

Fluoride content in children's dentifrices marketed in Argentina

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ABSTRACT

Fluoridated dentifrices are the most widely used formulations for caries prevention and control. However, there is great concern regarding legislation on the use of fluoride formulations in early childhood from the standpoint of avoiding increased risk of fluorosis while at the same time achieving a concentration that ensures anticaries activity. **AIM:** The aim of this study was to evaluate the stability of fluoride concentration in the main children's toothpaste brands marketed in Argentina. **Materials and Method:** Twenty different brands of children's toothpaste were evaluated by analyzing the concentration of total fluoride (TF), total soluble fluoride (TSF) and ionic fluoride (IF) in two or three samples of each brand. Each sample was analyzed in duplicate using an ion-specific electrode calibrated with fluoride standards, and the results were expressed in ppm ($\mu\text{g F/g}$). **Results:** TF was found to be lower than stated by the manufacturer in 85% of the brands analyzed. TF concentration found in fluoride toothpastes ranged from 651.5 to 1090.4 $\mu\text{g/ml F}^-$, while TSF ranged from 504.2 to 915.5 $\mu\text{g/ml F}^-$, and IF from 298.6 to 838.2 $\mu\text{g/ml F}^-$. **Conclusions:** The formulation and fluoride content in children's toothpastes marketed in Argentina vary greatly according to brand. In all the samples, TF concentration was lower than 1500 ppm F⁻, and TSF concentration was lower than 1000 ppm F⁻, the minimum amount necessary to ensure anticaries effect. This indicates the need for improved formulations and regulations.

Keywords: fluoride - toothpaste - dental caries - dental gel

Concentración de fluoruros en pastas dentales infantiles comercializadas en Argentina

RESUMEN

Los dentífricos fluorurados son las formulaciones más utilizadas para la prevención y el control de las caries. Sin embargo, existe una gran preocupación de las legislaciones sobre el uso de formulaciones fluoradas en la primera infancia y el mayor riesgo de fluorosis, en comparación con la preocupación de una concentración que asegura una actividad anticáries. **Objetivo:** El objetivo de este estudio fue evaluar la estabilidad de la concentración de fluoruro, en los principales dentífricos infantiles comercializados en Argentina. **Materiales y Método:** Se evaluaron 20 marcas diferentes de dentífricos infantiles, con análisis de la concentración de fluoruro total (TF), fluoruro total soluble (FST) y fluoruro iónico (IF) de dos o tres muestras de cada marca ($\mu\text{g/g F}$). Cada muestra se analizó por duplicado utilizando un electrodo específico de iones calibrado con estándares de fluoruro y los resultados se expresaron en ppm ($\mu\text{g F/g}$). **Resultados:** El TF encontrado fue inferior al declarado por el fabricante en el 85% de las marcas analizadas. La concentración de TF encontrada en los dentífricos fluorados varió de 651,5 a 1090,4 $\mu\text{g/ml F}^-$, mientras que el TSF varió de 504,2 a 915,5 $\mu\text{g/ml F}^-$ y el IF de 298,6 a 838,2. **Conclusiones:** Las pastas dentales comercializadas para niños en Argentina presentan una gran variabilidad en cuanto a marca, formulación y contenido de fluoruro. La concentración de TF en las muestras fue inferior a 1500 ppm de F⁻ y todas presentaron concentraciones de TSF inferiores a 1000 ppm de F⁻, la cantidad mínima necesaria para tener efecto anti-caríes. Esto indica la necesidad de mejorar las formulaciones y las regulaciones.

Palabras clave: fluoruro - pasta dental - caries dental - gel dental

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INTRODUCTION

Dental caries is a dynamic, biofilm-mediated disease caused by the production of acids by cariogenic microorganisms. Its development is modulated by dietary habits and influenced by a combination of biological, behavioral and social factors^{1,2}, including the anatomical characteristics of the tooth surface, salivary flow and composition, oral microbiome composition, and exposure to fluoride. Fluoride promotes remineralization and inhibits demineralization³.

