ORAL HEALTH

DECLARED FLUORIDE CONCENTRATION IN COMMERCIAL MOUTHWASHES: A MARKET ANALYSIS FROM NORTH MACEDONIA

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Abstract

The aim of this study was to determine the declared fluoride concentration in mouthwashes available on the market in the Republic of North Macedonia. Material and methods: To identify all available mouthwashes in the Republic of North Macedonia, a market analysis was conducted in the period between January 1, 2024 and July 1, 2024, including traditional markets and the online market. Two researchers recorded the ingredients declared by the manufacturer, while other two researchers verified the recorded ingredients. Results: There are 76 mouthwashes available on the market in the Republic of North Macedonia, out of which, 44 (57.9%) contained fluoride in the form of sodium fluoride or olaflur, or both. Of the 44 fluoride-containing mouthwashes, 9 (20.45%) did not declare the amount of fluoride. Most of the fluoride-containing mouthwashes used sodium fluoride alone or in combination with olaflur (n=42, 95.45%). The fluoride content in mouthwashes ranges from 98 ppm F to 475 ppm F, with the most common being 225 ppm F (n=9, 25.72%) and 250 ppm F (n=8, 22.85%). A total of 17 mouthwashes (51.42%) contain fluoride at a concentration of at least 230 ppm F. Conclusions: More than a half of the available mouthwashes contained fluoride in the form of sodium fluoride, olaflur or both. Among these, some of them did not declare the fluoride concentration despite stating the presence of sodium fluoride in their composition. Increased oversight by regulatory bodies is necessary to ensure the safety and proper labeling of these products.

ОРАЛНО ЗДРАВЈЕ

ДЕКЛАРИРАНА КОНЦЕНТРАЦИЈА НА ФЛУОРИДИ ВО КОМЕРЦИЈАЛНИТЕ ВОДИЧКИ ЗА ПЛАКНЕЊЕ НА УСТА: АНАЛИЗА НА ПАЗАРОТ ВО РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА

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Клучни зборови: флуориди, водички за испирање на уста, натриум флуорид

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Печатарски права: ©2024. . Киро Ивановски, Влатко Коколански, Марија Андоновска, Бојан Попоски, Спиро Спасовски, Мира Јанкуловска, Јулијана Николовска.. Оваа статија е со отворен пристап дистрибуирана под условите на нелокализирана лиценца, која овозможува неограничена употреба, дистрибуција и репродукција на било кој медиум, доколку се цитираа торигиналниот(ите) автор(и) и изворот.

Конкурентски интереси: Авторот изјавува дека нема конкурентски интереси.

Извадок

Целта на ова истражување беше да се утврди декларираната концентрација на флуориди во водичките за плакнење на уста достапни на пазарот во Република Северна Македонија. Материјали и методи: За да се идентификуваат сите достапни водички за плакнење на уста во Република Северна Македонија беше спроведена анализа на пазарот во период од 1 јануари до 1 јули 2024 година, која ги опфати традиционалните пазари и онлајн пазарот. Двајца истражувачи ги регистрираа состојките декларирани од производителот, додека други двајца истражувачи ги верификуваа регистрираните состојки. Резултати: На пазарот во Република Северна Македонија се достапни 76 водички за плакнење на уста, од кои 44 (57,9%) содржат флуориди во форма на натриум флуорид или олафлур или комбинација од натриум флуорид и олафлур. Од 44 водички за плакнење на устата што содржат флуориди, кај 9 (20,45%) не беше декларирана нивната концентрација. Повеќето водички за плакнење на устата што содржат флуориди, во својот состав имаа натриум флуорид или комбинација од натриум флуорид и олафлур (n=42, 95,45%). Концентрацијата на флуориди во водичките за плакнење на устата е во рамки од 98 ppm F до 475 ppm F, при што најчести се концентрациите од 225 ppm F (n=9, 25,72%) и 250 ppm F (n=8, 22,85%). Вкупно 17 водички за плакнење на уста (51,42%) содржат флуориди во концентрација од најмалку 230 ppm F. Заклучок: Повеќе од половина од достапните водички за плакнење на уста содржат флуориди во форма на натриум флуорид, олафлур или комбинација од натриум флуорид и олафлур. Од нив, некои производители не ја декларирале концентрацијата на флуориди и покрај тоа што навеле присуство на натриум флуорид во нивниот состав. Неопходен е зголемен надзор од страна на регулаторните тела за да се осигура безбедноста и правилното декларирање на овие производи

