

## Fluoride content in children's dentifrices marketed in Lima, Peru

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**Abstract:** The aim of the present study was to determine the concentration of total fluoride (TF) and total soluble fluoride (TSF) in children's dentifrices marketed in the city of Lima, Peru. Three samples of 23 dentifrices (4 without fluoride and 19 with fluoride) were purchased in different pharmacies in Lima, Peru. The TF and TSF concentrations found in the dentifrices were determined by ion-selective electrode, expressed in ppm F ( $\mu\text{g F/g}$  of dentifrice). The TF concentration in the majority of the fluoride toothpastes matched that shown on the label, except for one declared as 1450 ppm F by the manufacturer, whereas only 515.1 ppm F was found. The concentration of TSF found in the fluoride toothpastes ranged from 457.5 to 1134.8 ppm F. All the dentifrices were formulated with silica, but one also presented calcium carbonate. In conclusion, 83% of the children's dentifrices marketed in Lima, Peru, were fluoridated, but only 53% contained a TSF concentration greater than 1000 ppm F, the minimum concentration required to provide an anticaries effect.

**Keywords:** Fluorides; Pediatric Dentistry; Toothpastes.

### Introduction

The use of toothpaste with fluoride has been recommended for over 50 years to prevent and control dental caries.<sup>1</sup> Topical fluoride is considered one of the most effective public healthcare strategies to control caries, especially among the child population, which is the most vulnerable.<sup>2</sup> The anticaries effect of fluoride toothpastes, together with the correct toothbrushing technique, promotes the disruption of biofilm, and maintains the demineralization-remineralization balance.<sup>3</sup> An amount of 1000 ppm of F in toothpaste achieves this benefit, but the F must be in soluble form (SF) for it to be active in its formulation, and thus be able to interfere in the development of a disease.<sup>1,4,5,6,7,8</sup>

The presence of SF in a dentifrice depends on its formulation, in terms of type of fluoride salt and abrasive used. The dentifrices that contain sodium fluoride (NaF) have high fluoride availability, because they are formulated with silica as an abrasive agent. When the toothpaste is formulated with an abrasive containing calcium (calcium carbonate or dicalcium phosphate dihydrate), it must contain sodium monofluorophosphate (MFP) as a fluoridating agent, because the MFP ion does not react immediately with  $\text{Ca}^{++}$ .<sup>6,9</sup> However, this type of formulation

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is not totally stable, and the F concentration decreases by 40% one year after manufacture. For this reason, it is better not to purchase a product, if it does not show an expiration date.<sup>6,10,11</sup>

The recommendations for fluoride toothpaste use in infants and children have been modified in recent years in an effort to maximize caries prevention, and minimize the risk of dental fluorosis<sup>1</sup>. Some healthcare professionals put off using of fluoridated dentifrice in children; this is an inappropriate approach, since there is no scientific evidence to conclude that the use of fluoridated dentifrices in children under 12 months of age is associated with fluorosis.<sup>2,12</sup> On the other hand, recommending dentifrices without F or with a low F concentration to avoid fluorosis is irresponsible, since the at-home application of F through toothpaste is the best public healthcare strategy to prevent and control caries.<sup>13,14</sup> Scientific evidence indicates that fluoridated toothpaste should be used as soon as the first tooth appears in the oral cavity.<sup>13</sup> Therefore, it is up to pediatric health professionals to make recommendations regarding toothpaste expiration dates and minimum amount of F for an anticaries effect, especially in areas where fluoridated drinking water is not available.<sup>15,16</sup>

The regulations made by some countries, such as the US and Mercosur member countries, do not require companies to state the amount of SF in a given product.<sup>2</sup> Peru is subject to Sanitary Technical Standard 2001 regulating the addition of fluorides to toothpastes, approved by M.R. No. 454-2001-SA/DM, which states merely that toothpastes for children must have an SF concentration of less than 600 ppm one year after being manufactured, and 450 ppm until their expiration.<sup>17</sup> The last Peruvian study that evaluated the concentration and stability of fluoride was published in the mid-twentieth century.<sup>18</sup>

Considering the importance of the SF concentration in toothpastes, it was decided to evaluate this concentration in children's dentifrices marketed in the city of Lima, Peru, and to compare it with the information declared by the manufacturer on the packaging label, in order to substantiate information that guarantees the anticaries effect of dentifrices.