Although dental caries can affect all age groups, its consequences are particularly significant in children, in whom the disease is associated with pain, school absenteeism, emotional distress, and diminished quality of life¹. There has been a great effort to control dental caries in recent decades, with an essential role being played by dentifrice formulations. However, other non-bacterial pathologies such as enamel defects, which are also studied in the area of cariology, require attention too⁴.

Among preventive measures, fluoridated formulations – particularly toothpastes – have proven highly effective in reducing the incidence of caries. As products intended for daily oral hygiene, they deliver fluoride consistently to the oral environment, thereby supporting remineralization and inhibiting caries progression^{3,5-8}.

Concerns have been raised regarding the use of fluoridated toothpastes during early childhood, primarily due to the potential risk of dental fluorosis^{8,9}. However, fluorosis results from chronic excessive fluoride ingestion during enamel formation, regardless of the fluoride source, and not from appropriate topical use^{8,10}. Although caries and dental fluorosis both require attention, it is important to highlight that the critical period for fluorosis development is limited to the first 6–8 years of life, whereas caries risk persists throughout the individual's lifetime, beginning with the eruption of the first tooth. Caries leave consequences and increase healthcare costs¹¹⁻¹².

Fluoride toothpaste should be associated with tooth brushing as from the eruption of the first tooth. Considering both caries prevention and the risk of fluorosis, toothpastes with 1,000 to 1,500 ppm of total fluoride are recommended for children, with at least 1,000 ppm in soluble form^{6,13-15}. However, many toothpastes intended for children contain low fluoride concentration and therefore lack anti-

cavity efficacy⁷. These may only be recommended for children under 3 years of age with a low risk of cavities and a high risk of developing fluorosis in the permanent upper central incisors due to regular exposure to high fluoride intake from sources other than fluoridated toothpaste, such as food, especially if they live in an area with fluoridated water⁵.

Due to concerns about the risk of fluorosis, Mercosur legislation only prioritizes the safety of fluoridated toothpaste to the detriment of its anti-caries potential, as it only establishes that fluoride (F) concentration in the toothpaste shall not exceed 1,500 ppm, without establishing the soluble fluoride concentration¹⁴. Therefore, some toothpastes on the market contain more than 1,000 ppm (F), but with a high concentration of insoluble salts, and several others are formulated with less than 1,000 ppm F because it is allowed by legislation, which is not in accordance with the best current scientific evidence^{6,9,14-16}.

The aim of this study was to determine the fluoride content in toothpaste brands recommended for children in Argentina.

MATERIALS AND METHOD

Sampling

A survey was conducted through websites, supermarkets and pharmacies to identify all commercially available toothpaste brands intended for children in Buenos Aires, Argentina. A total of 13 brands and 20 different formulations were identified and acquired from various retail sources. For each brand, three distinct lots within the expiration date were purchased. All products were included in the analysis. Each sample was encoded, and the analysis sequence was randomized using Microsoft Excel to ensure blind evaluation (Table 1).

Determination of fluoride concentration

Fluoride concentrations were determined following the protocol described by Cury et al.¹⁷. Each sample was analyzed in duplicate, where 90 to 110 mg (± 0.01 mg) of each sample were weighed and homogenized under vigorous stirring with 10 mL of distilled water until a suspension was obtained. Two 0.25 mL aliquots of each suspension were transferred to test tubes to determine the concentration of total fluoride (TF) and soluble fluoride. The remaining suspension was centrifuged at 3,000 g for 10 minutes at room

Table 1. Dentifrices for children marketed in Argentina and analyzed in this study