Introduction

For millennia, oral care has been crucial across diverse populations and cultures worldwide. Effective oral hygiene requires controlling bacteria that cause dental plaque and bad breath, while also fortifying and protecting teeth to prevent dental caries[1]. Proper oral hygiene, including brushing, flossing, a suitable diet, and hydration, is foundational for a healthy oral cavity. Additionally, various adjunctive oral hygiene products like irrigators, tongue scrapers, and mouthwashes enhance oral care effectiveness. Mouthwashes, in particular, are widely used and there is a vast array of products available[2]. A mouthwash is defined as a non-sterile aqueous solution primarily used for its deodorant, refreshing, or antiseptic properties. Mouthwashes are intended to reduce oral bacteria, remove food particles, temporarily alleviate bad breath, and provide a pleasant taste. They are generally categorized as either cosmetic or therapeutic, or a combination of both. Cosmetic rinses are commercial products that eliminate oral debris before or after brushing, temporarily mask bad breath, reduce bacteria, and leave a refreshing taste. Therapeutic rinses, while also offering cosmetic benefits, contain active ingredients (such as fluoride or chlorhexidine) that help prevent or treat certain oral diseases[3,4]. Some mouthwashes are used for preoperative surgical treatment5, postoperative wound care[6,7], and during fixed orthodontic treatment[8]. Recently, commercial or over-the-counter mouthrinses have become one of the fastest-growing sectors in the oral care industry[9]. Mouthwashes contain various ingredients including oral health substances, solvents, surfactants, thickeners, sweeteners, plant extracts, preservatives, colorants, and flavoring agents. Several groups of oral health substances have been identified, with fluorine compounds being a notable inclusion[2]. Fluoride is naturally present in the environment and is a common part of daily life. It is found in water, soil, and air, and exposure occurs through diet, respiration, and supplements. While toxic at extremely high concentrations[10], fluoride is proven to prevent cavities or tooth decay. The role of fluoride in caries prevention was first noted by Black and McKay in the early 20th century[11]. The addition of fluoride to community water supplies and oral care products like toothpaste and mouthwash has been a significant public health measure (PHM), considered one of the top ten public health achievements of the 20th century[12]. Studies have shown that fluoride concentrations in community water supplies of 0.8-1.5 mg/L can reduce dental caries by over 60%. However, in the Republic of North Macedonia, drinking water, particularly in larger cities, usually contains fluoride concentrations lower than 0.2 mg/L[13]. Fluorides are categorized into systemic (such as fluoridated water, milk, salt, and supplements) and topical forms (including toothpaste, mouthwashes, varnishes, gels, foams, and slow-release devices)[12]. Fluoride strengthens the tooth's enamel. Despite concerns about potential adverse effects from excessive use, especially in young children who might ingest more toothpaste, appropriate use of fluoride products remains highly effective for caries prevention with minimal risk. Studies by Nakamoto *et al.*[14]

