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Rampant online marketing of teeth whitening products: Evaluation of online information, labelling accuracy and quantitative analysis of high peroxide content gels

Márton Fittler^a, Zsuzsanna Rozmer^b, András Fittler^{c,*}

^a Department of Dentistry, Oral and Maxillofacial Surgery, Medical School, University of Pécs, Pécs, Hungary

^b Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Pécs, Pécs, Hungary

^c Department of Pharmaceutics, Faculty of Pharmacy, University of Pécs, Pécs, Hungary

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ABSTRACT

Background: /Purpose: Online vendors seize the advantage of the high demand on home-use, doit-yourself dental bleaching products. The study aims to present the uncontrolled online market of dental products and provide evidence of consumer safety risks associated with the utilization of high peroxide content bleaching products without dentist's supervision, and also to identify misleading and insufficient information on content and compromised product quality.

Materials and methods: A complex risk-based methodology was used including website content evaluation focusing on ingredients, precautionary statements and directions for use provided by online retailers. Bleaching products were test procured in which packaging and labels were documented and assessed. Quality control was performed using the permanganometric method per the official European Pharmacopoeia.

Results: One (16.7%) of six test procured peroxide gels was not delivered. Another arrived without enclosed description or instructions. The ingredient list was incomplete or missing for all (100%) online products, however, it was listed on the label or in enclosed documentation in four out of five (80%) samples. Precautionary statements were scarcely (16.7%) disclosed online, contrarily, safety claims were emphasized by most (83.3%) websites. Contraindications and adverse effects were mentioned in the majority (80%) of the delivered product labels. One sample contained no active principle, in two sample' peroxide content exceeded the label's claim by 5.2–9.0% while in another two it was below the concentration indicated on the labels by 79.9–80.7%.

Conclusions: Dissimilarity in regulations elicits an opportunity for consumers to purchase inappropriately labeled, questionable quality, high peroxide content dental products without information regarding ingredients, application and risks. The uncontrolled market, easy access and unsupervised application of high peroxide-content teeth whiteners imply patient safety issues.

1. Introduction

Teeth whitening products are dental products widely known by the general public, since their debut on the marketplace in the late 1980's [1], and are now very attractive to a majority of clients, with an increasing demand in developed countries [2]. In addition to

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^{*} Corresponding author. Department of Pharmaceutics, Faculty of Pharmacy, University of Pécs, Rókus Street 2, 7624, Pécs, Hungary. *E-mail address:* fittler.andras@pte.hu (A. Fittler).

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in-office dental services and products, numerous at-home, over-the-counter (OTC) products are easily accessible online for consumers [3]. However, in the lack of professional oversight, whitening products raise patient safety concerns.

Many individuals avoided medical and dental care, due to the prohibition of care for non-acute cases and the sweeping paranoia of potential infection during the COVID-19 pandemic [4,5]. Strategies applied to combat infection rates saw a notable decline in access to health care services for a number of conditions [6], including chronic care and non-urgent procedures, such as cosmetic dental services. Patients' preferences regarding dental services suddenly changed, the number of cancelled visits and the percentage of patients who discontinued treatment rose substantially as compared to the preceding year [7]. Limited access to traditional offline health services and accelerated digitalization during the past years have driven individuals acquiring health-related information and even medical interventions towards alternative and non-professional resources [8]. In parallel, the number of online services and purchases on the internet has shown a significantly steady rise during the recent past, which has resulted in the development and wider acceptance of the online market of telemedicine and health products. According to a recent survey, the pandemic significantly increased the number of individuals purchasing medicines and health products online, indicating a tipping point, current to 2022, in which more than 50% of the survey participants practiced online medicine purchasing [9].

1.1. Product portfolio and risk assessment of available teeth whitening products

Toothpastes containing abrasive agents seem as an easy way of teeth whitening, while their effect may not be noted so quick, or nearly ever, since published studies have questioned the effectiveness of toothpastes used for whitening [10]. Rinses containing approximately 2% hydrogen peroxide are also an easy means in creating habit-forming routines for whitening following brushing one's teeth. Previous studies showed that rinses are considered as a less efficacious whitening method since 1–2 shades can be achieved over a three-month period [11]. Faster whitening can be accomplished with higher levels of hydrogen- or carbamide peroxide containing strips or paint-on-gels. These methods may provide 1–2 shade changes in just two weeks when used 30 min, twice a day, however, also have a higher (6%) percent of active ingredients than the previously mentioned procedures [11]. By increasing the peroxide concentration and contact time of the product, the negative effects of the whitening agent become more prevalent on oral structures. A 2014 publication cites that the sensitivity and gingival irritation as side effects are directly proportional to the concentration [11]. Teeth whitening using a tray and gels may be the fastest and most effective method used to whiten smiles. It can be done at home, with a custom tray customized by a technician or a do-it-yourself (DIY) universal moldable product [11]. A higher concentration (bleaching gel is placed in the tray and positioned up against the tooth surface and positioned for 1–2 h or even overnight depending on the concentration in the gel [12]. In the case of unsupervised do-it-yourself (DIY) treatments, the gel may be swallowed, overdosed or overused. Additionally, improperly fitting trays can lead to numerous potential side effects and health issues [13].

