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Citation for final published version:

Gupta, Anisha, Gallagher, Jennifer E., Chestnutt, Ivor G. and Godson, Jenny 2021. Formulation and fluoride content of dentifrices: a review of current patterns. *British Dental Journal* 10.1038/s41415-021-3424-y

Publishers page: <https://doi.org/10.1038/s41415-021-3424-y>

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Formulation and fluoride content of dentifrices:

A review of current patterns

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Abstract

Introduction: Consumer oral hygiene products play a key role in improving and maintaining population oral health. The oral personal care market is rapidly diversifying; a growing number of dentifrices marketed as 'natural' and fluoride-free are entering mainstream retailers, which may have implications for the oral health of the population with regards to caries risk.

Aims: To investigate the range of fluoride concentrations, flavour formulations and delivery mechanisms of dentifrices available on the UK market.

Methods: A cross-sectional survey was used to catalogue dentifrices sold in a range of supermarkets, high-street pharmacy and health chains and specialist online retailers. In addition, a standard search engine was used to examine dentifrice brands being sold in the UK. The fluoride content was recorded as parts per million (ppm), and the product name data was analysed for key terms using Excel. Excluded from the survey were mouthwashes, rinses, and non-dentifrice whitening products.

Results: 500 different toothpaste, toothpowder and tablet products from 95 different brands were recorded. Sixty percent of these contained a fluoride concentration of 1000ppm or above. Forty-five percent of all products had the recommended adult concentration of at least 1350ppm. Almost one third (31%) contained no fluoride and 4 percent of products did not specify the absence, presence, or concentration of fluoride.

Conclusions: This study has quantified and confirmed the increasingly diverse range of dentifrices for sale in the UK. A large number of fluoride-free products exist within a growing 'natural' and 'organic market'. The study also gives oral health professionals an insight into the diverse types of products available to consumers in order to appropriately advise patients on caries prevention.

Introduction

'Dentifrices' include toothpastes, gels, powders and chewable tablets, designed to be used primarily as adjuncts to mechanical cleaning i.e. toothbrushing. The introduction of fluoride toothpaste and other fluoride-containing tablet and powder dentifrices to the personal care market has coincided with a significant reduction in the caries incidence in the UK and the rest of the world. In 1956, Crest with Fluoristan, a dentifrice containing stannous fluoride, was released by Proctor and Gamble, off the back of the work of Dr Joseph Muhler, a dentist and professor of chemistry at Indiana University. This toothpaste later received approval by the American Dental Association, supporting the claims that brushing with a fluoride-containing toothpaste could lead to a 50% reduction in dental caries.¹ Since then, fluoride toothpastes have become ubiquitous, and form a mainstay of preventive dental care for the world's population, alongside a diet low in sugar and regular professional care. Brushing with toothpastes is the most common method of fluoride delivery to the teeth for the majority of the UK population; around 75% of the UK population report brushing their teeth twice a day according to the Consumer Oral Health Survey 2009². In addition, 94% of dentate adults reported using toothpaste with at least 1000ppm fluoride, according to the Adult Dental Health Survey 2009³.

Brushing twice daily with a fluoride toothpaste containing 1000ppm fluoride or above has been shown to be a safe and effective way to reduce caries in children and adults.^{4,5,6,7} Current UK Guidelines for evidence-based prevention, such as those outlined in Delivering Better Oral Health in England, recommend that children aged 2 years and under should be using a toothpaste containing no less than 1000ppm fluoride, whilst children and adults aged 3 years and above should be using toothpastes containing between 1000-1500ppm fluoride.^{8,9}

Alongside leading household brands from the larger and more established pharmaceutical and personal care manufacturers, there are a growing number of boutique, independent and alternative brands offering dentifrice products, readily available in high street and online retailers. Niche toothpaste brands have been experiencing market success in part due to an increasingly diverse retail landscape¹⁰, with the global herbal toothpaste market valued at 1.5 billion USD in 2018.¹¹

Dentifrices are generally formulated to contain cleansing agents in the form of abrasives, surfactants, binding and thickening agents and rheology modifiers, humectants, preservatives, and additives to improve sensorial experience such as colouring and flavouring agents.¹² In addition, many dentifrices contain active ingredients designed to prevent oral disease such as caries and periodontal disease. These ingredients include essential oils, remineralising agents, and antibacterial compounds. Dentifrices are increasingly formulated, labelled, and marketed to help manage or treat specific conditions, including dental caries, periodontal and gingival health, bad breath, staining, sensitivity, and tartar formation. A range of ingredients are included to do this, either in addition to or as an alternative to fluoride.¹³ Among these are triclosan, calcium phosphate, nano-hydroxyapatite and xylitol. However, these compounds have less substantial evidence of their anti-caries or anti-bacterial action compared to fluoride. There is low quality evidence indicating that xylitol may have an anti-caries property when combined in a fluoride dentifrice.^{14,15,16}