and Dhar *et al*.[15] highlight risks like dental fluorosis and systemic toxicity from excessive fluoride intake. Nonetheless, when used correctly, fluoride products are the most effective means of caries prevention with minimal adverse effects. According to the World Health Organization, dental caries affect 60-90% of school-age children and nearly 100% of adults worldwide[16]. Comprehensive prevention programs, including the use of fluoride-containing products like toothpaste, mouthwashes, gels, foams, and varnishes, have been shown to significantly reduce caries prevalence[17]. Regular mouthrinsing with fluoride solutions has proven to be an effective caries prevention method for schoolchildren[18]. Marinho *et al*.[19] reviewed 37 trials from various countries, confirming the effectiveness of supervised use of fluoride mouthrinses in reducing caries in permanent teeth. They also noted limited data on adverse effects and treatment acceptability. In Japan, where water fluoridation is not practiced, a school-based fluoride mouth-rinsing program (S-FMR) began in Niigata Prefecture in 1970 and expanded nationwide by 2005[20]. Matsuyama *et al*.[21] conducted a study across all 47 Japanese prefectures, finding that high S-FMR utilization significantly correlated with lower DMFT (Decayed, Missing, Filled Teeth) rates in 12-year-olds. Yonezawa and Yagi[22] concluded that participation in the FMR program during elementary school offered a significant protection against dental caries. This paper aimed to determine the declared fluoride concentration in mouthwashes available on the market in the Republic of North Macedonia.

Materials and methods

Between January 1, 2024, and July 1, 2024, a market analysis was conducted in the Republic of North Macedonia. This study encompassed traditional markets (pharmacies, cosmetic chains, and consumer goods markets) as well as the online market. Four researchers (VK, KI, SS and BP) carried out this research, aiming to identify all available mouthwashes. One to three packs of each mouthwash were purchased directly from vendors without requesting free samples from manufacturers or importers. Mouthwashes were selected based on the following inclusion criteria: intended for maintaining oral hygiene, preventing oral diseases, or having a therapeutic effect; available over-the-counter; and in the pharmaceutical forms of either a solution intended for direct use or a concentrate to be dissolved in water, regardless of their regulatory status (medicine, medical device, cosmetic product). The exclusion criteria were: tablets that dissolve in water or other liquids, chewing tablets, saliva substitutes; products containing antibiotics, steroids, parasympathomimetic saliva stimulants, topical local anesthetics, and other prescription drugs; liquids taken orally but not intended for maintaining oral hygiene; liquids in the form of sprays, toothpastes, gels, powders, foams, homeopathic products, and products without a fully available composition.

Two researchers (MJ and JN) recorded the ingredients declared by the manufacturer in an Excel spreadsheet (Microsoft Corporation, Redmond, Washington, United States). The

other two researchers (KI and MA) verified the recorded ingredients to eliminate errors. The manufacturers were not contacted to request missing data about fluoride concentrations, assuming the accuracy of the provided data. Frequency analysis of substances was performed using Microsoft Excel v. 2016 (Microsoft Corporation, Redmond, Washington, United States) and SPSS Statistics v23 for Windows (IBM Corp., Armonk, NY), while the difference between the proportions means was performed with Difference test in StatSoft STATISTICA v12.5 (StatSoft, Inc., Tulsa, Oklahoma, United States).

Results

There are 76 mouthwashes available on the market in the Republic of North Macedonia. A comprehensive list of these mouthwashes, including those with declared fluoride content and the specified amount of fluoride (expressed in ppm F), is provided in Annex 1. Out of the 76 mouthwashes, 44 (57.9%) contained fluoride in the form of sodium fluoride or olaflur, or both. There is a statistically significant difference in the number of available mouthwashes containing sodium fluoride compared to those that do not ($p<0.001$). Table 1, based on the analysis of fluoride forms in mouthwashes, shows the number of products declaring fluoride in their composition and the specific form of the fluoride component.

Table 1. Frequency of the type of fluorine compounds

Type of fluorine compounds	Number of mouthwashes (%)
sodium fluoride	37 (84.1%)
olaflur	2 (4.54%)
sodium fluoride and olaflur	5 (11.36%)
Total	**44 (100%)**

Of the 44 fluoride-containing mouthwashes, 9 (20.45%) did not declare the amount of fluoride. Most of the fluoride-containing mouthwashes used sodium fluoride alone or in combination with olaflur (n=42, 95.45%).

Table 2 displays the declared fluoride concentrations (in ppm F) and the frequency of mouthwashes with various fluoride concentrations.