1.2. Adverse events of peroxide-containing teeth whitening products

During World War I, carbamide peroxide was used as an antiseptic agent to treat acute necrotizing ulcerative gingivitis and its whitening side effect was discovered sheerly by accident [1]. Today, more than a century later, teeth whitening with hydrogen- or carbamide peroxide is considered a safe aesthetic intervention in dentistry, however tooth-sensitivity and gingival irritation must be considered as undesirable potential side effects. One of the most common side effects of peroxide-based bleaching is tooth sensitivity, due to releasing oxidative free radicals, in particular, when used in high concentrations. Additionally, glycerin, the most widely used carrier compound found in peroxide gels, can cause dehydration of tooth surface due to its hydrophobic nature and it may also contribute to the sensitizing effect. Post-whitening sensitivity is dependent upon both whitening duration and concentration [14]. The morphology and structure of the tooth can also be compromised due to bleaching agents. Similarly to sensitivity, the frequency and severity of these side effects may intensify depending on the concentration of the bleach and the duration of the treatment. Literature data suggests hydrogen peroxide concentrations exceeding 15% only increases the adverse effects (e.g., reduction of microhardness and mineral content of the tooth) without increasing the whitening effect. Additionally, high peroxide concentrations irritate the soft tissues such as the gum and the marginal gingiva or may even result in oral cavity burns. If the whitening agent is ingested, it could lead to gastric pain, without severe consequences [11]. Moreover, whitening agents can also have detrimental effects on restorative material and dental fillings, decreasing their adhesive properties [15]. Finally, also bond strength of orthodontic devices [16] and flexural properties of restoratives [17] can be compromised.

Peroxide compounds including hydrogen peroxide and carbamide peroxide have been used in various dental procedures for many years. Teeth whitening products contain carbamide or hydrogen peroxide. Carbamide peroxide is a structural complex, which is stable. However, when it contacts water, carbamide breaks down to active components. First, it becomes urea and hydrogen peroxide, while hydrogen peroxide breaks down into water and free oxygen species. The oxygen radicals react with the chromogens within the tooth by breaking down their double bonds, which results in their elimination or makes the tooth reflect light in a more optimal, aesthetic way [1]. The key advantage of carbamide peroxide is its stability and slower degradation resulting in longer lasting whitening process.

To identify the teeth whitening product category with the highest level of safety concern, we conducted a risk assessment of currently available products. Although several products are marketed for aesthetic purposes [10,13,18,19], peroxide-based teeth bleaching gels offer the highest expected efficacy achieved within the shortest period of time and the most cautious adverse event profile [20,21]. Consequently, we have selected peroxide containing gels for our research (frisk assessment based on previously published methodology [18,22] in **Supplement 1**.) with highest probability of online purchase and potential patient health concern in case of at-home, do-it-yourself (DIY) use.

By using the example of today's popular teeth bleaching products, we aim to present the uncontrolled online market regarding DIY

dental products, inhering misleading or insufficient product information and compromised product quality. The objective of this study was to gather evidence of patient/consumer safety risks associated with high peroxide containing dental preparations freely available without dental supervision procured over the internet.

2. Materials and methods

In our study, we adapted and applied a complex risk-based methodology [22] to identify and evaluate teeth whitening dental products available for online retail purchase. The methodology consisted of three parts: (1) assessment of search engine results, (2) website content and product label evaluation, and (3) product quality analysis. Search engine result (SER) assessment permits the evaluation of the probability of the online purchase of teeth whitening products. Website content evaluation, including health claims, side effect information and directions of use indicate severity of potential patient safety risks associated with internet procurement of bleaching products. Finally, test purchase including content evaluation of shipped product information and analytical quality control of peroxide content gels provide evidence for product safety and labeling accuracy issues.