Code	Brand	Country	Lot1 Lot2 Lot3	Abrasive stated	Source of (F)	Total Fluoride stated (ppm or %)	Other information stated
A	BUCALTAC	Argentina	06/24 07/23 07/25	CaCO ₃ / Hydrated Silica	MFP	700	
B	CHICCO Niños 6-24 meses	Italy	0POL5053	Hydrated Silica	NaF	1000	Xilitol
C	CREST Kids	Greece USA	0434GR 31984354P1	Hydrated Silica	NaF	0,243%	
D	COLGATE Kids	Brazil	2277BR122K 2195BR121C 2185BR122C	Hydrated Silica	NaF	1100	
E	COLGATE Kids Zero	Mexico	1277MX111H 2039MX112H 1242MX111H	Hydrated Silica	NaF	1100	
F	COLGATE Smiles	Mexico	2206MX1116 2132MX1126 2036MX1116	Hydrated Silica	NaF	1100	
G	COLGATE Teens	Brazil	153BR122G 2034BR122K 2230BR121G	Hydrated Silica	NaF	1100	
H	ELGYDIUM Niños 2/6 años	France	G00015 G00005 G00008	Hydrated Silica	Amine fluoride	500	Silylglicol
I	ELGYDIUM niños 3/6 años	France	G00043 G00039	Hydrated Silica	Amine fluoride	1000	Silylglicol
J	ELGYDIUM Junior 7/12 años	France	G00036 G00033 G00011	Hydrated Silica	Amine fluoride	1400	Silylglicol
K	FARMACITY	Argentina	11011 30711 05521	CaCO ₃ / Silica	MFP/ NaF	700	
L	FLUOROGEL Chiquitos	Argentina	14585 14577 14589	Hydrated Silica	NaF	543	Xilitol 10%
M	FLUOROGEL Junior	Argentina	02604 02605 02602	Hydrated Silica	NaF	1086	Xilitol 10%
N	FRESH DENT Kids	unknown	220405 220102 220407	CaCO ₃ / Hydrated silica	MFP/ NaF	1000	
O	GUM	Argentina	220921 220307 220516	Hydrated Silica	NaF	1100	
P	JUNIOR SMILE (Dia)	Argentina	09521 11211 24321	CaCO ₃ / Hydrated silica	MFP NaF	700	
Q	ODOLITO	Brazil	2221BR122C 2095BR122C 2221BR121C	Hydrated silica	NaF	1100	
R	ORAL B Kids	Mexico	21434354P0	Hydrated silica	NaF	1100	

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Table 1. Dentifrices for children marketed in Argentina and analyzed in this study (cont.)

S	ORAL B Stages	Mexico	2146435402 2192435401 2172435401	Hydrated silica	NaF	1100	
T	SENSODYNE PRO-ESMALTE Niños	Slovaquia	20502KWC 13092KWA 11032KWC	Hydrated silica	NaF	1100	

Sample information: code, brand, country of origin, lot numbers, abrasive substance stated, source of (F), total fluoride stated (ppm or %) by manufacturers and other information stated.

temperature to separate the insoluble fluoride bound to abrasives.

For each lot, two 0.25 mL aliquots of the supernatant were transferred to test tubes to determine the concentration of total soluble fluoride (TSF) and to other tubes to determine the ionic fluoride (IF) concentration. All test tubes received 0.25 mL of 2.0 M HCl. TF and TSF tubes were incubated at 45 °C for 1h. All samples were neutralized by adding 0.5 mL of 1.0 M NaOH and buffered with 1 mL of TISAB II (acetate buffer, pH 5.0, containing 1.0 M NaCl and 0.4% CDTA), and analyses were performed to determine the fluoride content.

Specimens were analyzed using the potentiometry method with an ion-specific electrode (Orion 96-09) coupled to an ion analyzer (Orion EA-740; Orion Research). Prior to analysis, the electrode was calibrated using standard fluoride solutions with final concentrations of 0.5, 1.0, 2.0, 4.0, 8.0, 16.0, and 32.0 µg/mL (ppm F).

Data analysis

A linear regression equation correlating the logarithm of fluoride concentration in the standards with the measured electrode potential (mV) was calculated for each calibration ($r^2 > 0.999$) using GraphPad Prism software. This equation was applied to determine the fluoride concentration in each sample, expressed in parts per million (ppm or µg/g F).