## Methodology

Twenty-three dentifrices marketed for children's use and found in different pharmacy chains in the city of Lima, Peru, during the period from June to July 2017, were purchased in triplicate of different batches (total = 69). The samples were coded to allow blind analysis. The manufacturer's information about the dentifrices are described in Table 1.

In regard to chemical analysis, total soluble fluoride (TSF or free F) concentrations were determined, including F ion (FI) and fluoride as sodium monofluorophosphate (MFP), and total fluoride (TF), corresponding to the sum of TSF and insoluble F (IF), which may be bound to the abrasive. Ninety to 110 mg of each dentifrice ( $\pm 0.01$  mg) were weighed and homogenized vigorously in 10.0 ml of deionized water. An aliquot of 0.25 ml of the suspension was transferred from each toothpaste tube (total = 69) to TF-labeled test tubes, and 0.25 ml of 2 M HCl was added. The tubes were heated to 45°C and kept at this temperature for 1 hour to hydrolyze the MFP ion to the F ion, and to dissolve the IF bound to the abrasive.

The resulting acid suspension was neutralized with 0.5 ml of 1 M NaOH, and buffered with 1 ml of TISAB II (1 M acetate buffer, pH 5.0, containing 1 M NaCl and 0.4% CDTA). The suspension was centrifuged for 10 min to 3000 g at room temperature to remove the IF, and the supernatant was used to determine TSF and IF. Afterwards, 0.25 ml of the supernatant was transferred to tubes labeled as TSF, and treated as described for TF. The F concentrations in the tubes (TF and TSF) were evaluated using an F electrode (Thermo Scientific Orion 96-09, Orion Research, Cambridge, MA, USA), coupled to an ion analyzer (Star A214, Thermo Scientific Orion). The electrode was calibrated with standard F solutions from 0.06 to 8.0  $\mu\text{g F/mL}$ , prepared in 0.25 M NaOH, 0.25 M HCl and TISAB II 50% (v/v). A linear regression between the logarithm of F concentrations in standard and respective mV values was determined using Excel software (Microsoft, Redmond, USA). The mathematical regression equation was used to calculate the concentration of F in dentifrice (Figure 1). Using the determined amounts of TF and TSF, the IF concentration was calculated as  $\text{TF} - \text{TSF}$ , and the percentage of IF was obtained by dividing the IF concentration by TF,

**Table 1.** Information regarding the dentifrices analyzed (Lima, Peru).

Sample	Name	Fluoride declared on packaging (ppm)	Active ingredient	Abrasive specified on packaging	Manufacture date	Expiration date	Country of manufacture
A	Denture BB	Without fluoride	Lacking	Silica, hydrated silica	Jul 16	Jul 19	Ecuador
B	Dentito Baby	Without fluoride	Lacking	Silica	Apr 17	Aug 19	Peru
C	Aquafresh Baby teeth	Without fluoride	Lacking	Silica	Not specified	Apr 18	USA
D	Colgate My First	Without fluoride	Lacking	Hydrated silica	Not specified	Oct 17	USA
E	Farma Dent Kids	452	NaF	Silica	Not specified	Jul 21	China
F	Colgate Smiles (Sponge Bob, Barbie)	500	NaF	Hydrated silica	Not specified	Jan 20	Mexico
G	Denture Kids	Not specified	MFP	Silica	Aug 16	Aug 19	Ecuador
H	Aquafresh Little Teeth	500	NaF	Hydrated silica	Not specified	Jan 18	USA
I	Oral B Stages (Frozen, Star Wars, Princesses, Mickey Mouse)	500	NaF	Hydrated silica	Oct 16	Sep 18	Mexico
J	Dentito gum flavor	550	MFP	Silica	Not specified	May 20	Peru
K	Dentito Chicha Morada flavor	550	MFP	Silica	Not specified	Mar 20	Peru
L	Tuinies Hello Kitty	580	NaF	Hydrated silica	Not specified	Jul 20	China
M	Tuinies Peppa Pig	1450	NaF	Hydrated silica	Not specified	Jun 21	China
N	Oral B 123	1000	NaF	Hydrated silica	Not specified	Jun 18	Mexico
O	Dento Junior watermelon flavor	1100	NaF	Silica	Not specified	Oct 19	Peru
P	Colgate Kids strawberry flavor	1100	NaF	Hydrated silica	Not specified	Feb 20	Brazil
Q	Ipana	1100	NaF	Hydrated silica	Not specified	Feb 20	Peru
R	Colgate Kids grape flavor	1100	NaF	Hydrated silica	Not specified	Feb 20	Brazil
S	Colgate Smiles (Barbie, Minions, Spiderman)	1100	NaF	Hydrated silica	Not specified	Feb 20	Mexico
T	Colgate Kids tutti-frutti flavor	1100	NaF	Hydrated silica	Not specified	Feb 20	Brazil
U	Tuinies Hello Kitty-Xtreme White	1450	NaF MFP	Hydrated silica	Not specified	July 20	China
V	Vitis Junior	1000	NaF	Silica	Not specified	Dec 19	Spain
W	Aquafresh "My Big Teeth"	1150	NaF	Hydrated silica	Not specified	Feb 19	USA