2.1. Obtaining and evaluation of search engine results

To simulate consumer's internet search behavior and to find potential websites most likely pursued when searching for teeth whiteners, the widely used internet search engine Google was used with both Hungarian and English search expressions: "teeth whitening" and "peroxide" and "buy". By utilizing this multilingual approach, our study simulates both national and global search. The first thirty organic (non-paid) SERs were evaluated using the Chrome browser in a private mode to eliminate influence of previous search and user account settings in February 2022. Search results included the most relevant links consumers will click on, thus it can be considered a representative sample for online market evaluation as most individuals do not scroll past the first three result pages during online search. Documented search result data include the following: date of search, uniform resource locator (URL), domain name, SER ranking, website category, language of operation and the possibility of product purchase. Following the manual evaluation of links, websites were labeled as per the following 6 categories: Business-to-Consumer (B2C) web shops offering online retail sale for consumers; global e-commerce websites (e.g., Amazon, AliExpress) adopting both Business-to-Business (B2B) and B2C model; dental practice web sites; dentist office product suppliers; price comparison or intermediary pages; and informative websites (e.g., news, authority, medicine database) without direct/indirect purchase opportunity. Only websites operating in English and Hungarian and offering peroxide-based gels for retail use, indicating either hydrogen- or carbamide peroxide as active ingredient were included in our study. The number of teeth whitening gels for sale were documented for each website, and the one with the highest peroxide concentration was included for further website content evaluation and test purchase. Gels with the same formulation and concentration as another product were considered as duplicates and were excluded from test purchase. Websites offering no direct purchase (e.g., referral to other sites) or those not shipping their products to Hungary were excluded from the study.

2.2. Evaluation of websites offering teeth bleaching products for retail use and labeling accuracy of test purchased products

Consumer safety issues were determined based on information regarding health claims on the website and the comprehensiveness regarding product description and side effect information provided by vendors. Without detailed and appropriate guidance on the use of bleaching products, their appropriate use cannot be guaranteed, hindering the efficacy of teeth whitening and increasing the risk of adverse effects. Furthermore, the quantity and quality of product information available online or in the disclosed product information of delivered products, the consumer may apply and store teeth whiteners in an inappropriate manner or a lengthy span of time, further compromising product quality and safety. The following website content and product label information were documented: product name, ingredients, quantity in milliliters and the concentration of hydrogen/carbamide peroxide, price in USD and shipping fees; instructions for use (application, length of treatment), efficacy statements (e.g., shade change), precautions (contraindications, warnings), and general quality of text (e.g., legibility, typing errors). Furthermore, we have documented the number of teeth whitening products offered, available payment methods and vendor contact information including telephone number and street address, if indicated online. The products delivered were photo-documented and stored according to packaging instructions, or, if not provided, stored at room temperature until quantitative analysis.

2.3. Quantitative analysis of test-purchased products

The quantitative analysis of hydrogen peroxide content in test-purchased samples was performed using a permanganometric method according to the currently applying official European Pharmacopoeia (Ph.Eur.) [23]. The samples contain carbamide peroxide according to their descriptions. If carbamide peroxide meets water through dissolution, carbamide peroxide breaks down to active components. First, it becomes urea and hydrogen peroxide. To determine the hydrogen peroxide concentration, 1.00 g of the accurately weighed sample was diluted with 100.0 mL of purified water. Afterwards, to 10.0 mL of the diluted sample, 20 mL of sulfuric acid solution (0.1 M H₂SO₄) was added prior to titration. The solution was titrated with 0.02 M potassium permanganate solution (KMnO₄), until the pale violet color of potassium permanganate remained, which means a small amount of excess of it, after the reaction took place in a stochiometric way. The procedure was performed up to three times and for three independent measurements (9 parallel) for each sample.

Descriptive statistics was used to describe search engine results, website content evaluation and peroxide content of test-purchased

products.

3. Results

Among the various teeth whitening procedures available, high promised efficacy (color change) teeth whitener gels with hydrogen peroxide concentration higher than 6% (or equivalent concentration of carbamide peroxide) used in home braces were identified with the highest risk (see Supplementary table) and included for complex risk assessment and test purchase.

