



**Evaluation of synthetic amorphous silica (SAS) by the
Scientific Committee on Consumer Safety:
A public health perspective**

Executive summary

This evaluation considers the public health impacts in Europe of a possible SAS (synthetic amorphous silica) ban, specifically because of its role as the abrasive of choice in effective toothpastes.

Abrasive agents are essential for a toothpaste to be effective in removing plaque and dental stains. SAS is a unique abrasive that delivers excellent adaptive cleaning efficacy whilst enhancing the bioavailability and stability of fluoride and other toothpaste ingredients, providing numerous health benefits from twice daily brushing with toothpaste. Fluoride toothpastes are essential for protecting teeth against decay because they deliver a low level of bioavailable fluoride. Their clinical efficacy has been confirmed in multiple studies, systematic reviews, and meta-analyses.

Untreated tooth decay is the most prevalent non-communicable disease in Europe and globally. Tooth decay rates are considerably higher in areas of social deprivation, both within and between countries. The excessive economic and social costs of tooth decay are well documented and recognised, including the burden of disease, pain, and productivity loss. Although largely preventable, it remains a major public health issue and effective and affordable fluoride toothpaste must be accessible to European citizens.

In the EU, approximately 80% of effective toothpastes are currently formulated with SAS and alternatives with the same performance characteristics are not immediately available. Extensive evidence from clinical trials has shown that silica-based toothpastes in combination with a fluoride source deliver a safe and effective public health strategy in preventing caries.

A ban on SAS in toothpastes would therefore have severe public health and economic impacts, both in terms of direct costs of treatment and indirect costs of lost productivity. In Europe (EU-28 countries), the direct costs of treating tooth decay are estimated at 90 billion EUR and the productivity-related costs are approximately 49 billion EUR.

A ban on SAS use in toothpastes would cause an increase in the prevalence of tooth decay – affecting general health, longevity and increasing economic costs to society. The raw materials to facilitate such a change in fluoride toothpaste formulation are also not available to the extent that would be required. A ban on SAS would almost inevitably lead to a shortage of supply of effective fluoride toothpastes together with increased toothpaste prices, reducing accessibility and affordability of toothpaste and exacerbating social inequalities. Such an outcome is totally unacceptable from a public health perspective.

Consequently, we would ask the Commission to consider the compelling evidence of the public health importance of fluoride toothpaste within the overall discussion on a potential ban on SAS.

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I. Caries as a critical public health issue

a) Caries is the most prevalent of all non-communicable diseases despite being preventable

Tooth decay, also known as dental caries, is the world's most prevalent non-communicable disease¹. Caries and subsequent tooth cavities affect people across the life course, with untreated caries in the permanent dentition (permanent teeth) being the most prevalent and untreated caries in the primary dentition (baby teeth) the 10th most prevalent non-communicable disease worldwide¹. The high numbers of children still suffering from untreated caries, alongside an ageing population with increasing levels of caries and cavities, shows that we must minimise caries risk for all age groups². Overall, 34% of the global population has untreated tooth decay in their permanent teeth³.

Early childhood caries (ECC) has an adverse effect on development, affecting nutrition and speech development as well as educational attainment^{4, 5}. In many EU countries admission to hospital for tooth extraction as a result of ECC is the most common cause of hospital admission for general anaesthetics in children.

At the other end of the age spectrum, excessive tooth loss among adults aged 50 and over, which is usually the end result of dental caries and periodontal disease, considerably impairs their functional ability and participation in society, thereby negatively impacting on healthy ageing⁶. In high and middle-income countries, the nature of caries has changed from a rapidly progressing disease of childhood to a slowly progressing disease throughout adulthood and even old age³.

Dental decay is directly linked to living and social conditions and lifestyle, as well as the prevalence of public health measures⁷. There is a distinct socio-economic variation in the distribution of caries, and the prevalence is particularly high amongst disadvantaged population groups³. Inequalities in the distribution of caries are apparent both at a country level and on a global scale. Health inequalities are one of the most important problems of social injustice in Europe. Evidence from different European countries shows that people with lower socioeconomic status (SES) are more likely to have poorer oral health than their higher SES counterparts^{7,8}. In a recent systematic review, Schwendicke et al. assessed current evidence for the association between SES and caries. They concluded that the odds of having any caries lesions or caries experience were significantly greater in those who have (or whose parents have) a disadvantaged educational or occupational background, or a low income. This divide

was even more marked in highly developed countries⁹. Tackling such inequalities in oral health has increasingly become a goal of governments in European countries and access to affordable and quality fluoride toothpaste is part of this.