RESULTS

This study analyzed 720 aliquots corresponding to 56 samples (1-3 lots per brand) of 20 brands of dentifrices for children (Table 1). Sixty-five percent were formulated with sodium fluoride (NaF), 5% were formulated with sodium monofluorophosphate (MFP) alone, 15% combined NaF with MFP, and 15% used amine fluoride as the active agent. Regarding abrasive components, 80% contained

hydrated silica, and the other 20% had a mixture of CaCO₃ and hydrated silica.

In 85% of the evaluated brands, the measured total fluoride (TF) was significantly lower than the amount stated by the manufacturer. Only three brands – H, I and K – had TF concentrations exceeding their labeled values.

The concentration of TF found in the fluoride dentifrices ranged from 651.5 to 1090.4 µg/ml F⁻, TSF ranged from 504.2 to 915.5 µg/ml F, and IF ranged from 298.6 to 838.2 (Table 2).

All evaluated samples exhibited total soluble fluoride (TSF) levels below 1000 ppm, the minimum threshold generally accepted for effective anti-caries action.

There were statistically significant differences between the TF stated on the label and the TF found in our study in all samples except samples B and I. Interestingly, in sample R, TF and TSF did not differ significantly (Table 2).

DISCUSSION

This study aimed to evaluate the fluoride content in children's toothpastes marketed in Argentina by assessing total fluoride (TF), total soluble fluoride (TSF) and ionic fluoride (IF), which are crucial for understanding the potential anti-caries effectiveness of these formulations.

Regarding geographic origin, 40% of the products were manufactured in Argentina, followed by Mexico (20%), France (15%), Slovakia (5%), Greece (5%) and Italy (5%). These origins may involve differences in regulatory frameworks, manufacturing standards, or formulation practices that could influence fluoride content and availability. Previous studies on fluoride concentrations in dentifrices have primarily focused on products intended for adult use. In Argentina, for example, available data from Cury et al.¹⁸ and Valadas et al.¹⁶ have assessed adult formulations.

Table 2. Concentration ($\mu\text{g/ml F-}$) of total fluoride stated and TF, TSF and IF found in the analysis of dentifrices sold in Argentina

Dentifrice label information ($\mu\text{g/ml F}$)	Fluoride ($\mu\text{g/ml F}$)	Mean	CI 95% (LL-UL)	<i>p-value</i> <i>Student one-sample test</i>
A (700)	TF*	651.5	627.1 - 675.9	<0.001
	TSF	566.1	511.8 - 620.3	
	IF	471.9	409.7 - 533.9	
	TF-TSF*	85.5	23.2 - 147.7	
B (1000)	TF	961.3	771.4 - 1151.1	0.662
	TSF	711.7	626.6 - 796.6	
	IF	556.8	464.7 - 648.8	
	TF-TSF*	249.6	122.1 - 377.1	
C (1500)	TF*	772.3	731.6 - 812.8	<0.005
	TSF	504.2	498.7 - 509.6	
	IF	466.6	456.5 - 476.5	
	TF-TSF*	268.1	225.6 - 310.6	
D (1100)	TF*	989.7	823.5 - 1155.9	<0.005
	TSF	772.4	739.1 - 805.7	
	IF	709.8	694.4 - 725.1	
	TF-TSF*	217.3	71.9 - 362.7	
E (1100)	TF*	891.2	845.6 - 936.9	<0.001
	TSF	713.7	677.4 - 749.9	
	IF	447.1	353.6 - 540.5	
	TF-TSF*	177.5	117.5-237.6	
F (1100)	TF*	880.9	819.3 - 942.4	<0.001
	TSF	508.6	474.7 - 542.5	
	IF	298.6	187.7 - 409.4	
	TF-TSF*	372.3	335.3 - 409.2	
G (1100)	TF*	954.2	916.4 - 991.9	<0.001
	TSF	760.5	711.7 - 809.3	
	IF	680.2	614.9 - 745.3	
	TF-TSF*	193.6	144.2 - 243.1	
H (500)	TF*	871.2	803.4 - 938.8	<0.001
	TSF	653.7	553.4 - 753.9	
	IF	496.0	478.1 - 513.8	
	TF-TSF*	217.4	116.4 - 381.5	
I (1000)	TF	1058.6	987.5 - 1129.7	>0.05
	TSF	764.7	711.6 - 817.6	
	IF	597.9	506.9 - 688.8	
	TF-TSF*	293.9	271.1 - 316.7	
J (1400)	TF*	1090.4	1054.5 - 1126.2	<0.001
	TSF	868.8	801.2 - 936.3	
	IF	758.4	680.1 - 836.8	
	TF-TSF*	221.6	133.6 - 309.6	