Fluoride is present in a number of formulations, most commonly as sodium fluoride, sodium monofluorophosphate and stannous fluoride. Fluoride exerts its anticariogenic effect via two main mechanisms – (i) the presence of fluoride in the plaque biofilm facilitates remineralisation and (ii) incorporation into the tooth structure in the form of hydroxyfluoroapatite, which is more resistant to acidic demineralisation.¹⁷

The majority of toothpastes in the UK, are not considered to be medicinal products or medical devices by the Medicines and Healthcare Products Regulatory Agency (MHRA). The standards around formulation, labelling, marketing and distribution come under that of the cosmetics industry standards,¹⁸ and currently come under the EU Cosmetics Regulation (EC). These are less stringent than those that relate to medicines or pharmaceutical preparations, 1223/2009. In the US, the FDA considers toothpaste containing fluoride whose intended purpose is anti-caries (eg disease-preventing), to be a drug; whilst toothpastes that do not contain known medicinal compounds and intended to be used simply for aesthetic benefits, are considered cosmetics.¹⁹ Exceptions to this include high fluoride toothpastes available only on prescription including 2800ppm and 5000ppm, and desensitizing toothpastes, which are largely categorized as medical devices.²⁰

There are literally hundreds of products available on the market, with a wide range of marketing claims and stated benefits. Patients increasingly see themselves as discerning consumers of oral health²¹, and there is greater interest and knowledge amongst consumers regarding the ingredients contained within their personal care products. There is evidence that when purchasing personal care and hygiene products, such as skincare and cosmetics, consumers value ingredient transparency.²² Consumers of oral health products have access to resources such as blogs and consumer review websites, allowing them to be more informed and discerning about which products they buy and the benefits offered.²³ As well as having an increased preference for products with low amounts of packaging and single use plastic, patients may also have a strong preference or aversion to certain flavoured dentifrices; an aversion to strong mint flavours appearing to be relatively common, particularly in younger children.

New varieties of toothpastes are continuously being added to the market, and brands reformulate, rename, rebrand and repackage products frequently. As with any retail product, popular and highly selling products tend to stay on the market longer, whilst poorly performing products get replaced more frequently. Some retailers, particularly third party merchants online or in local street markets, are known to stock products which may be counterfeit, out of date, no longer being manufactured, or proprietary products manufactured in countries with different regulations regarding formulation and labelling.

In an ever-changing market economy it is important for oral health practitioners to have an understanding of the products available to patients and the public.

Aims

The primary aim of this study was to review the number and types of products available on the UK market, and to quantify the relative proportions of low or no-fluoride dentifrices. A secondary aim was to qualitatively assess how manufacturers label and promote their products, and advertise on the basis of a product offering a cosmetic or health benefit (e.g. whitening, sensitivity, anti-caries), or particular type of ingredient (e.g. natural, organic). A further aim was to consider the implications of these labelling and promotion strategies on wider oral health messaging.

Methods

A comprehensive survey of toothpastes available in the UK markets was undertaken in 2007 at the time of the publication of the first edition of Delivering Better Oral Health – the Department of Health’s toolkit designed to provide guidance on oral health promotion in primary care²⁴. The fourth edition of this toolkit is in preparation and the work reported here has been carried out to inform this edition using the same methodology as that used previously.

This survey examined dentifrices being sold in a range of high street and online retailers between September 2019 – December 2019. The products were recorded on an Excel spreadsheet. Fields collected in the table included manufacturer or brand name, product name and fluoride concentration.

The search strategy used web-based search engine to find UK-based retailers of dentifrices. Products were catalogued by manufacturer/brand and specific product name, recording fluoride concentration in parts per million.

The survey included all products to be used as an adjunct to mechanical cleansing i.e. to be used with a toothbrush to mechanically clean the teeth. This also included toothpastes and powders offering whitening benefits, dentifrices marketed as cosmetics, as well as those listed as medicinal products/medical devices due to their desensitising properties.