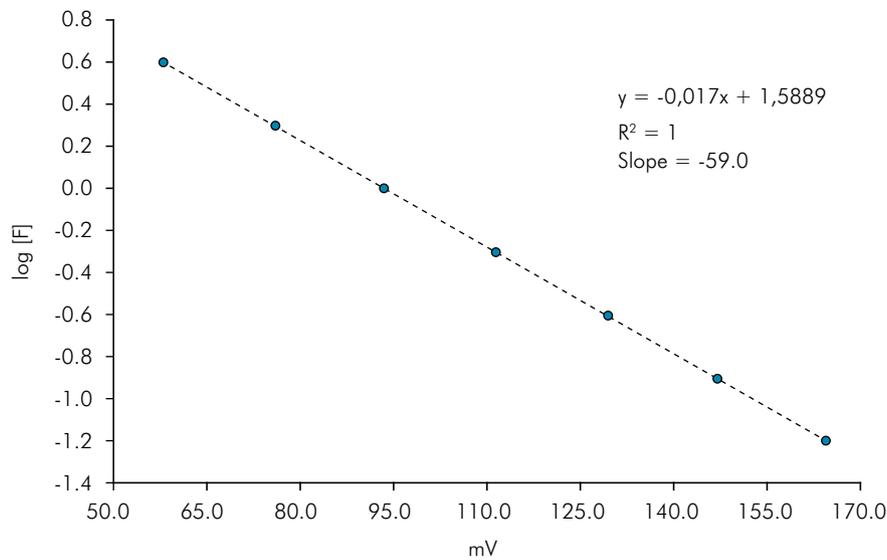
NaF: Sodium fluoride; MFP: Sodium monofluorophosphate (MFP =  $\text{Na}_2\text{FPO}_3$ ).

and multiplying by 100. The analysis of each tube of toothpaste was carried out in triplicate.

The data were reported by the biochemistry laboratory of the School of Dentistry, University of Piracicaba (Unicamp), Brazil, and were processed according to an automated tabulation method, after which an analysis of frequency was performed according to the objectives specified.

## Results

The 23 dentifrices analyzed in this study included four dentifrices without F, one with an unspecified concentration of F, and 18 with F concentrations from 452 to 1450 ppm. The main active ingredients used were NaF, present in 15 of the analyzed samples, and MFP, present in three; one sample contained both active ingredients (NaF and MFP) (Table 1). In relation to the



**Figure 1.** Calibration curve (n = 4) and data on the correlation between the logarithm of fluoride concentrations in the standard and relative mV values generated

abrasives reported on the packaging, the most common were silica and hydrated silica. The abrasive agents declared by the manufacturer matched those found, except for Sample U (Tuinies Hello Kitty Extreme White), whose packaging indicated silica, but whose analysis revealed calcium carbonate. The expiration date was informed on all the products; however, the manufacture date was reported on just four.

The TF concentration declared on the packaging of 21 of the 23 dentifrices analyzed in this study was close to the value found (Table 2 and Figure 2). Only Denture Kids toothpaste (Sample G) did not declare any F content on the packaging, but the analysis found an amount of 476.4 ( $\pm 2.8$ ) ppm of F in its composition. In addition, Tuinies Peppa Pig toothpaste (Sample M) declared a concentration of 1450 ppm of F in its composition, whereas the laboratory analysis revealed a concentration of only 515.1 ( $\pm 10.5$ ) ppm of F.