3.1. Search engine results for teeth whitening products

A sum of 60 SER links were independently reviewed by the authors to effectively determine eligibility for relevancy, test purchase and extract information in support of the study. Most links accessed in Google directed individuals to dental practitioners' sites (26.7%) offering whitening services, or non-commercial informative sites (28.3%) linking to news articles, blogs, research articles or educational content (Table 1.). Nine links led to international B2C or B2B e-commerce websites, two to national price comparison pages, while six to webshops providing online retail purchase opportunity for participating consumers. Price comparison pages were excluded, since they were not providing direct access to consumers. Four global e-commerce websites with links to Alibaba.com were excluded since no consumer purchase was available. One Ebay link was not relevant since it did not list a gel dosage form peroxide product, and one Amazon.com link was excluded due to it being a duplicate. Furthermore, one webshop was considered irrelevant since it was not offering peroxide whitening gel, while two other online retailers were excluded since these sites did not ship to Hungary. Finally, six (10%) links were included for test purchase, since these links lead to vendor web pages offering direct purchase opportunity of high promised efficacy peroxide-based teeth whitening gels for consumers and they also ship to Hungary. In the case of multiple products available on a given web page, we made a test purchase of the smallest package size offered, and whitening gel with the highest promised concentration and efficiency (e.g., tooth color shade change or peroxide content). In the case of identical or equivalent products, only one was selected for test purchase and further analysis.

3.2. Content evaluation regarding websites offering teeth whiteners for retail use and labeling accuracy of test purchased products

Six products were test-purchased online (see website content and product information in Table 2). The product price ranged from 10.8 to 85.2 USD, excluding shipping fees (mean = 26.9, SD = 28.7 USD). Shipping fees spanned from (free shipping) 0 up to 17.3 USD, which can be considered a significant price element, making up 0%–42.5% of the total purchase price. Delivery times ranged from 7 to 55 days (mean = 30.6, SD = 17.5 days) with test samples being shipped from the Netherlands, United Kingdom and the United States. It must be noted, one product (sample E) was not delivered, highlighting a potential financial concern of online purchases. Three vendor sites stated carbamide peroxide in the product description, two sites mentioned unspecified "peroxide", while the remaining one noted an unnamed whitening agent as its active ingredient. This latter product (sample C) was included in our test purchase as the promised 8 to10 shade changes in 10 days and expressively highlighted a presupposed high peroxide content. Half of the (n = 3.50%) products exhibited efficacy statements, promising a change of 7–10 shades following treatment. Only two websites (33.3%) of purchased products had detailed written instructions for use online, while every second (n = 3.50%) online vendor failed to provide any instructions on how to apply the bleaching product.

Precautionary statements were generally insufficient as only one (16.6%) vendor website urged precaution, as in the case of pregnancy and lactation. Alarmingly, the vast majority (n = 5, 83.4%) of vendors did not disclose any information regarding precautions, contraindications or potential adverse events associated with teeth bleaching procedures on their websites. On the contrary, several (n = 4, 66.7%) high peroxide content products highlighted misleading safety information stating no sensitivity and 100% safety.

Global B2C websites provide opportunities for individual vendors to offer their products online. These vendors seize the advantage of the high number of visitors and potential customers, however, peruse their business activities with veiled anonymity provided by the global marketplaces and the internet. Alarmingly, consumers cannot access the contact information (name, telephone and street address) linked to sellers on global B2C marketplaces, making personal liability claims questionable. Meanwhile, all webshops

Table 1

Summary of search engine results for peroxide-based teeth bleaching products.

	Search engine result	S	Total		
Links categorized by accessed websites	English (n)	Hungarian (n)	links (n)	percentage	
dental practice website	3	13	16	26.7%	
dentist office product supplier (B2B)	3	7	10	16.7%	
informative websites ^a	12	5	17	28.3%	
price comparison or intermediary pages	0	2	2	3.3%	
global e-commerce websites (B2C, B2B)	7	2	9	15.0%	
web shop	5	1	6	10.0%	
Sum	30	30	60	100.0%	

^a e.g., news, authority, medicine database or blogs without product purchase opportunity.

Table 2 Summary of product information provided by vendors and shipment of test-purchased teeth bleaching gels available over the internet.

