# Fluoride in Oral Hygiene Products: Exposure and Non-carcinogenic Risk Assessment

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#### Abstract

Fluoride is a key component in oral hygiene products, widely recognised for its role in preventing dental caries. However, excessive fluoride intake poses potential health risks, particularly to vulnerable populations. This study evaluates fluoride exposure and non-carcinogenic health risks associated with commercial oral hygiene products in Bosnia and Herzegovina (B&H). Based on fluoride concentration in toothpaste and mouthwash samples, estimated daily intake (EDI) and hazard quotient (HQ) values were calculated for four age groups: children under two years of age (< 2 years), children (2–6 years), teenagers (6–16 years), and adults (≥ 16 years). The results revealed that toothpaste contributed more to fluoride exposure than mouthwash across all age groups. Children exhibited higher EDI and HQ values due to increased ingestion rates, with HQ exceeding 1 for some toothpaste samples, indicating potential non-carcinogenic health risks. In contrast, teenagers and adults had HQ values below 1, suggesting minimal risk. A comparative analysis with international studies demonstrated that fluoride exposure levels in B&H are generally lower, although certain samples exceeded safe intake thresholds. This study underscores the importance of monitoring fluoride concentrations in oral hygiene products and educating the public on their proper use to balance dental health benefits with potential risks.

#### Keywords

Fluoride exposure, toothpaste, mouthwashes, hazard quotient (HQ)

## 1 Introduction

Fluorine does not occur in its elemental state on Earth because it is the most electronegative element but exists in the form of fluoride. Fluorides occur naturally in soil, water, and certain minerals such as apatite, fluorite, claystone, cryolite, hornblende, and numerous pegmatites such as topaz and tourmaline. Industrial emissions and volcanic activity also contribute to environmental fluoride levels. <sup>1,2</sup> Inorganic fluorides, such as sodium fluoride (NaF), calcium fluoride (CaF<sub>2</sub>), and sodium hexafluorosilicate (Na<sub>2</sub>SiF<sub>6</sub>), are commonly used in water fluoridation and oral hygiene products to prevent dental caries. <sup>3</sup> Hydrogen fluoride (HF) and sulphur hexafluoride (SF<sub>6</sub>) have industrial applications but differ in toxicity. HF is highly corrosive and toxic, while SF<sub>6</sub> is an inert, non-toxic gas primarily used as an electrical insulator. <sup>4</sup>

Human exposure to fluorides mainly occurs through the consumption of fluoridated water, food, beverages, cow's milk, fluoride supplements, and dental products like toothpaste and mouthwash.<sup>5</sup> Fluorides are often added to public water supplies to prevent dental caries, which has proven effective in reducing cavity prevalence, especially in communities with limited access to dental care. Additionally, fluoride occurs naturally in varying concentrations in groundwater, with some regions experiencing higher concentrations due to geological factors such as mountainous areas and regions with geological deposits of marine

origin.<sup>2</sup> Proper fluoride intake is essential for dental health, as it helps remineralise enamel and inhibit the activity of bacteria that cause tooth decay. However, excessive fluoride exposure, particularly in children during enamel development, can lead to dental fluorosis.<sup>6</sup> This condition, characterised by discoloration, pitting, and in severe cases, structural damage to tooth enamel, is caused by prolonged exposure to high fluoride levels during critical growth periods.<sup>7</sup> Beyond dental fluorosis, chronic overexposure to fluoride can result in skeletal fluorosis, a condition that affects bones and joints, causing pain, stiffness, and reduced mobility. Studies have also explored the potential systemic effects of excessive fluoride intake, including impacts on thyroid function and neurodevelopment.<sup>8,9</sup> Public health measures, such as monitoring fluoride levels in water and educating the public on the proper use of dental products, are crucial for mitigating the risks associated with excessive fluoride intake.