Table 2. Frequency of declared amount of fluorides

Concentration of fluoride	Number of mouthwashes (%)
98 ppm F	1 (2.86%)
100 ppm F	1 (2.86%)
135 ppm F	1 (2.86%)
220 ppm F	5 (14.28%)
225 ppm F	9 (25.72%)

230 ppm F	1 (2.86%)
250 ppm F	8 (22.85%)
450 ppm F	8 (22.85%)
475 ppm F	1 (2.86%)
Total	**35 (100%)**

The fluoride content in mouthwashes ranges from 98 ppm F to 475 ppm F. The most common fluoride concentrations are 225 ppm F (n=9, 25.72%) and 250 ppm F (n=8, 22.85%). A total of 17 mouthwashes (51.42%) contain fluoride at a concentration of at least 230 ppm F. There is a statistically significant difference in the number of mouthwashes with fluoride concentrations between 220 and 250 ppm F compared to others (n=23; 65.71%, p=0.086).

Discussion

This is the first study that evaluated the declared fluoride concentration in mouthwashes in the Republic of North Macedonia. The market analysis in our study identified a total of 76 available mouthwashes. As mentioned before, based on the presence or absence of chemically active ingredients, mouthwashes can be classified as cosmetic (absence of chemically active ingredients) and therapeutic (presence of chemically active ingredients, such as cetylpyridinium chloride, chlorhexidine, fluoride, or hydrogen peroxide)[23]. Initially, we separated the mouthwashes containing fluorides as a chemically active ingredient, which comprised 44 out of the available 76 (57.9%). The fluoride ion concentrations in the available mouthwashes ranged from 98 to 135 ppm (8.58%), 220 to 250 ppm (65.71%) and 450 to 475 ppm (25.71%), with 9 out of 44 fluoride-containing mouthwashes (20.45%) not declaring the fluoride concentration. In general, sodium fluoride (NaF) is the most commonly used fluoride agent in mouthwashes[24], but from the available literature we know that mouthwashes can also contain other fluoride compounds such as stannous fluoride (SnF2), sodium monofluorophosphate (SMFP), acidulated phosphate fluoride (APF), amine fluoride (AmF), olaflur (C27H60F2N2O3), nicotinyl alcohol HF (fluorinol, nicomethanol hydrofluoride) (C6H8FNO), fluorohydroxyapatite (Ca10(PO4)6F2), potassium fluoride (KF), and calcium fluoride (CaF2)[2]. The use of various fluoride preparations has a long history, with sodium fluoride being the first used in solutions. Subsequently, stannous fluoride was introduced, and since 1960, organic fluorides (AmF) have been clinically applied, followed by other complex fluoride compounds over the years[25]. The market analysis we did in the Republic of North Macedonia in this study identified that sodium fluoride, alone or with olaflur, was the most prevalent fluoride compound in the mouthwashes (n=42, 95.45%). Only 2 of the 44 fluoride-containing mouthwashes (4.55%) did not contain sodium fluoride. In Poland, a study by Radzki *et al.*2 found that 63.5% of mouthwashes contained fluoride compounds, including olaflur (11.8%), nicotinyl alcohol HF (2.0%), fluorohydroxyapatite (1.3%), sodium monofluorophosphate (6.5%), sodi-