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Table 2. Concentration ($\mu\text{g/ml F-}$) of total fluoride stated and TF, TSF and IF found in the analysis of dentifrices sold in Argentina (cont.)

K (700)	TF*	849.0	804.6 - 893.4	<0.001
	TSF	770.0	702.8 - 837.1	
	IF	472.4	280 - 664.8	
	TF-TSF*	79.0	35.8 - 122.1	0.002
L (543)	TF*	977.0	952.1 - 1001.9	<0.001
	TSF	775.2	756.3 - 794.1	
	IF	368.4	230.6 - 506.1	
	TF-TSF	201.8	161.9 - 241.8	
M (1086)	TF*	855.6	831.6 - 879.5	<0.001
	TSF	829.1	800.1 - 858.1	
	IF	767.1	752.7 - 781.4	
	TF-TSF*	26.4	4.8 - 48.2	0.021
N (1000)	TF*	837.1	809.2 - 864.9	<0.001
	TSF	796.8	780.3 - 813.2	
	IF	760.6	735.9 - 785.2	
	TF-TSF*	40.3	8.7 - 71.8	0.017
O (1100)	TF*	975.1	951.9 - 998.3	<0.001
	TSF	910.7	896.7 - 924.7	
	IF	833.2	784.7 - 881.7	
	TF-TSF*	64.4	32.2 - 96.6	0.001
P (900)	TF*	890.4	846.5 - 934.3	<0.001
	TSF	843.6	818.3 - 868.8	
	IF	815.8	779.3 - 852.2	
	TF-TSF*	46.8	2.4 - 91.3	0.04
Q (1100)	TF*	899.7	861.6 - 937.7	<0.001
	TSF	813.5	802.1 - 824.9	
	IF	786.4	726.8 - 845.9	
	TF-TSF*	86.2	43.9 - 128.5	0.001
R (1100)	TF*	911.0	896.3 - 925.5	<0.001
	TSF	915.5	902.1 - 928.8	
	IF	838.2	823.9 - 852.3	
	TF-TSF	-4.5	-24.9 - 15.8	0.635
S (1100)	TF*	892.9	853.1 - 932.8	<0.001
	TSF	853.8	832.7 - 874.7	
	IF	824.6	811.2 - 837.9	
	TF-TSF*	39.1	6.4 - 71.9	0.023
T (1100)	TF*	968.5	935.9 - 1001.1	<0.001
	TSF	896.3	846.2 - 946.4	
	IF	784.7	762.3 - 807.1	
	TF-TSF*	72.2	28.6 - 115.7	0.004

Abbreviations: IF, ionic fluoride; TF, total fluoride; TSF, total soluble fluoride.

*Statistical significant differences ($p < 0.05$)

It is important to note that children's dentifrices contain flavoring agents to make them more appealing by improving taste and scent. These components can also provide breath-freshening benefits by masking odors and creating cooling or warming sensations. However, rather than merely encouraging regular use, pleasant flavors in children's toothpaste may increase the risk of accidental ingestion^{19,20}. This is of particular concern because during the enamel development phase, children younger than 8 years old are at risk of developing dental fluorosis, a condition that causes enamel discoloration and, in severe cases, affects enamel structure^{21,22}.