However, concerns regarding the health risks associated with excessive fluoride exposure, particularly from oral hygiene products, have gained increasing attention. While fluoride is generally considered safe at the concentrations used in most oral care formulations, inadvertent ingestion, especially in children, has been identified as a potential risk factor for adverse health outcomes. 10,11 The health risks linked to fluoride exposure are primarily associated with its accumulation in the body, leading to conditions such as dental fluorosis and skeletal fluorosis, as well as potential developmental and neurobehavioral effects. 12 Children are particularly vulnerable to fluoride toxicity due to their higher likelihood of swallowing toothpaste and mouthwash.

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The present study aimed to assess the potential health hazards of fluoride exposure from oral hygiene products available on the B&H market, considering factors such as ingestion rates, product formulations, and individual susceptibility. By evaluating fluoride exposure from these commonly used products, this assessment seeks to inform safe usage practices and regulatory guidelines, ensuring both the effectiveness of fluoride in oral health, and the prevention of its excessive intake.

#### 2 Materials and methods

A health risk assessment for fluoride exposure through water, milk, food, and toothpaste, involves evaluating both the potential health benefits and risks associated with fluoride ingestion. This is particularly relevant across different age groups and requires assessing exposure levels, potential toxicity, and long-term health effects.<sup>5</sup>

## 2.1 Estimated Daily intake of fluoride

Human health risk assessment involves evaluating the potential for adverse health effects in individuals exposed to chemicals in contaminated environmental media, either currently or in the future. This study conducted a quantitative assessment of health risks associated with fluoride exposure from oral hygiene products across various age groups in B&H. The analysis considered fluoride concentrations in commercially available toothpaste and mouthwash. The population was categorised into four age groups based on physiological and behavioural characteristics, following the methodology of *Youssefi et al.*: children under two years of age (< 2 years), children (2–6 years), teenagers (6–16 years), and adults (≥ 16 years).<sup>12</sup>

Fluoride exposure to each age group was estimated using Eq. (1), which accounts for the daily fluoride intake from oral hygiene products, the frequency of their use, and the body mass specific to each age group. <sup>12</sup> This approach enabled the assessment of individual risk of systemic fluoride exposure and the identification of populations with a potentially increased risk of fluoride toxicity:

$$EDI = \frac{C_{F} \cdot IngR}{BW}$$
 (1)

Estimated daily intake (EDI) of fluoride was calculated based on the daily minimal ingestion rate of fluoride (IngR) and maximal ingestion rate via toothpaste (P1-P5) and mouthwash (T1-T5), concentration of fluoride ion ( $C_F$ ), and body weight (BW). EDI is expressed in milligrams per kilogram of body weight per day.

According to *Pazalja* et al. <sup>13</sup>, the fluoride content of five toothpaste samples and five mouthwash samples from the B&H market is presented in Table 1. The minimal ingestion rate for toothpaste was 0.26 g and maximal was 0.77 g, <sup>5</sup> while for mouthwash the minimal ingestion rate was 0.24 mg and the maximal rate was 0.44 mg. <sup>14</sup>

The assumed body weights for the target groups were: 10 kg for children (2 years old), 15 kg for children (2–6 years old), 50 kg for teenagers (6–16 years old), and 78 kg for adults ( $\geq$  16 years old).

Table 1 – Concentration of fluoride in toothpaste and mouthwash<sup>13</sup>

Tablica 1 – Koncentracija fluorida u pastama za zube i vodicama za ispiranje usta<sup>13</sup>

F-/mgl-1
1286
388
1416
1211
2.00
185.4
203
0.10
198.4
241.2

#### 2.2 Non-carcinogenic risk assessment of fluoride

The hazard quotient (HQ), used to estimate the minimum and maximum health risks associated with fluoride exposure from oral hygiene preparations, was calculated by integrating both exposure and toxicity data. The non-carcinogenic risk of fluoride to human health can be expressed as HQ using Eq. (2):<sup>15</sup>

$$HQ = \frac{EDI}{RfD}$$
 (2)