um fluoride (86.9%), potassium fluoride (1.3%), stannous fluoride (1.3%), and calcium fluoride (0.7%). The fluoride ion concentrations ranged from 98 to 135 ppm (9.8%), 187 to 250 ppm (66.7%), 400 to 500 ppm (11.8%), 900 to 1136 ppm (5.2%), and 1450 ppm (0.7%), with 5.9% not declaring fluoride concentration. Sodium fluoride was the predominant fluoride compound 2, known for its high solubility and proven effectiveness[26]. In Turkey, Yazicioglu *et al.*[27] identified 28 mouthwashes containing sodium fluoride (62.22%), one with olaflur (2.22%), one with stannous fluoride (2.22%), and two with sodium monofluorophosphate (4.44%). Sodium fluoride concentrations ranged from 217 to 500 ppm in 23 of 45 different mouthwashes, with some containing significantly lower percentages. In Saudi Arabia, Aldrees *et al.*[28] evaluated the fluoride concentration in commercial mouthrinses, finding that most provided topical fluoride at levels below the manufacturers' label values but above the recommended 0.05%. There were discrepancies within and between batches, indicating variability in fluoride content. In the Russian Federation, researchers compared active and total fluoride concentrations in 10 mouthwashes. Using direct potentiometry, they found that most mouthwashes contained sodium fluoride, with other fluoride sources being Na2PO3F, AmF, and AlF3. The study highlighted the need for methods that better reflect in vivo conditions to accurately evaluate free fluoride content[17]. In the Netherlands, van Swaaij et al. found that 32 of 54 mouthwashes (59%) contained fluoride, mostly sodium fluoride (78%), sodium monofluorophosphate (9%), and a combination of amine fluoride and sodium fluoride (13%). The total soluble fluoride ranged from 229 to 500 ppm, with discrepancies between labeled and measured concentrations, indicating higher soluble fluoride than labeled[29]. In Thailand, a study on 19 children's mouthwashes found fluoride concentrations ranging from 0.00 ppm to 106 ppm. Only four brands had concentrations matching their labels, with one brand providing lower than labeled values. The authors recommended labeling fluoride concentrations and pH for better dental advice[30]. Valdivia-Tapia *et al.*[31] evaluated fluoride concentration in 20 mouthrinses from Chile and Brazil, finding that the fluoride concentrations were close to those declared by manufacturers. The results indicated consistency with regulatory standards. Most mouthwashes in the European Union are classified as cosmetic products, subject to regulation (EC) No. 1223/2009, which mandates specific conditions for fluoride oral products. The maximum concentration of fluoride in ready-to-use preparations is limited to 0.15% (as F)[32]. The European Academy of Paediatric Dentistry (EAPD) recommends daily use of 0.05% NaF (225 ppm F) for primary teeth and weekly use of 0.2% NaF (900 ppm F) for permanent teeth, under supervision, as part of preventive programs for children[33]. The NHS Public Health guidance in England recommends 0.05% fluoride mouthwash (230 ppm) for children from age 8 years onwards, and adults at a higher risk of caries[34]. Despite these recommendations, global studies still call for further research on fluoride mouthwash effectiveness in various populations[23]. Our results indicate

that 51.42% of commercially available mouthwashes in North Macedonia with labeled fluoride concentrations contain at least 230 ppm F, aligning with NHS recommendations. Additionally, 77.14% contain at least 225 ppm F, meeting EAPD guidelines. No mouthwashes had concentrations above 475 ppm F, precluding the implementation of 900 ppm F weekly application programs recommended by the EAPD.

At last, our study has several limitations. We did not perform chemical analysis of the fluoride concentrations, but instead, we used the data indicated on the packaging by the manufacturer. There is a possibility that not all mouthwashes available on the market were found, but we took measures to reduce bias, and the market research was carried out by 4 researchers. It is possible that the manufacturer did not declare the fluoride components on the packaging, which is against the national regulation, but we worked with the assumption that the data provided by the manufacturers were accurate.

Conclusion

In the Republic of North Macedonia, more than a half of available mouthwashes contained fluoride in the form of sodium fluoride or olaflur, or both. Among these, some of them did not declare the fluoride concentration despite stating the presence of sodium fluoride in their composition. Increased oversight by regulatory bodies is necessary to ensure the safety and proper labeling of these products, irrespective of whether they are classified as medicines, medical devices, or cosmetic products.

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Annex 1: List of the available mouthwashes with non-declared and declared fluoride content and the specified amount of fluoride (expressed in ppm F)