ID	Product name ^a	Website domain, category (vendors contact information	Active ingredient and concentration (H ₂ O ₂ equivalent) ^b	List of ingredients	Price (+shipping	Delivery information	Efficacy statement	Instructions of use online	Contraindication and adverse effect information ^c
A	Teeth whitening Kit Dental Peroxide whitening KITS With Tooth whitening Pen gel 4 \times 3 mL	AliExpress.com global B2C e-commerce (no contact information	44% peroxide type not indicated	not available on website	14.2 (+10.5 USD	delivered in 55 days from the Netherlands	7-10 shades change	detailed online	No precautionary statements, disclaimer information ^a only. "100% Natural, 100% Safe, 100% Effective" and "no teeth sensitivity"
В	Teeth whitening 44% Peroxide Dental Bleaching System Gel Kit, gel, 6 × 3ml	AliExpress.com global B2C e-commerce (no contact information	44% peroxide type not indicated	not available on website	10.8 (+3.1 USD	delivered in 37 days from the Netherlands	7-10 shades change	detailed online	No precautionary statements, disclaimer information ^a only. "Premium quality", "100 safe easy to use"
С	$\begin{array}{l} \mbox{Smile Science Harley Street}\\ \mbox{- Professional Teeth}\\ \mbox{Whitening Gel Refill Kit,}\\ \mbox{gel, } 2\times 5\mbox{ml} \end{array}$	Amazon.co.uk global B2C e-commerce (no contact information	not available	not available on website	14.9 (+8.7 USD	delivered in 7 days from United Kingdom	8-10 shades in 10 days	no directions online	No precautionary statements, disclaimer information ^a . "Gentle and 100% safe for enamel with zero sensitivity and discomfort"
D	Bleach refill gel, 1×10 ml	bleachrefills.co.uk webshop (address, e- mail and phone number available	44% carbamide peroxide (15.6% H ₂ O ₂	not available on website	21.1 (+0 USD	delivered in 25 days from California, USA	no referral to shade change	no directions online	No precautionary statements
E	ProWhiteSmile Carbamide Peroxide Gel Refill Large gel, 1×10 ml	prowhitesmile.com webshop (address and phone number available	22% carbamide peroxide (7.8% H ₂ O ₂	not available on website	15.4 (+3.6 USD	not delivered	no referral to shade change	no directions online	No precautionary statements. "Gluten free, kosher" "safe for enamel as well as caps, crowns and veneers"
F	Expertwhite 44%CP - Extreme Whitening gel, 4 \times 3ml	hu-expertwhitegel. glopalstore.com webshop (address and phone number available	44% carbamide peroxide (15.6% H ₂ O ₂	only glycerin mentioned	85,2 (+17.3 USD	delivered in 29 days from California, USA	no referral to shade change, "the strongest teeth whitening gel available"	brief, one sentence online	Only pregnancy and breastfeeding warning mentioned. "Safe and non-toxic"

^a Commercial name of the product was available only for samples C, E and F, while samples A, B and D were unbranded "generic" products without any commercial name indicated on the website or product label. Manufacturer information was not visible on any delivered product.

^b Hydrogen peroxide is converted to the equivalent hydrogen peroxide concentration (H2O2) using the 2.82:1 ratio.

^c Disclaimer information: Websites indicated claims including "the item may be intended for use by professional health care providers only"; or "We recommend that you do not solely rely on the information presented on our website. Please always read the labels, warnings, and directions provided with the product before using or consuming a product."

included in our study disclosed their physical location and provided telephone number contact information for their customers on their websites. Generally low-quality product information is provided on global B2C websites with missing precautionary information and inadequate instructions of use. Legal protection of the website operator is assured by highlighting disclaimer information urging the consumer to check product descriptions of delivered goods or suggesting consultation with healthcare professionals prior to administration of the product or in order to avoid unwanted side effects.

When information provided online including the content of the package label and shipped product was comparatively assessed, the following observations were made. Despite the different seller information and product names, sample A and B proved to be the same products with different quantity of syringes shipped from the same country, however, at different times. A list of ingredients was provided on the labels for four samples, with the exception regarding sample C. It must be noted, sample C was delivered in a bubble mailer envelope without any enclosed product description, secondary packaging or instructions for use (see Fig. 1). The type of peroxide is not disclosed for samples A and B, neither online nor with the delivered product, only "peroxide" is listed among the ingredients. Although peroxide content of sample F is not mentioned online, the product label lists "sodium carbonate peroxide" among the ingredient list of the whitening agent without noting the concentration of the supposedly active ingredient. Consequently, an ingredient list was incomplete or missing from all (100%) product descriptions online, while ingredients were listed on the label or enclosed documentation in four out of five (80%) delivered samples.