Products not included in this study were oral hygiene products not designed to be used with a toothbrush, including mouthwashes and rinses (including oil-pulling products), chewing gums and breath fresheners, and whitening gels/pens or serums. High-fluoride dentifrices (both branded and generic) of 2800ppm and 5000ppm were also excluded from this analysis as they are available only on prescription.

Whilst this research was conducted in London, the involvement of major retail chains and the incorporations of online outlets mean that the products sampled are likely representative of those available throughout the United Kingdom.

Fluoride Concentration

The concentration of fluoride contained in the dentifrices was obtained, where possible, via the International Nomenclature of Cosmetic Ingredients (INCI) list printed directly on the product packaging or listed on the product website. Concentrations of sodium fluoride, stannous fluoride, or sodium monofluorophosphate, stated in percentages, were converted to parts per million of fluoride ions (ppm F⁻). Where the ingredients information was unavailable it was obtained via the customer services departments of the brand, either via email or phone call. Some brands did not respond to requests for information on the fluoride concentration of the products.

Descriptive analysis was undertaken to determine fluoride concentration categorised as: 0 ppm, 1-999ppm, 1000-1349ppm, and greater than or equal to 1350ppm.

Product Name/Description Analysis

To visually analyse the frequency of specific terms used in product names and on packaging, a 'word cloud' was generated to highlight the relative frequency. This was created using a free online word cloud generator at <https://www.wordclouds.com/> and using the list of product names as the source data. The word 'toothpaste' was excluded from the analysis in order to more clearly visualise other key words, such as 'whitening' or 'natural'.

Using the search function on Excel, the number of products containing a reference to a specific flavour ingredient was recorded.

Results

A total of 500 different dentifrice products were recorded across 95 proprietary brands, with fluoride concentrations ranging from 0 to 1500ppm. Twenty products had an unknown concentration of fluoride, with the information not being readily available through the retailer website or after attempts to contact the manufacturer.

Dentifrice types found included toothpastes, gels, toothpowders, and solid toothpaste tablets. Ten products were powder formulations, seven as tablets. One particular dentifrice was labelled and sold as an oil-based product to be used with a toothbrush – in contrast to oil-pulling products designed to be used as mouthrinses, which were not included in this analysis.

A majority (60%) of dentifrice products contain the recommended fluoride content of 1000ppm or above as recommended for effective caries prevention; however, almost one third (31%) of the products analysed contained no fluoride at all.

Figure 1 - Distribution of labelled fluoride content across 500 dentifrices sampled

The number of products designated specifically for children was 73, representing 14.6% of products. This was based on the presence of the word 'kids', 'children', 'baby', or a specified age range contained in the product name. Of these 73 products, 30 products contained less than the recommended minimum concentration of fluoride of 1000ppm.

Figure 2 - Wordcloud: Frequency of terms contained in product names

The most frequent words to appear in the product names were white, whitening, sensitive, mint, fresh, charcoal, and natural. In total, 153 products (30% of the total) contained the word 'white' or 'whitening' in the name.

Thirty-six different flavour ingredients were identified across the range of products, the most frequently occurring being mint (including peppermint and spearmint), charcoal (used as an active as well as flavouring ingredient), coconut, and aloe vera.

Figure 3 - Frequency of flavours/key ingredients contained in 500 dentifrices sampled

Discussion

As illustrated by the findings of this survey, the number of toothpastes and other tooth cleaning products available to consumers in the United Kingdom is vast and has grown substantially since a similar survey in 2014²⁵ The 'natural' cosmetics market is causing an increase in the range and number of fluoride-free toothpastes available marketed to adults and children. The range of different flavours that are currently incorporated in toothpaste formulations is similarly large, the traditional mint flavour comprising only a fraction of the multifarious flavours marketed, appealing to different patient preferences and sectors of the market.

Examples of manufacturers producing more environmentally-friendly toothcleaning products include a leading proprietary brand recently releasing a toothpaste in the world's first fully-recyclable High-Density Polyethylene (HDPE) plastic toothpaste tube, itself packaged in recyclable cardboard. The package labelling featured a simplified list of the main ingredients on the front, outlining their respective health and sensory benefits.²⁶ The brand also intends to share the intellectual property behind the recyclable packaging with its leading competitors, and released the product after previously releasing a biodegradable bamboo toothbrush in the previous quarter. Another product was recently released by a group of well-known UK cosmetic dentists – a toothpaste tablet containing fluoride in recyclable packaging, and launched with an extensive marketing campaign across social media platforms, particularly Instagram.²⁷ Both of these releases are evidence of how both mass-market and luxury consumers are becoming more conscious of the formulation and sustainability of their oral hygiene products, and the increasing role of direct-to-consumer and social media-based advertising and marketing.