Furthermore, we found that the average concentration of TF was slightly lower than the concentration of TSF in 18 of the 19 fluoridated dentifrices analyzed. Only the Tuinies Hello Kitty - Xtreme White sample (Sample U) showed a concentration of TF (1,307.6  $\pm 22.3$ ) greater than TSF (1,061.4  $\pm 56.1$ ). Almost 20% of the TF of this formulation is insoluble (Table 2). Although the label indicates that the abrasive is silica, we checked and were surprised

to find that the abrasive was calcium carbonate, not silica. In regard to the dentifrices claiming they did not contain F (17% of the total dentifrices analyzed), the information declared is similar to what was actually found. Of the 23 dentifrices analyzed, 53% (n = 13) showed that a minimum concentration of F had a high anticaries potential (Table 3 and Figure 3).

## Discussion

The therapeutic efficacy of a toothpaste is based on the release of fluoride into the oral environment at the time of brushing; for this reason, its formula must provide SF.<sup>19-21</sup> In our study, only 53% of the samples had the minimum concentration needed to promote an anticaries effect (1,000 ppm).

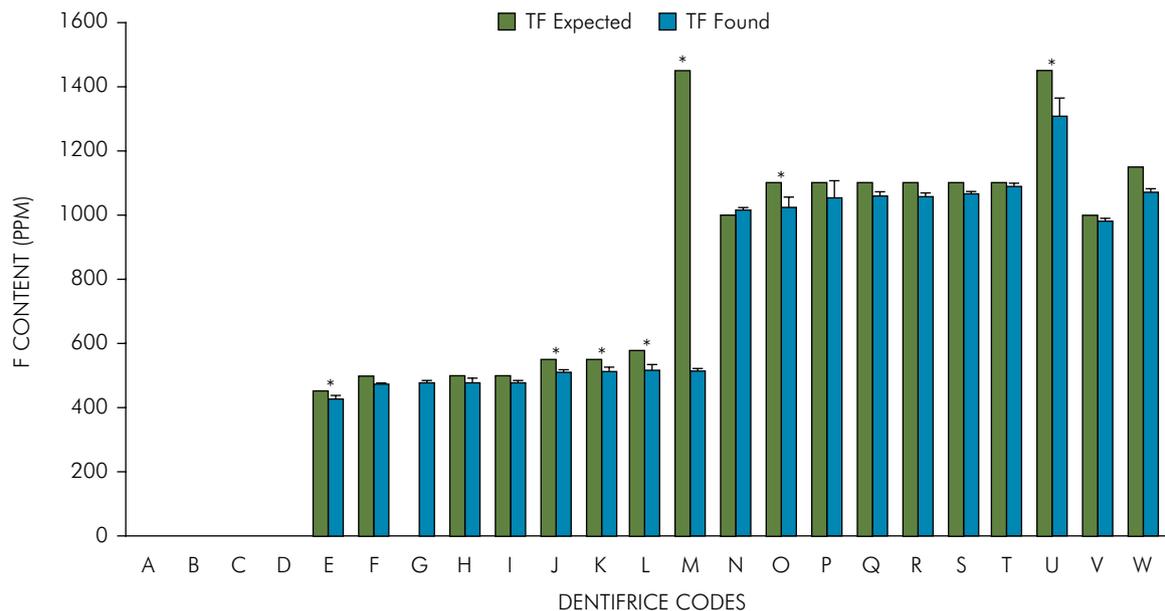
Sample G (Denture Kids) does not state the concentration of F on the packaging, and the analysis showed 492.1 ppm of F, whereas Sample M (Tuinies Peppa Pig) states 1,400 ppm F, with the analysis showing only 38% of the value declared (531 ppm F). A discordant value was also found in the study by Giacaman et al.<sup>16</sup> (Chile), who found a dentifrice whose amount of F declared by the manufacturer was 450 ppm, whereas the amount of F found exceeded this amount threefold.

These discordant values between the F declared by the manufacturer on the packaging and the F

**Table 2.** As declared on label: total fluoride (TF) and total soluble fluoride (TSF) concentration (mg F/kg) found, and % of insoluble fluoride (IF) in the dentifrices analyzed (average ± sd; n = 3).