Although directions of use were provided on every second vendor's webpage only, a majority of delivered products ($n = 4\,80\%$) explained how to use the whitening gel on the product label or user manual. Instructions were not provided within the delivered package for sample D, leaving consumers without any directions for use. Similarly, precautionary statements were also missing from sample D. Contraindications regarding overly sensitive, decayed or loosening teeth, age younger than 18 years, pregnancy and lactation were listed within the purchase agreement for samples A and B. On the other hand, product F had a more detailed list including ten contraindications of use on the packaging of the shipped product including periodontal disease, colitis and jaw problems. Furthermore, this product contained an exoneration statement, "*By using Expertwhitening products, you accept all risks & release & hold manufacturer & seller harmless from any issues/complications arising from/connected with teeth whitening*.", disavowing any responsibility when negative side effects are experienced. An analogous statement was present in both samples A and B user manuals stating, "*Liability is limited to the cost and amount of the product.*" Sample F recommended only discontinuation after irritation occurs and application only above the age of 16 years. Consequently, precautionary statements are generally (83.3%) not disclosed online by vendors, and, on the contrary, claims indicating safety and no irritation are emphasized by most (83.3%) sellers on their websites. From a different perspective, contraindications and adverse side effect information is mentioned to a varied extent regarding the majority (80%, n = 4) of the products delivered.

The safe use of a given cosmetic product is determined by expiration date (shelf life) and Period After Opening (PAO, indicated by an open cream jar icon). This information was highlighted on the labels of samples A and B as 24 months shelf life, however, there was no reference on PAO regarding syringe dispensers. Expiry date was not documented on any of the products delivered. Only PAO information was available on sample C (6 months) and F (12 months). Sample D was shipped without any enclosed documentation or

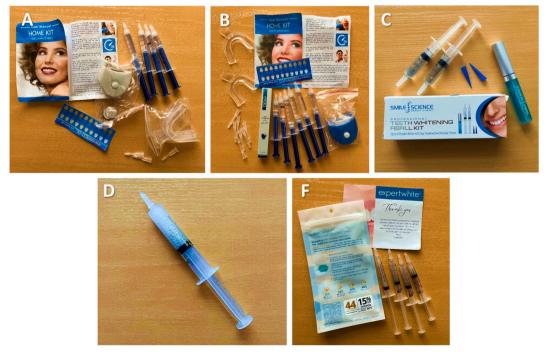


Fig. 1. Package content of delivered teeth bleaching test-purchase samples purchased online.

instructions, in which no expiry or PAO time was printed on the syringe.

3.3. Peroxide content of bleaching products and the results of the quantitative analysis

According to online information provided by sellers and the labels, of the product delivered four samples (A, B, D and F) contained carbamide peroxide, and sample C contained sodium percarbonate (a synonym for sodium carbonate peroxide). Carbamide peroxide is a water-soluble, white crystalline solid agent composed of urea and hydrogen peroxide. Upon dissolving in water, the 1:1 complex dissociates back to urea and hydrogen peroxide. Much like hydrogen peroxide, carbamide peroxide is an oxidizer yet its release at room temperature proceeds in a controlled manner [24]. Thus, the compound is suitable as a safe substitute for the unstable aqueous solution of hydrogen peroxide. Hydrogen peroxide-urea is mainly used as a disinfecting and bleaching agent in cosmetics and pharmaceuticals. Hydrogen peroxide concentration of the samples can be measured using a simple permanganometric titrimetric method. Results are shown in Table 3. Carbamide peroxide (CP) content of the samples can be determined according to the hydrogen peroxide levels, since carbamide peroxide contains 35.4% by weight of hydrogen peroxide (HP). Formula for calculation is CP=HP x 2.825. Two products' (D and F) actual whitening agent amount was somewhat higher (109.0% and 105.2% respectively) than the value indicated in the labeled information. While peroxide content in samples A (20.1%) and B (19.3%) was substantially below the labeled concentration.

Sodium percarbonate $(2 \text{ Na}_2\text{CO}_3 \bullet 3\text{H}_2\text{O}_2)$ is an adduct of sodium carbonate and hydrogen peroxide. It is a colorless, crystalline, and water-soluble solid [24]. Once dissolved in water, sodium percarbonate yields a mixture of hydrogen peroxide (which eventually decomposes to water and oxygen), sodium cations and carbonate anions. Sodium percarbonate functions by acting as a convenient source of hydrogen peroxide with the same properties as hydrogen peroxide. Percarbonate offers the advantage of safer handling and more environmental friendly features than other common oxidants [25]. Titration with permanganate is a simple and satisfactory method to examine the quantity of hydrogen peroxide, with the same effort, that of. A sodium percarbonate of the sample, since sodium percarbonate contains 32.5% of the weight of hydrogen peroxide [24,26]. As shown in Table 3., the titration of sample C did not reveal any hydrogen peroxide and, based on this, nor sodium percarbonate.