WHO data suggests that, thanks to the introduction of effective fluoride toothpaste around the globe, the prevalence of caries on a global level has been controlled to a certain extent¹⁰. Despite a considerable decline in incidence among children, as a result of effective fluoride toothpastes, caries still affects 60–90% of children worldwide¹¹. Among socially deprived populations, the prevalence of caries remains high in all age groups¹².

b) Economic and social impact of caries

Untreated caries and cavities create sizeable economic challenges with huge costs³. On one hand, we have the direct costs of caries treatment. On the other, we have indirect costs related to productivity losses or absences from work or school. Lack of access to health services, e.g., due to cost, travel distance, or waiting times, results in unmet needs, particularly among people experiencing social deprivation. This lack of access also reflects inequalities in healthcare service uptake. In Europe, the financial burden people face for access to dental care varies widely.

The total cost of treating all oral diseases (including caries) in the EU-28 countries is an estimated 90 billion EUR per year, third among all conditions¹³, following diabetes and cardiovascular diseases. Dental treatment is costly, averaging 5% of total health expenditure and 16% of private health expenditure across Organisation for Economic Co-operation and Development (OECD) countries in 2009¹⁴. Recent data¹⁵ reveal that dental care expenditure is highest in Western Europe. Public expenditure for dental treatment was between 3 and 8% of national health spending in individual European states. Demographic, economic, and political factors ensure that the demand for dental services continues to rise. As the baby boomer generation ages, providing treatment for people in need of care is becoming a major challenge¹⁶.

Oral diseases also have indirect costs, mainly from productivity losses due to absences from work and the impact of poor oral health on children's school attendance and performance. Productivity losses due to dental diseases in the EU-28 countries are estimated to reach 49 billion EUR a year¹⁷. The highest productivity losses were found in Western Europe. Of the indirect costs of major dental diseases in Europe in 2010, 49% were attributable to severe tooth loss, 37% to severe periodontitis, 14% to untreated caries in permanent teeth and 0.7% to untreated caries in children's deciduous teeth. The GBD 2015 data on productivity losses were summarised by Righolt et al.¹⁸ and published in the Journal of Dental Research in May 2018 (see Appendix 1).

For children, poor oral health has been shown to affect school attendance and performance. Studies from different settings, including some from European countries, have shown that children with oral health problems are more likely to miss school, have lower school grades, have problems at school, and are less likely to do their homework¹⁹⁻²⁴. These learning outcomes are important not only in their own right, but also given their strong relationship with future economic performance, labour market outcomes and other lifetime outcomes^{24,25}.

c) Caries and quality of life

Dental caries is an unevenly distributed, preventable disease with considerable economic and quality-of-life burdens. The relationship between caries and quality of life has been clearly presented⁴. Even though dental caries can be asymptomatic, particularly in its initial stages, the disease is associated with diminished quality of life for people affected and their families²⁶. Untreated caries can lead to pain, tooth loss and infection, potentially affecting the ability to eat and thereby impairing growth and development². Toothache and tooth decay are commonly associated with worse oral health-related quality of life in adults²⁶.

A recent systematic review by Barasoul et al. (2020) highlighted the strong association between toothache (as a result of dental caries) and reduced oral health related quality of life²⁷. Another systematic review looked at broader aspects of quality of life and showed that caries and tooth loss (most often a result of caries) had a negative impact on health-related quality of life²⁸. The impact of untreated caries on quality of life, along with the time required to access treatment, can result in absences from both school and work. This has a negative effect not only on the patient, but also on their employer and the economy². Globally, untreated caries accounted for almost 5 million disability adjusted life years (DALYs) in 2010, with a further 4.5 million DALYs attributed to excessive tooth loss. Untreated dental caries contributed to DALYs across the life course, with more of an impact on children and young adults, while tooth loss affected primarily middle aged and older adults¹.

II. The importance of daily use of effective fluoride toothpaste

The benefits of fluoride in preventing caries from developing and/or progressing are evident worldwide. The use of fluorides in toothpastes is credited with the overall global reduction in caries in many countries over recent decades, as tooth brushing with toothpaste is so widely accepted as a behavioural norm. The preventive contribution of the fluoride toothpaste outweighs that from brushing per se⁴. It is an effective solution at a public health level, which is both accessible and low cost²⁹.

a) Toothpaste regulation

It should be noted that fluoride was originally added to the Cosmetic Products Directive (Council Directive 76/768/EEC) because of its public health importance and the desire to enable daily-use fluoride toothpastes to be sold in shops, rather than classifying them as medicinal products and thus restricting fluoride-containing products to pharmacy distribution in most EU countries.

More recently, the importance of fluoride toothpaste for the population was reconfirmed by the WHO's decision to add it to the list of essential medicines for adults and children³⁰, therefore the availability and affordability of fluoride toothpaste is paramount.

b) Role of abrasives in toothpaste

Abrasive agents are important for a toothpaste to be effective as a dental plaque and stain removing agent. Toothbrushing effectiveness is reduced with the use of an abrasive-free formula, due to the poor cleaning capacity of the toothbrush alone. In turn, such reduced effectiveness results in increased tooth staining and poor plaque control.