Sample	Dentifrice	Expected TF (ppm)	TF found	TSF found	IF (%)
A	Denture BB	Without fluoride	0.0 ± 0.0	0.0 ± 0.0	na
B	Dentito Baby	Without fluoride	0.0 ± 0.0	0.0 ± 0.0	na
C	Aquafresh Baby Teeth	Without fluoride	0.0 ± 0.0	0.0 ± 0.0	na
D	Colgate My First	Without fluoride	0.0 ± 0.0	0.0 ± 0.0	na
E	Farma Dent Kids	452	428.3 ± 1.5	457.5 ± 10.5	0.0
F	Colgate Smiles (Sponge Bob, Barbie)	500	472.3 ± 7.7	489.6 ± 2.0	0.0
G	Denture Kids	Not specified	476.4 ± 2.8	492.1 ± 5.7	0.0
H	Aquafresh Little Teeth	500	477.3 ± 29.3	481.8 ± 13.2	0.0
I	Oral B Stages (Frozen, Star Wars, Princesses, Mickey Mouse)	500	479.1 ± 5.6	499.1 ± 6.5	0.0
J	Dentito gum flavor	550	510.0 ± 9.3	551.7 ± 9.8	0.0
K	Dentito Chicha Morada flavor	550	512,6 ± 8.2	550.6 ± 15.6	0.0
L	Tuinies Hello Kitty	580	514.7 ± 19.4	541.4 ± 20.6	0.0
M	Tuinies Peppa Pig	1450	515.1 ± 10.5	531.0 ± 8.6	0.0
N	Oral B 1-2-3	1000	1017.2 ± 8.6	1055.0 ± 7.6	0.0
O	Dento Junior watermelon flavor	1100	1022.8 ± 46.5	1063.7 ± 35.7	0.0
P	Colgate Kids strawberry flavor	1100	1055.5 ± 58.1	1134.8 ± 52.1	0.0
Q	Ipana	1100	1056.5 ± 21.1	1104.1 ± 16.5	0.0
R	Colgate Kids Grape	1100	1058.5 ± 21.1	1081.7 ± 9.0	0.0
S	Colgate Smiles (Barbie, Minions, Spiderman)	1100	1065.7 ± 15.4	1093.9 ± 5.6	0.0
T	Colgate Kids tutti-frutti flavor	1100	1085.9 ± 16.8	1127.9 ± 13.9	0.0
U	Tuinies Hello Kitty - Xtreme White	1450	1307.6 ± 22.3	1061.4 ± 56.1	18.8
V	Vitis Junior	1000	982.4 ± 18.6	1001.1 ± 4.9	0.0
W	W Aquafresh "My Big Teeth"	1150	1069.1 ± 6.7	1112.2 ± 13.1	0.0

TF: Total fluoride; TSF: Total soluble fluoride; IF: Insoluble fluoride.



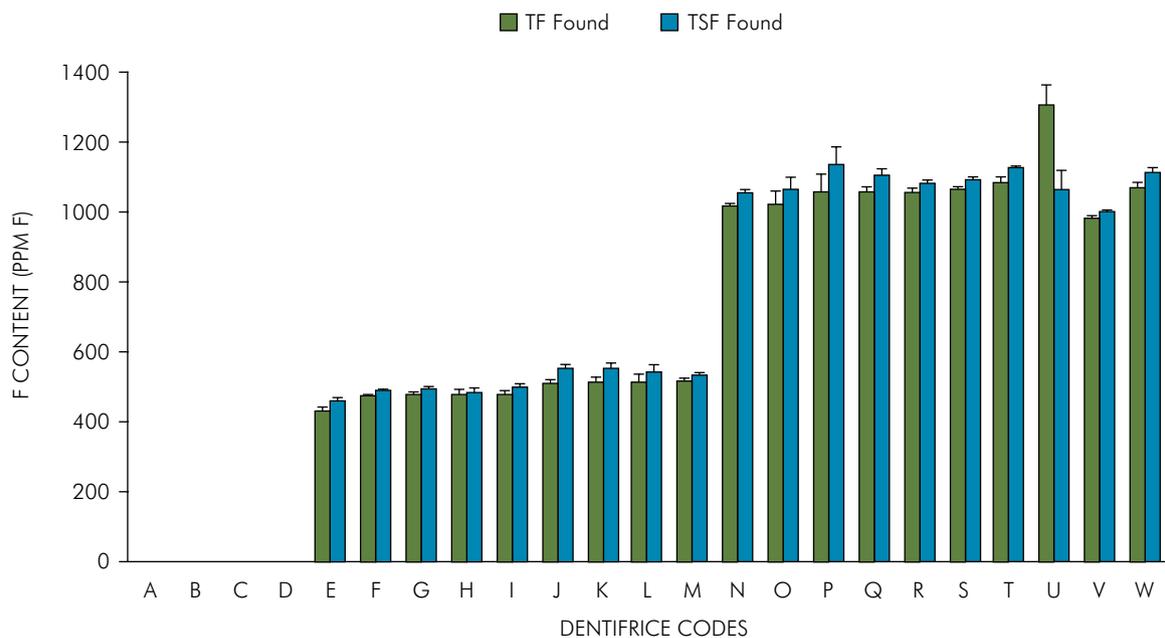
\*Difference between TF found and expected of analytical significance (± 5%).