The reference dose (RfD) is a parameter used in risk assessment to estimate the daily exposure level for humans that is not expected to cause significant adverse health effects over a lifetime. For fluoride (F), the oral RfD of 0.06 mg kg<sup>-1</sup> day<sup>-1</sup> was derived from the Integrated Risk Information System (IRIS) of the U.S. Environmental Protection Agency.<sup>16</sup> The HQ was calculated as the ratio of the EDI to the RfD. An HQ less than 1 suggests that even vulnerable populations are unlikely to experience harmful health effects. An HQ greater than 1 indicates that the non-carcinogenic risk exceeds acceptable limits, implying a potential for adverse health impacts.<sup>15</sup>

#### 3 Results and discussion

The data in Table 2 present the estimated daily intake (EDI) of fluoride from oral hygiene products across different age groups, demonstrating age-specific patterns of fluoride exposure and their potential health implications.

Table 2 – EDI (mg kg<sup>-1</sup> day<sup>-1</sup>) estimates for minimal and maximal ingestion rate of oral hygiene products across different age groups Tablica 2 – EDI vrijednosti (mg kg<sup>-1</sup> dan<sup>-1</sup>) za minimalnu i maksimalnu stopu unosa proizvoda za oralnu higijenu u različitim dobnim skupinama

Sample	Group 1 (< 2 years)		Group 2 (2 to < 6 years)		Group 3 (6 to < 16 years)		Group 4 (≥ 16 years)	
	min IngR	max IngR	min IngR	max IngR	min IngR	max IngR	min IngR	max IngR
P1	$2.57 \cdot 10^{-2}$	$7.58 \cdot 10^{-2}$	$1.71 \cdot 10^{-2}$	$5.05 \cdot 10^{-2}$	$5.14 \cdot 10^{-3}$	$1.52 \cdot 10^{-2}$	$3.29 \cdot 10^{-3}$	$9.72 \cdot 10^{-3}$
P2	$7.75 \cdot 10^{-3}$	$2.29 \cdot 10^{-2}$	$5.17 \cdot 10^{-3}$	$1.52 \cdot 10^{-2}$	$1.55 \cdot 10^{-3}$	$4.57 \cdot 10^{-3}$	9.94 · 10-4	$2.93 \cdot 10^{-3}$
P3	$2.83 \cdot 10^{-2}$	$8.34 \cdot 10^{-2}$	$1.89 \cdot 10^{-2}$	$5.56 \cdot 10^{-2}$	$5.66 \cdot 10^{-3}$	$1.67 \cdot 10^{-2}$	$3.63 \cdot 10^{-3}$	$1.07 \cdot 10^{-2}$
P4	$2.42 \cdot 10^{-2}$	$7.14 \cdot 10^{-2}$	$1.61 \cdot 10^{-2}$	$4.76 \cdot 10^{-2}$	$4.84 \cdot 10^{-3}$	$1.43 \cdot 10^{-2}$	$3.10 \cdot 10^{-3}$	$9.15 \cdot 10^{-3}$
P5	$3.98 \cdot 10^{-5}$	1.17 · 10-4	$2.65 \cdot 10^{-5}$	$7.83 \cdot 10^{-5}$	$7.96 \cdot 10^{-6}$	$2.35 \cdot 10^{-5}$	$5.10 \cdot 10^{-6}$	$1.51 \cdot 10^{-5}$
T1	$3.71 \cdot 10^{-3}$	$4.82 \cdot 10^{-3}$	$2.47 \cdot 10^{-3}$	$3.21 \cdot 10^{-3}$	$7.42 \cdot 10^{-4}$	$9.64 \cdot 10^{-4}$	$4.75 \cdot 10^{-4}$	6.18 · 10-4
T2	$4.06 \cdot 10^{-3}$	$5.28 \cdot 10^{-3}$	$2.71 \cdot 10^{-3}$	$3.52 \cdot 10^{-3}$	8.12 · 10-4	$1.06 \cdot 10^{-3}$	5.21 · 10-4	6.77 · 10 <sup>-4</sup>
T3	$2.00 \cdot 10^{-6}$	2.60 · 10-6	$1.33 \cdot 10^{-6}$	$1.73 \cdot 10^{-6}$	4.00 · 10 <sup>-7</sup>	$5.20 \cdot 10^{-7}$	$2.56 \cdot 10^{-7}$	$3.33 \cdot 10^{-7}$
T4	$3.97 \cdot 10^{-3}$	$5.16 \cdot 10^{-3}$	$2.65 \cdot 10^{-3}$	$3.44 \cdot 10^{-3}$	7.94 · 10-4	$1.03 \cdot 10^{-3}$	5.09 · 10-4	6.61 · 10-4
T5	$4.82 \cdot 10^{-3}$	$6.27 \cdot 10^{-3}$	$3.22 \cdot 10^{-3}$	$4.18 \cdot 10^{-3}$	$9.65 \cdot 10^{-4}$	$1.25 \cdot 10^{-3}$	$6.18 \cdot 10^{-4}$	$8.04 \cdot 10^{-4}$