	Commercial name	Fluoride concentration (ppm F)
1	Doctor's Mint Mouth Wash	/
2	Doctor's HERBAL MOUTH WASH	/
3	Doctor's ANTITARTAR MOUTH WASH	/
4	Doctor's PROPOLIS MOUTH WASH	/
5	Doctor's SMOKERS MOUTH WASH	/
6	Alur Care Mouthwash cool mint	non-declared
7	Bilka Dent Expert Classic Parodont Protect	/
8	Alverde Pro Climate 5 in 1 Mondspulung	450 ppm F
9	Dontodent Protect & Care 10 in 1 Rundumschutz	450 ppm F
10	Dontoent Zahnfleisch Intensiv - Pflege	450 ppm F
11	Dontodent Sensitive Intensiv - Schutz	450 ppm F
12	Dontodent Neue Rezeptur Mundwasser Konzentrat	/
13	Bilka Homeopathy Grapefruit Mouthwash	/
14	Dontodent Junior Lerneffekt - spulung	/
15	Dontodent Junior mund - spulung	250 ppm F
16	Parodontax Active Gum Health	225 ppm F
17	Betadine Gargle	/
18	Stomatidin	/
19	Oralsept	/
20	Elmex Caries Protection	250 ppm F
21	Elmex Sensitive	250 ppm F
22	Colgate Plax ICE	225 ppm F
23	Lacalut Micellar Sensitive Mouthwash	non-declared

24	Lacalut Micellar tartar protection micellar water	non-declared
25	Listerine Total Care Clean Mint 6 in 1 Mild Taste	450 ppm F
26	Listerine Total Care Clean Mint 6 in 1	450 ppm F
27	Listerine Natural Enamel protect	220 ppm F
28	Listerine Naturals Sabor Suave	/
29	Listerine Advanced Defence Sensitive	220 ppm F
30	Listerine Advanced White Mouthwash Mild Taste	220 ppm F
31	Listerine Green Tea Mild Taste	220 ppm F
32	Listerine Total Care Tartar Protect	220 ppm F
33	Listerine Teeth&Gum Defence	non-declared
34	Listerine Smart Rinse	100 ppm F
35	Listerine Cool Mint	/
36	Listerine Fresh Burst	/
37	Astera Total All-in-one	225 ppm F
38	Parodont Active	450 ppm F
39	Oral B Pro-Expert	98 ppm F
40	Gengigel Oral Solution	/
41	Colgate Cool Mint	225 ppm F
42	Colgate plax white+charcoal	225 ppm F
43	Colgate max white	225 ppm F
44	Colgate plax soft mint	225 ppm F
45	Edel+White Fresh+Protect	250 ppm F
46	Lacalut Micellar Whitening Mouthwash	non-declared
47	Lacalut Multi-Effect Micellar Mouthwash	non-declared
48	Lacalut Flora	non-declared
49	Lacalut Aktiv	225 ppm F
50	Lacalut white	135 ppm F
51	Lacalut Sensitive	250 ppm F
52	Curaprox Perio Plus Balance CHX 0.05	230 ppm F
53	Curaprox Perio Plus + Protect CHX 0.12	/
54	Curaprox Perio Plus Forte CHX 0.20	/
55	Curaprox Regenerate CHX 0.09	/
56	Alkmene Tea Tree Mouthwash	475 ppm F
57	Aquafresh Fresh & Minty	250 ppm F
58	Ben & Anna Natural Mouthwash Sensitive	/

59	Eco Denta Refresh & Protect Mouthwash	non-declared
60	Natura Siberica Whitening & Enamel Protection	/
61	Natura Siberica Plaque Control & Fresh Breath	/
62	Natura Siberica Strong Teeth & Gums	/
63	Cosmos Organic People Mouthwash Coconut & Mint	/
64	Maxlab Silver Water	/
65	Aquafresh Big Teeth Mouthwash	225 ppm F
66	Intermed Unisept Mouthwash	/
67	Intermed Chlorhexil Extra 0,20% Mouthwash	/
68	Intermed Chlorhexil 0.12% Mouthwash	/
69	Intermed Kids Mouthwash	non-declared
70	ESI Aloe Fresh Collutorio	/
71	Limes Rosa Fresh Concentrate	/
72	Dr. Silver Mouthwash Total Care	/
73	Green Fresh Concentrate Mouthwash	/
74	FrezyDerm Sensitive Teeth Mouthwash	250 ppm F
75	FrezyDerm Plaque&Tartar Mouthwash	250 ppm F
76	Oral B Gum & Enamel Care Fresh Mint	450 ppm F