Therefore, current guidelines recommend that adults and caregivers supervise children's toothbrushing using fluoridated toothpastes with standard concentrations (1,000–1,500 ppm F), while ensuring that only age-appropriate amounts are applied¹².

The above highlights the importance of knowing the amount of fluoride content in each toothpaste, especially in those marketed for children. In its 2022 consensus statement, the International Association of Paediatric Dentistry (IAPD)²³ recommended brushing children's teeth twice daily with fluoridated toothpaste containing 1,000–1,500 ppm of fluoride. The guideline emphasizes adjusting the amount of toothpaste to the child's age ("smear" for children under 3 years; "pea-sized" for ages 3–6), rather than reducing fluoride concentration. Even with the recommendation to reduce the quantity and not the concentration of toothpastes, 25% of toothpastes in Argentina contain less than 1,000 ppm. There is evidence suggesting that using low-fluoride toothpastes in children increases the risk of caries in primary teeth¹³.

Anticaries activity is related to the available soluble fluoride concentration, which must be at least 1000 ppm. While laws in USA, Canada, Australia and Chile require dentifrice labels to specify the concentration of soluble fluoride, Argentina follows Mercosur legislation¹⁴, which only establishes that the maximum concentration of TF in a toothpaste should be 1500 ppm, whether for adults or children. The same is true in Brazil and Mexico⁶.

In the current study, in 100% of the samples, the soluble fluoride concentration was lower than the 1000 ppm suggested by scientific evidence. The total fluoride (TF) levels in 85% of the analyzed brands were lower than those stated by the manufacturer, except for Dentifrices *Elgydium niños 2/6 años*,

Elgydium niños 3/6 años and *Farmacy*, which contained higher levels than stated. However, even when the concentrations were higher than stated, they were still well below the 1,500ppm limit established by Mercosur legislation.

Several of the evaluated brands have also been assessed in previous studies conducted in Latin America. For example, the values we found for brands E and F were much lower than those reported by Chavez et al.¹⁵ in Peru, and Leite Filho et al.⁶ in Brazil and Mexico. The concentration we found in brand F was also lower than those reported by Loureiro et al.²⁴ in Uruguay and Valadas et al.⁹ in Brazil. Brands R, S, D and G in our study presented slightly lower fluoride values than those reported by Valadas et al.⁹, and brands D, G and H contained lower concentrations than those reported by Leite Filho et al.⁶ in Brazil. Brands C, D, R and S in our study contained lower concentrations than samples from Mexico reported by Leite Filho et al.⁶. On the other hand, brand O was found to have levels similar to those reported by Valadas et al.⁹.

The findings suggest that most children's dentifrices marketed in Argentina do not meet the stated fluoride content, potentially reducing their effectiveness in preventing dental caries. The presence of lower soluble fluoride levels highlights the need for regulatory revisions to ensure compliance with scientific recommendations and maximize anti-caries benefits.

This study did not include an analysis of the chemical interaction between fluoride and the abrasive used in each toothpaste, which can affect fluoride solubility and bioavailability. Future research should explore how specific abrasive components influence fluoride stability over time, particularly after product exposure to air or during repeated use, to better simulate real-world conditions. Additionally, long-term stability studies could help determine whether the soluble fluoride content declines over the shelf life of these products.

CONCLUSIONS

Children's toothpastes marketed in Argentina showed substantial variability in formulation and fluoride content. Although all products complied with the regulatory upper limit of 1,500 ppm total fluoride (TF), none of them contained the minimum recommended concentration of 1,000 ppm total soluble fluoride (TSF) necessary to provide

effective anti-caries effect. These findings suggest the need to revise current regulatory policies to ensure that fluoride content is both accurately

labeled and aligned with evidence-based thresholds for anticaries efficacy.

CONFLICT OF INTERESTS

The authors declare no potential conflict of interest regarding the research, authorship and/or publication of this article.

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