**Figure 2.** Concentration (ppm F) of total fluoride declared by the manufacturer (TF expected) and found in the toothpastes analyzed (TF found)

**Table 3.** Concentration of total soluble fluoride (average  $\pm$ sd; n=3) in the dentifrices analyzed, and their anticaries potentials.

Sample	Dentifrice	Average TSF found ( $\pm$ sd)	Anticaries potential
A	Denture BB	0.0 $\pm$ 0.0	None
B	Dentito Baby	0.0 $\pm$ 0.0	None
C	Aquafresh Baby Teeth	0.0 $\pm$ 0.0	None
D	Colgate My First	0.0 $\pm$ 0.0	None
E	Farma Dent Kids	457.5 $\pm$ 10.5	Low
F	Colgate Smiles (Sponge Bob, Barbie)	489.6 $\pm$ 2.0	Low
G	Denture Kids	492.1 $\pm$ 5.7	Low
H	Aquafresh Little Teeth	481.8 $\pm$ 13.2	Low
I	Oral B Stages (Frozen, Star Wars, Princesses, Mickey Mouse)	499.1 $\pm$ 6.5	Low
J	Dentito gum flavor	551.7 $\pm$ 9.8	Low
K	Dentito <i>Chicha Morada</i> flavor	550.6 $\pm$ 15.6	Low
L	Tuinies Hello Kitty	541.4 $\pm$ 20.6	Low
M	Tuinies Peppa Pig	531.0 $\pm$ 8.6	Low
N	Oral B 1-2-3	1055.0 $\pm$ 7.6	High
O	Dento Junior watermelon flavor	1063.7 $\pm$ 35.7	High
P	Colgate Kids strawberry flavor	1134.8 $\pm$ 52.1	High
Q	Ipana	1104.1 $\pm$ 16.5	High
R	Colgate Kids Grape	1081.7 $\pm$ 9.0	High
S	Colgate Smiles (Barbie, Minions, Spiderman)	1093.9 $\pm$ 5.6	High
T	Colgate Kids tutti-frutti flavor	1127.9 $\pm$ 13.9	High
U	Hello Kitty - Xtreme White	1061.4 $\pm$ 56.1	High
V	Vitis Junior	1001.1 $\pm$ 4.9	High
W	W Aquafresh "My Big Teeth"	1112.2 $\pm$ 13.1	High

TSF: Total soluble fluoride.



**Figure 3.** Concentration (ppm F) of total fluoride (TF found) and total soluble fluoride found (TSF found) in the toothpastes analyzed.

analyzed are seriously prejudicial to consumers, since this misinformation violates their right to truthful information. It is troublesome that the products do not reflect the real value. In 17 (73.9%) dentifrices analyzed, the TF declared by the manufacturer on the label was lower than that found. This percentage contrasts with that of Cury et al.<sup>2</sup> and Loureiro et al.,<sup>22</sup> who found a respective 84.4% and 83.3% similarity between the F declared and the F found in Brazilian dentifrices. Nevertheless, the similarity in values found by Carrera et al.<sup>23</sup> was 77.2% between the F declared and the F found. On the other hand, in a study<sup>24</sup> with 22 fluoride toothpastes commercially available in South Africa, the TF concentration of all the toothpastes was lower than that declared by the manufacturers, with one in four having TSF concentrations of less than 1,000 ppm F.