4. Discussion

We hypothesized numerous patients were driven to obtain dental products during the coronavirus pandemic which should primarily only be used in office settings and prescribed by a dentist. Incompetent use of dental products purchased with the intention of "self-medication" in this form may not only lead to further health damage but may even cross the threshold of legality in cases of excessive peroxide content. Following the identification of teeth whitening products with the highest potential consumer risk, we conducted market research referencing high peroxide content bleaching gels available from the internet and completed a comprehensive analysis of test purchased products. Our study results showed, high peroxide content gels are marketed online without information on the use and health risks. We have found numerous vendors on the internet providing misleading safety and content information for bleaching products. Analytical evaluation of the test-purchased products provided evidence for the active ingredient content not being consistent with amount indicated on the label. Interestingly, we identified only one peer reviewed journal publication on the online availability of peroxide containing whitening products. Oude-Alkin et al., in their recent publication, evaluated adherence to legal requirements of online entities advertising and selling OTC peroxide bleaching products to New Zealand customers [3]. Following the content evaluation of 24 websites, only 50% of them provided an ingredients list and 4% mentioned all precautionary statements online. Similarly to our current findings, Oude-Alkin et al. concluded objective and evidence based information regarding tooth sensitivity and irritation not being mentioned at most websites, nor did vendors directly advise customers to consult with dental professionals prior to using the whitening product.

Peroxide based teeth whitening products are popular, and during and following the coronavirus pandemic, the utilization of athome products most likely increased. DIY bleaching products are freely accessible online for retail purchase, offering an

Table 3

Measured peroxide content and label accuracy of delivered teeth whitening products sold online.

1		5	01		
Sample ID	Product name	Measured Hydrogen peroxide concentration (% (mean ± SD	Calculated Carbamide peroxide concentration ^a (%) (mean \pm SD)	Labeled Carbamide peroxide concentration (%)	Relative deviation (Actual/Labeled
А	Teeth whitening kit 4 \times 3ml	3.13 ± 0.08	8.85 ± 0.22	44	-79.9%
В.	Teeth whitening kit 6 \times 3ml	3.01 ± 0.05	8.51 ± 0.15	44	-80.7%
D	Bleach refill gel 1×10 ml	16.98 ± 0.67	$\textbf{47.97} \pm \textbf{1.89}$	44	+9.0%
F	Expertwhite Extreme Whitening gel 4 \times 3ml	16.38 ± 0.49	$\textbf{46.28} \pm \textbf{1.38}$	44	+5.2%
			Sodium percarbonate concer	tration (%) ^b	
С	Smile Science Harley Refill Kit $2 \times 5ml$	none	none	n/a	n/a

^a Carbamide peroxide (CP) contains 35.4% by weight of hydrogen peroxide (HP), formula for calculation is CP—HP x 2.824 [24].

^b Sodium percarbonate contains 32.5% by weight of hydrogen peroxide.

inexpensive, easy, and seemingly effective alternative to dental services highlighting professionally supervised, in-office teeth whitening procedures. Our complex risk assessment indicated high peroxide content teeth bleaching gels with the highest probability of online purchase due to convenient use, high expected efficacy within a few weeks' time and significant interest in online searches. At once, these high concentration products bear the probability of unwanted effects, especially when used without the supervision of dental professionals.

Active ingredient information was missing or incomplete for most of webpages included in our study, however, it was provided on the labels in all but one shipped product. One out of six test purchased samples was not delivered and two products were somewhat under labeled. We identified two significantly over-labeled products containing approximately only one-fifth of the labeled carbamide peroxide concentration. Although low concentration is less concerning from the perspective of unwanted effects, in our study we have found evidence of deceptive product information and dubious quality. In addition to issues with product quality, insufficient and misleading product information is a disturbing threat to consumer/patient safety. Online information provided by vendors is an alarming concern, since less than one-third of purchased products provided some directions of use, while the majority of vendors failed to mention precautionary statements on contraindications for use or potentially adverse effects regarding teeth bleaching procedures.