Clinical Implications

Comparison with the findings of the previous survey (which this work mirrored) indicates the change and growth in the market in the last five years. When comparing to 2014, this analysis identified a greater total number of dentifrice products (500 vs 142), of which a greater proportion contained no fluoride (31% vs 10%).²⁸

The 'green', 'natural' and 'organic' beauty and personal care markets have shown considerable growth,²⁹ with consumers increasingly concerned with potential toxicity and environmental sustainability of the everyday household and personal care products they are using. Despite evidence showing low toxicity and low risk of harm when using topical fluoride appropriately,³⁰ fear of fluoride toxicity has been observed for decades,³¹ and companies seek to gain consumer trust by offering a wide range of fluoride-free formulations, often claiming many of the same oral health benefits as traditional fluoridated dentifrices.

The total fluoride content in parts per million that manufacturers declare on their products, however does not always reflect the true bioavailable ionic fluoride content on brushing as shown by a recent study³². This is due to both the molecular form of fluoride present in the product, as well as issues such as storage and chemical degradation of product by the time they reach the consumer. Further work into understanding the mechanisms of action, bioavailability, and relative efficacy of different types of fluoride or dentifrice ingredients, would be useful to the wider dental profession. In addition, a better understanding of the therapeutic effects of combining fluoride with other ingredients in complex formulas would also provide greater clarity to patients and consumers about the efficacy of the products.

Harm reduction approaches should be employed when giving oral health advice to patients who choose not to use fluoride-containing toothpastes, including evidence-based advice on low-sugar diets, use of novel non-fluoride anti-caries agents such as nanohydroxyapatite or xylitol, and potentially increasing recall frequency for dental attendance, dependent on the patient's individual caries risk and personal circumstances.

The large number of tooth cleaning products that are flavoured other than by mint is an important consideration, particularly in the case of young children. To prevent fluorosis it is important that children do not swallow, lick the tube, or eat toothpaste, and are supervised when brushing. This may be more likely to happen if the toothpaste has an appealing flavour.^{33,34} This is considered less likely to happen with strong mint flavoured products – although toothpaste, like all medicines should be stored securely out of the reach of children. It is important to also consider the potential for mixed-messaging; toothpastes

flavours based on confectionary or alcohol (such as cola, bubblegum, gin and tonic) could be seen as promoting consumption of cariogenic sugary or alcoholic foods and drinks. There appears to be a large number of 'niche' products in the dentifrice market, focusing on 'natural', 'organic', 'eco', and 'fluoride-free' formulation and packaging. Alongside this there is a large number of premium branded or luxury dentifrices, focusing on 'whitening' and cosmetic benefits, alongside premium packaging and a premium price point. Many whitening products are labelled as suitable only for children aged 7+ years, and labelling requirements around whitening and suitability for children may impact whether certain products are used by all age-groups within a household. Toothpaste tablets, designed to be more eco-friendly due to requiring less packaging and water, appear to be addressing contemporary concerns. Manufacturers and brands are seemingly aware of the desire that consumers have for transparency, accountability and sustainability, and produce diverse products in terms of taste and texture to cater to wider consumer audiences. Manufacturers often spend large sums of money within their market research activities to understand what priorities their target market have, and then use this information to promote products. This study of consumer/patient priorities may prove a useful strategy in improving how clinicians and public health organisations deliver oral health messages.

Whilst the price of products was not the focus of this analysis, at the time of writing, the products ranged in price from 95p per unit to over £140 per unit, reflecting a huge variation.

The increasing availability of luxury and high-end dentifrice products,³⁵ suggest a general trend towards the commodification of basic hygiene items,³⁶ and it would appear that the majority of the fluoride-free products have a higher price point than the mass-market fluoridated brands. Having a low income is associated with higher risk of oral disease, including tooth decay,³⁷ and therefore it could be seen as encouraging that decay-preventing fluoride toothpastes remain at the more affordable and widely available end of the dentifrice market spectrum. This is important to emphasise, so as not to further perpetuate oral health inequalities that may result from hygiene poverty. However, due to branding and marketing there is a risk that people from lower socio-economic groups may spend a disproportionate amount of their income on high cost fluoride-free dentifrices, ineffective against caries. There is some evidence to show that subsidising the cost of

