 3.—ACCEPTABLE TEST VALUES FOR 1,000 PPM THEORETICAL TOTAL FLUORINE STANNOUS FLUORIDE DENTIFRICES IN A PASTE DOSAGE FORM

I. Soluble Fluoride Ion (F<sup>-</sup>)

Abrasive	Fresh F <sup>-</sup> value <sup>1</sup>	Aged minimal F <sup>-</sup> value <sup>1,2</sup>	Test dilution (w/w)
Insoluble sodium metaphosphate	700 ppm	650 ppm	1:3
Silica	600 ppm	500 ppm	1:10
Calcium pyrophosphate	288 ppm	108 ppm <sup>3</sup>	1:3

II. Soluble Stannous Ion (Sn<sup>++</sup>)

Abrasive	Fresh Sn <sup>++</sup> value <sup>1</sup>	Aged minimal Sn <sup>++</sup> value <sup>1,2</sup>	Test dilution (w/w)
Insoluble sodium metaphosphate	2,000 ppm	Qualitatively detectable	1:10
Silica	Qualitatively detectable	Qualitatively detectable	1:10
Calcium pyrophosphate	900 ppm	Qualitatively detectable	1:3

## III. Hydrogen Ion Concentration (pH)

Abrasive	Test value	Test dilution (w/w)
Insoluble sodium metaphosphate	4.2 to 5.4	1:4
Silica	4.6 to 5.1	1:4
Calcium pyrophosphate	4.4 to 5.1	1:3

<sup>1</sup> Values listed are parts of the measured substance per million parts of the whole dentifrice.

<sup>2</sup> Values listed are intended for use in determining expiration dating for fluoride dentifrices covered by the final monograph. These values are not intended to be used to determine if a dentifrice meets monograph requirements, i.e., is safe and effective.

<sup>3</sup> Value corresponds to that of aged product found clinically effective.

TABLE 4.—ACCEPTABLE TEST VALUES FOR ALL OTC FLUORIDE DENTIFRICES IN A PASTE DOSAGE FORM

I. Theoretical Total Fluorine<sup>1</sup>