One product (sample C), offering the highest efficacy in ten days' time, and, without specifying the active principle responsible for the whitening effect on the seller's webpage on Amazon, was found to list unspecified concentration levels of peroxide percarbonate content on the secondary packaging of the delivered product. However, no active ingredient (peroxide) concentration was identified by quantitative analysis in the product. After accessing the manufacturer's website (smilescience.co.uk) we identified a dubious claim under the subtitle, "frequently asked questions," stating the product as having a safe and effective optimal formulation comparable to hydrogen peroxide. A substance releasing oxygen, water and soda, however, not declaring hydrogen peroxide. Evidently, this communication is misleading to lay individuals without basic knowledge of chemistry, since the hydrogen peroxide released after dissolution and this active principle will decompose into oxygen and water. Although we could not measure peroxide in this sample, there was either no sodium percarbonate present in it, or it had already decomposed. Thus, the oxidant itself is no longer in the product, which raises yet another question. What, exactly, does the whitening material consist of?

Regulation of peroxide concentration in teeth whiteners for retail use is not internationally conformed. According to current European law, tooth whiteners are declared as cosmetics. Products containing or releasing between 0.1% and 6% hydrogen peroxide should not be made directly available to the consumer, other than through professional treatment by a registered dentist [27]. Consequently, our current study shows evidence of illegal marketing and delivery of high peroxide content products to European consumers without professional control. In Great Britain, a similar regulation applies to bleaching products. Whiteners containing or releasing hydrogen peroxide between 0.1% and 6% are legal so long as the following conditions are met: first, they are sold to dental practitioners; secondly, the first treatment is administered by a dental practitioner or under their direct supervision; and third, the patient must be 18 years of age or older. Products containing or releasing more than 6% hydrogen peroxide are illegal, while those containing or releasing less than 0.1% are freely available [28]. Previous reports indicate, peroxide containing whiteners used in the USA can be classified into three categories: high concentration hydrogen peroxide (30-35%) or carbamide peroxide (35%) products for professional use only; materials which are dispensed by dentists and used by patients at-home (up to 10% hydrogen, or 16% carbamide peroxide); and OTC products with hydrogen peroxide content up to 6%, are available to consumers for home use [29]. In Australia, teeth whitening products containing more than 6% hydrogen peroxide or 18% carbamide peroxide may only be sold, supplied and used by registered dental practitioners as part of their dental practice. Teeth whitening products containing hydrogen peroxide 3-6% and carbamide peroxide 9-18% are considered as Schedule 5 Substances, thereby requiring a cautionary use label with stipulated safety warnings when sold directly to consumers [30]. Attention should be paid to natural whitening compounds such as low particle size charcoal [31] and natural toothpastes [32] as safe options for DIY at-home teeth whitening solutions.

The main strength of our study is the application of a complex methodology incorporating the risk assessment of teeth whitening products, vendor website content evaluation, test purchase, labeling evaluation and the quantitative analysis of the products delivered. Its limitations include sampling of the online market without the evaluation of offline retail channels, a relatively small number of test-purchased products and the evaluation of search engine results limited to only two languages. Admittedly, we have focused only on high peroxide concentration gels and excluded further whitening products (toothpaste, rinse, strip, paint-on brush/pen), as these DIY bleaching products yielded highest potential for patient safety risk (see Comprehensive risk assessment table in Supplement 1.) Future research in adapting our methodology, should provide additional evidence for the issues (consumer information, legislation, product quality) of uncontrolled and potentially illegal sale of high peroxide content bleaching products at the international level. Evidently, assessment of all available teeth whitening products for retail use online or offline requires more attention from the academic sector and tighter quality control by authorities.

5. Conclusion

Potential customers of high peroxide containing teeth whitening products should be effectively educated on the risks of using such products without the expert guidance of a licensed dental professional. Dentists are qualified to determine if teeth whitening is an appropriate intervention for the individual patient and is also clear about the regulations and recommendations regarding the concentration of hydrogen peroxide in DIY at-home whitening products. Stricter evidence-based and unified legal regulation concerning the minimally required product information including the ingredients list, the instructions of use and the warning statements on vendors' website is urgently needed.

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Institutional review board statement

Institutional review board confirmation was not applicable for our study as no patients were involved.

Author contribution statement

Márton Fittler: Performed the experiments, Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, Wrote the paper. Zsuzsanna Rozmer: Performed the experiments, Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, Wrote the paper. Andras Fittler: Conceived and designed the experiments, Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, Wrote the paper. Andras Fittler: Conceived and designed the experiments, Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, Wrote the paper. All authors have substantially contributed to the drafting the manuscript and the revision process, read and approved the final submitted version.

Data availability statement

Data included in article/supp. Material/referenced in article.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Dr. Andras Fittler reports financial support was provided by Hungarian Academy of Sciences. Dr. Marton Fittler reports financial support was provided by The Ministry for Innovation and Technology.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2023.e19463.

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