healthier consumer products, or a relative increase of the cost of unhealthier products (e.g. tobacco and alcohol), has a progressive effect on public health outcomes.³⁸ There has been a push to remove the VAT on other consumer products that are considered essential for maintaining good health, such as menstrual products, in order to reduce inequalities³⁹. Reducing the cost of toothpaste by removing the VAT status, might be seen as a potential health-promoting fiscal measure by governments to further encourage the use of fluoride toothpastes and address health inequalities linked to hygiene poverty. However, how this would affect the balance between consumption of fluoride/non-fluoride brands is uncertain. Affordability of toothpaste and hygiene products remains a barrier to oral health⁴⁰, with many consumers relying on purchasing toothpaste from discount variety stores and single price stores, and street markets, where imported products may be counterfeit or poorly regulated, with unknown levels of fluoride.^{41,42} Non-fluoridated products and abrasive powders are heavily marketed to consumers via traditional advertising routes and social media, and may pose a risk to certain patients in terms of caries risk or tooth surface loss.

Limitations and Future Research

There is a great need for understanding how market and commercial forces influence public health behaviours. This is only a cross-sectional study, and more empirical research is needed to understand market growth and the factors involved in consumer choices to ensure safe and effective products appeal to consumers. In order to create effective policy and health-promoting environments, it is important to know how consumers make choices relating to their oral health. Factors such as availability, affordability, sustainability and safety, all factor into purchasing decisions made by consumers buying toothpastes and other dentifrices, arguably as much as any direct oral health benefits of the products. It is important from a dental public health perspective, that the significant gains made in caries prevention since the availability of fluoride toothpastes,^{43,44} are not lost in an attempt to reduce the environmental burden of consumer oral care products. The relative risks and benefits, both to dental health and the wider environment, of these products being repackaged or reformulated need to be considered.

Conclusion

New varieties of dentifrices have emerged into the market, and dental care professionals should have an awareness of the types of products available to buy in their local markets, particularly as patients become increasingly discerning and informed consumers. There are three key issues arising from this survey: the larger proportion of products which do not contain fluoride, the number of products flavored with other than mint and the expanding eco-organic marketing of products. In addition, there are potentially useful lessons from the commercial sector, in relation to addressing societal priorities and behaviour, in order to inform and improve the delivery of oral health messages. As discussed above, these factors all have implications for the advice given by dental team members.

Figure 1.