As for the active ingredients used, the type of F declared on the dentifrices coincides 100% with that found in the analysis. In silica-based preparations of 1000 ppm of F, NaF constitutes 0.22% of the dentifrice and is highly ionizable; therefore, it becomes active as soon as it enters the mouth, stimulating the remineralization of decalcified enamel and interfering in the growth and development of bacteria in dental plaque.<sup>20</sup> NaF was present in 70% of the samples analyzed (E, F, H, I, L, M, N, O, P, Q, R, S, T, V, W), and MFP, in 30% of the samples (G, J, K). These results agree with those of Loureiro's study<sup>22</sup> in Uruguay, in which most of the dentifrices that he evaluated were found to use NaF. A previous study<sup>25</sup> developed with toothpastes on the Belgian market, using a specific method to determine the amount of NaF, sodium monofluorophosphate (SMFP) and amine fluoride (AmF), also found all the samples analyzed to be in conformity with the local guidelines. However, the maximum total fluoride concentration allowed by European guidelines is 0.15 % (1,500 ppm F).

Regarding the active ingredient used, only Sample U (Tuinies Hello Kitty - Xtreme White) uses two types of F (MFP and NaF), similar to the findings of the study by Benzian<sup>26</sup> in Brunei, Cambodia, Laos, the Netherlands and Suriname, in which two dentifrices were found to combine MFP and NaF. Most silica-based toothpastes contain highly ionizable NaF, which is activated as soon as it comes into contact with the tooth

surface. If NaF is combined with a calcium carbonate-based abrasive agent, it binds to the calcium of the abrasive agent, forming calcium fluoride (CaF<sub>2</sub>) inside the toothpaste tube and not on the tooth surface. In this case, the CaF<sub>2</sub> formed in the toothpaste does not release F, thus inhibiting its preventive action.

Abrasives can include silica, hydrated silica and calcium carbonate (or dicalcium phosphate dihydrate). It is important to note that dentifrices containing calcium carbonate or dicalcium phosphate dihydrate as an abrasive must be formulated with MFP, whereas NaF-based ones must have silica (hydrated silica) as their abrasive agent. In this study, the abrasive appearing on the packaging was mostly hydrated silica: 61%, followed by silica: 35%, and both: 4%. According to the label, toothpaste U (Tuinies Hello Kitty - Xtreme White) was formulated adequately with a NaF/MFP silica-based abrasive, but we found that the abrasive was actually calcium carbonate. This is explainable, because we found 20% of IF in this formulation. A study developed with toothpastes marketed in India<sup>27</sup> also found that the mean percentage of TSF concentration in SMFP/CaCO<sub>3</sub>- (calcium carbonate) based toothpastes was 86% (SD = 16%), whereas that in NaF/Si- (silica) based toothpastes was 98% SD 1%, and that in the remaining toothpastes with unknown abrasive was 95% SD 1%.

The present study provides results that can contribute to modifying the current guidelines that regulate the concentration of children's toothpaste marketed in Peru. The last national caries survey found a prevalence of dental caries in deciduous, mixed and permanent dentitions of 59.1%, 85.5% and 57.6%, respectively.<sup>28</sup> Pertinent changes in the Peruvian regulations on adequate F concentration could guarantee the use of toothpastes that effectively control dental caries.<sup>29,30</sup> Accordingly, it could reduce the polarization of dental caries according to socioeconomic status, since children from low-income families usually have more dental caries than those with a higher income.<sup>30</sup> In addition, the prevention of oral conditions can minimize social, functional, economic and behavioral impacts on children and/or parents.<sup>29,30,31</sup>

The present results are an alert for other regions of the world having resolutions that lack guidelines on the beneficial anticaries effect of fluoride, as

in Mercosur countries.<sup>32</sup> Knowing the benefit of toothpastes with adequate concentrations of fluoride allows effective strategies to be established to control caries. In addition, the present study shows that the Peruvian health surveillance system fails to control imported dentifrices from China, corroborating a previous analysis on the dentifrice market in Chile.<sup>16</sup>

## Conclusion

Most of the children's dentifrices marketed in Lima, Peru, at the time of this study, were fluoridated, but only 53% contained a TSF concentration greater

than 1000 ppm F, the minimum concentration needed to provide an anticaries effect. Therefore, the concentrations of F in toothpastes for children in Lima seem inappropriate for dental caries control, and must be rectified in public health policies.

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