EDI values for mouthwash samples were lower than those for toothpaste, indicating that fluoride exposure from mouthwash is lower compared to toothpaste. The EDI values showed a decline in fluoride exposure as age increased. Group 1 (< 2 years) exhibited the highest fluoride intake values for both minimal and maximal ingestion rates, with Sample P1 showing an EDI range from  $2.57 \cdot 10^{-2}$  to  $7.58 \cdot 10^{-2}$  mg kg<sup>-1</sup> day<sup>-1</sup>. Conversely, Group 4 ( $\geq$  16 years) demonstrated the lowest EDI values, with Sample P1 ranging from  $3.29 \cdot 10^{-3}$  to  $9.72 \cdot 10^{-3}$  mg kg<sup>-1</sup> day<sup>-1</sup>. This trend reflects the physiological and behavioural differences between age groups, as younger children are more likely to swallow toothpaste due to underdeveloped motor skills, while older individuals exhibit better control and reduced ingestion.<sup>17</sup> Excessive fluoride intake during early childhood is associated with a higher risk of dental fluorosis, a condition caused by disordered enamel formation.<sup>18</sup> Samples P3 (toothpaste) and T5 (mouthwash) consistently showed higher fluoride intake across all age groups than other products. In Group 1, the maximal ingestion rate for Sample P3 was  $8.34 \cdot 10^{-2}$  mg kg<sup>-1</sup> day<sup>-1</sup>, which exceeds the U.S. EPA's reference dose of  $6.00 \cdot 10^{-2} \text{ mg kg}^{-1} \text{ day}^{-1}$ for safe fluoride intake.<sup>19</sup> This variability underscores the influence of product formulations on fluoride exposure, with some products containing higher fluoride concentrations or being more palatable, leading to increased ingestion.<sup>20</sup>

Although no health risk assessment for mouthwash has been conducted, available studies on toothpaste indicate potential health risks from excessive fluoride intake. The results in Table 2 show that fluoride intake in the studied age groups generally fell below the optimal levels required for caries prevention, with most values (except for maximums in samples P1, P3, and P4) below the threshold for fluorosis risk. In contrast, other studies report a wider range of fluoride intake in children, from  $1.50 \cdot 10^{-2}$  to  $1.23~{\rm mg\,kg^{-1}\,day^{-1}}$ , with some values exceeding the optimal level and posing a risk for fluorosis.  $^{17}$ 