Distribution of labelled fluoride content across 500 dentifrices sampled

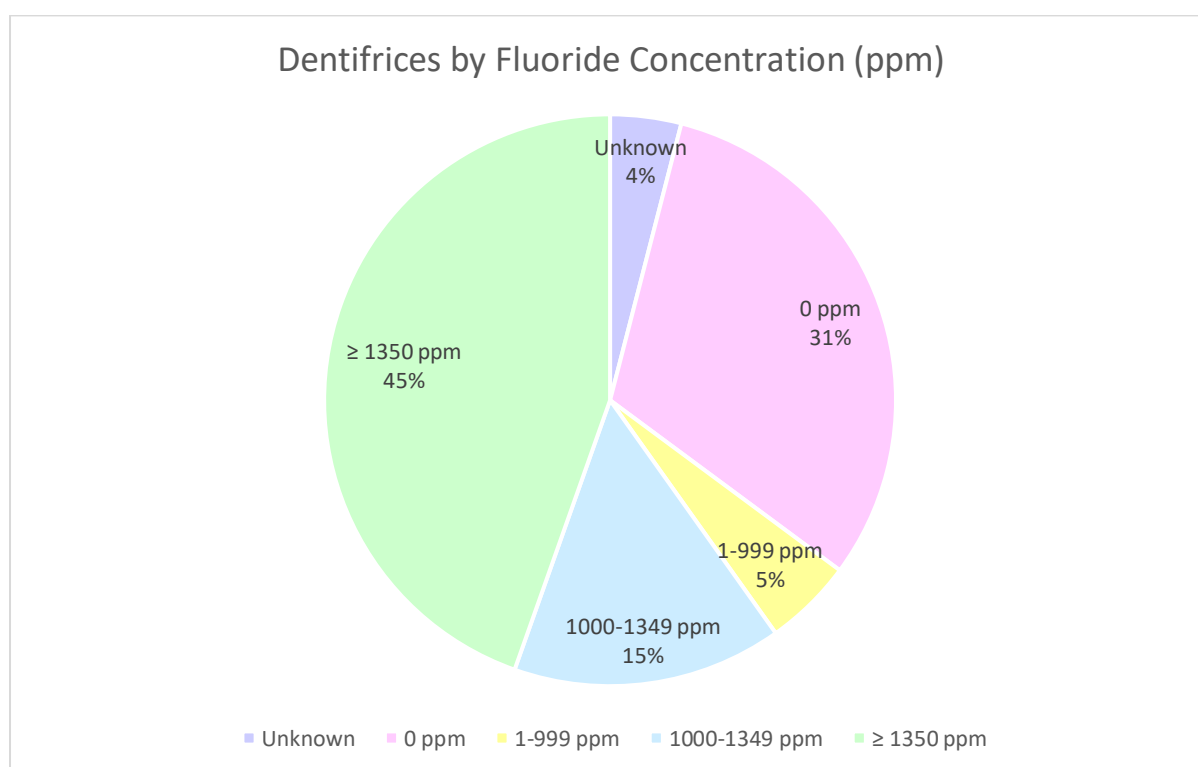


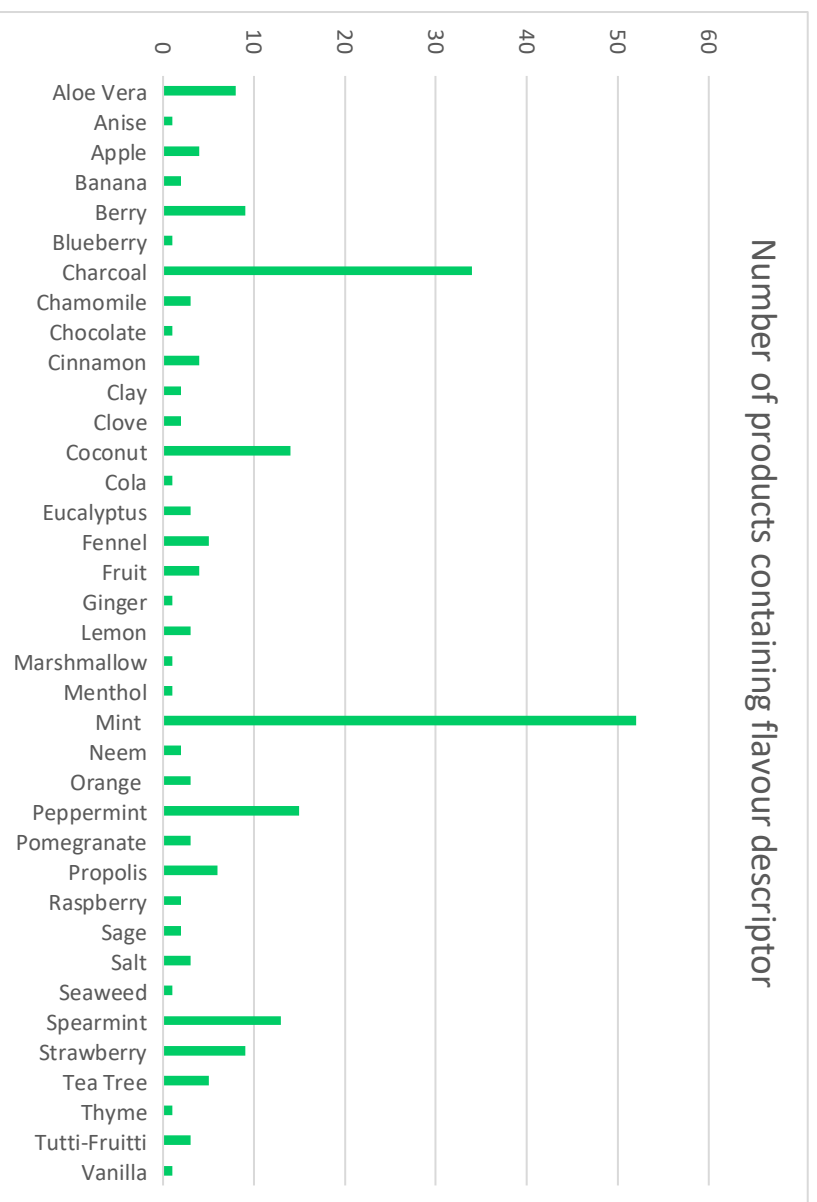
Figure 2.

Frequency of terms contained in product names



Figure 3.

Frequency of flavours contained in 500 dentifrices sampled



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