Erdal and Buchanan examined fluoride intake in children aged 3–5 years and found that daily fluoride intake from toothpaste ranged from  $1.50\cdot 10^{-2}$  mg kg $^{-1}$  day $^{-1}$  (with one brushing per day) to  $1.30\cdot 10^{-1}$  mg kg $^{-1}$  day $^{-1}$  (with three brushings per day). Their observed values for three brushings per day were higher than those found in the present study. Similarly,  $Duki\acute{c}\cdot\acute{c}osi\acute{c}$  et al. calculated fluoride intake in preschool children, with estimated daily intake levels from toothpaste and water ranging from  $1.25\cdot 10^{-2}$  to  $3.30\cdot 10^{-2}$  mg kg $^{-1}$  day $^{-1}$ , which is consistent with our findings.  $^{17}$ 

The HQ values of fluoride for four different age groups: a) Children aged under two years, b) children, c) teenagers, and d) adults are presented in Fig. 1. An HQ below 1 (< 1) is considered safe, whereas an HQ greater than 1 (> 1) suggests a likelihood of adverse health effects occurring within the population. 19,21 For Group 1 (children under 2 years old), HQ values exceeded 1 (> 1) in three toothpaste samples (P1, P3, and P4) when calculated based on the maximum ingestion rate. Furthermore, the HQ (Maximum IngR) values for Group 2 (children aged 2 to 6 years) were close to the limit values for the same toothpaste samples. Since the HQ values for fluoride in toothpaste samples for Groups 1 and 2 were higher than or close to 1, this suggests that the long-term use of such toothpaste by children aged 2 to 6 years may pose —non-carcinogenic health risks. Paul et al. assessed fluoride levels and health risks in commercial toothpaste in Bangladesh.<sup>15</sup> Their findings showed that the HQ values for fluoride exposure through toothpaste ingestion in the adult population ranged from  $5.90 \cdot 10^{-2}$  to  $7.30 \cdot 10^{-1}$ , higher than those observed in our study for Groups 3 and 4. Such variability in HQ values for different age groups underscores the importance of public health campaigns that promote correct brushing techniques and emphasise the risks of excessive toothpaste ingestion, especially in children.

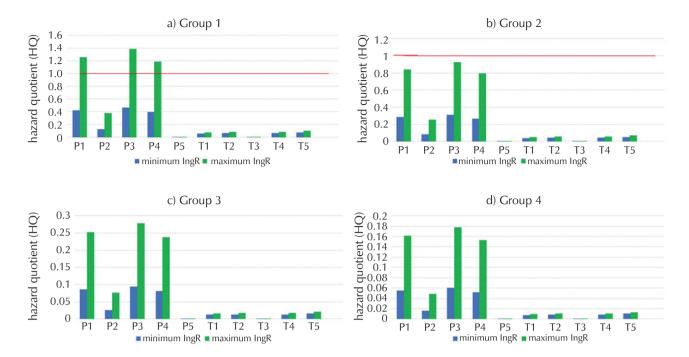


Fig. 1 — Hazard quotient (HQ) of fluoride from oral hygiene products across four age groups: a) Children under two years of age, b) children, c) teenagers, and d) adults

Slika 1 – Kvocijent opasnosti (HQ) fluorida iz proizvoda za oralnu higijenu za četiri dobne skupine: a) djeca mlađa od dvije godine, b) djeca, c) tinejdžeri i d) odrasli

### 4 Conclusion

This study highlights the importance of evaluating fluoride exposure from oral hygiene products to ensure safe usage, particularly among vulnerable populations such as children. The findings indicate that fluoride exposure from toothpaste is higher than from mouthwash across all age groups. Younger age groups, especially children aged under 6 years, exhibited elevated EDI and HQ values. HQ values in some toothpaste samples exceeded the safety threshold (HQ > 1), posing potential non-carcinogenic health risks. These results emphasise the necessity for region-specific risk assessments, especially in areas where additional fluoride exposure may occur through drinking water or dietary sources.

In contrast, teenagers and adults showed HQ values below 1, suggesting minimal risk in these age groups. The variability in fluoride exposure between different products underscores the need for stricter regulatory control over fluoride concentrations in commercially available oral hygiene products. Public health measures should focus on educating parents and caregivers about the risks of excessive fluoride ingestion by children, and the importance of supervising proper brushing techniques to minimise ingestion.

Comparisons with international studies indicated that fluoride exposure levels in B&H are generally lower, but certain products still pose a risk when used at maximum ingestion rates. This emphasises the need for continuous monitoring and adherence to recommended fluoride lim-

its in oral care products, ensuring an optimal balance between dental health benefits and the prevention of adverse health effects.

## List of abbreviations Popis kratica

B&H / BiH - Bosnia and Herzegovina

	– Bosna i Hercegovina
EDI	<ul><li>estimated daily intake</li><li>procijenjeni dnevni unos</li></ul>
HQ	<ul><li>hazard quotient</li><li>kvocijent opasnosti</li></ul>
IngR	<ul><li>ingestion rate of fluoride</li><li>stopa unosa flurida</li></ul>
BW	– body weight – tjelesna težina
Min IngR	<ul><li>minimal ingestion rate of fluoride</li><li>minimalna stopa unosa flurida</li></ul>
Max IngR	<ul><li>minimal ingestion rate of fluoride</li><li>maksimalna stopa unosa flurida</li></ul>
RfD	<ul><li>reference dose</li><li>referentna doza</li></ul>
IRIS	<ul><li>Integrated Risk Information System</li><li>Integrirani informacijski sustav rizika</li></ul>
U.S. EPA's	<ul> <li>United States Environmental Protection Agency</li> <li>Agencija za zaštitu okoliša Sjedinjenih Američkih Država</li> </ul>

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# SAŽETAK

# Fluoridi u proizvodima za oralnu higijenu – procjena izloženosti i nekarcinogenog rizika

Mirha Pazalja\* i Mirsada Salihović

Fluoridi su ključna komponenta u proizvodima za oralnu higijenu, široko prepoznati po svojoj ulozi u prevenciji zubnog karijesa. Međutim, prekomjeran unos fluorida može predstavljati potencijalne zdravstvene rizike, osobito za osjetljive populacije. Ova studija procjenjuje izloženost fluoridima i nekarcinogene zdravstvene rizike povezane s komercijalnim proizvodima za oralnu higijenu u Bosni i Hercegovini (BiH). Na temelju koncentracije fluorida u uzorcima zubne paste i vodice za ispiranje usta, izračunate su vrijednosti procijenjenog dnevnog unosa (EDI) i kvocijenti opasnosti (HQ) zá četiri dobne skupine: djecu mlađu od dvije godine (< 2 godine), djecu (2-6 godina), tinejdžere (6–16 godina) i odrasle (≥ 16 godina). Rezultati su pokazali da je zubna pasta u svim dobnim skupinama više doprinosila izloženosti fluoridima nego vodica za ispiranje usta. Djeca su pokazala veće EDI i HQ vrijednosti zbog povećane stope gutanja, pri čemu je HQ za neke uzorke zubne paste prelazio dozvoljenu vrijednost 1, što ukazuje na potencijalne nekarcinogene zdravstvene rizike. Nasuprot tome, tinejdžeri i odrasli imali su HQ vrijednosti ispod 1, što ukazuje na minimalan rizik. Usporedna analiza s međunarodnim studijama pokazala je da su razine izloženosti fluoridima iz navedenih proizvoda u BiH općenito niže, iako su pojedini uzorci premašili sigurne granice unosa. Ovo istraživanje naglašava važnost monitoringa koncentracija fluorida u proizvodima za oralnu higijenu i edukacije javnosti o njihovoj pravilnoj uporabi da bi se uskladila dentalna zdravstvena korist s potencijalnim rizicima.

#### Ključne riječi

Izloženost fluoridima, zubne paste, vodice za ispiranje usta, kvocijent opasnosti (HQ)

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