Toothpaste is not only used to reduce stain and plaque build-up but to help prevent oral diseases. Toothpastes also have other active ingredients that help prevent tooth decay (dental caries) and gum disease (gingivitis & periodontitis) and may assist in suppressing bad breath, tartar build up or hypersensitivity.

SAS is unique among abrasive substances in that it improves uptake and stability of a variety of toothpaste ingredients (including fluorides) which are responsible for the numerous health benefits, including caries prevention. The formulation of toothpaste is critical to its efficacy. Toothpaste formulations seek to find the right balance between abrasiveness and cleaning whilst also ensuring sufficient uptake of other active ingredients to deliver their respective benefits.

To prevent tooth decay through twice-daily brushing with fluoride toothpaste, the fluoride must be sufficiently chemically available to the teeth (in other words, it must be 'free fluoride'). Silica is the most effective abrasive to enable this bioavailability for the currently available fluoride compounds. There is no alternative to silica to ensure similar or higher availability of free fluoride from key compounds like NaF, Amine Fluoride or Stannous Fluoride, and we are unaware of any clinically superior fluoride/abrasive combination.

In summary, silica is the preferred abrasive for use in toothpastes because it has controlled abrasiveness, while providing effective stain and plaque removal and causes little or no interference with delivery of free fluoride and other active ingredients at effective levels during brushing.

c) Effective Fluoride toothpaste as a universal good practice for prevention

In the 1980s, silica abrasives that were compatible with key fluoride compounds became available and allowed effective toothpastes to be widely developed. These formulas were tested and proven to be clinically effective against caries because they deliver a high level of available free fluoride to the teeth.

The introduction of clinically proven effective fluoride toothpastes resulted in a decline in caries incidence in developed countries³¹. Supported by more than half a century of research, the benefits of fluoride toothpastes are firmly established³². Clinical trials with fluoride toothpastes are of relatively high quality and provide clear evidence that fluoride toothpastes are effective in preventing caries.

Many clinical studies, systematic reviews and meta-analyses have confirmed the anti-caries clinical efficacy of effective fluoride toothpastes. An early meta-analysis of clinical trials showed that NAF-based toothpastes (in combination with SAS abrasive) were significantly and clinically more effective than sodium mono-fluorophosphate (SMFP) toothpastes³³. A subsequent Cochrane systematic review, that included more studies and compared different types of fluoride agents (NAF-based, SMFP-based, stannous fluoride, amine fluoride) in a meta-regression, showed no significant differences between the different types of fluoride, documenting the effectiveness of fluoride toothpastes for the reduction of caries³³. A review in 2009³⁴ stated that there was strong evidence that daily use of fluoride toothpaste has a significant caries-preventive effect in children compared with placebo. The latest version of the Cochrane Review, published in 2019¹⁵, included 96 studies published between 1955 and 2014 and again confirmed the benefits of using fluoride toothpaste in preventing caries when compared to non-fluoride toothpaste.

The Lancet series on Oral Health in 2019 clearly stated that, to reduce caries in the world even further, the use of effective and affordable fluoride toothpaste should be encouraged and enabled¹².

d) Recent developments and policy recommendations reaffirming the importance of fluoride toothpastes

To date, oral health has been a neglected issue on the global health agenda³⁴. The adoption of a resolution on oral health at the WHO's 2021 World Health Assembly on May 27, 2021, was, therefore, an important step forward^{36,37}. The resolution calls for the development of a global oral health strategy by 2022 and action plan by 2023, including a monitoring framework aligned with the non-communicable disease (NCD) and universal health coverage (UHC) agendas³⁷.

This resolution intends to pave the way to better global oral health. The WHO recognises that oral diseases disproportionately affect poor and socially disadvantaged populations. Oral diseases have been linked with other noncommunicable diseases, such as cardiovascular diseases and diabetes, as well as pneumonia, adverse pregnancy outcomes and early onset of frailty and dementia. The WHO states that most oral diseases are largely preventable and urges Member States to move from a focus on reactive treatment and cure to a preventative approach.

Oral hygiene is a key part of dental disease prevention, which includes twice-daily brushing for 2 minutes with an effective fluoride toothpaste that has been confirmed to substantially reduce the risk of dental caries. The WHO states that fluoride toothpastes containing between 1000 and 1500 ppm fluoride are the standard dental public health measure for the prevention of caries³⁸.

Health inequalities have also worsened during the COVID pandemic, placing an additional burden on oral health because of practice closures and restrictions on referrals to specialists thus making the use of effective fluoride toothpastes even more essential.

The European Commission recently awarded a certificate of best practice to a project designed to improve oral health among children, particularly those from the most deprived backgrounds. ChildSmile, run by the Scottish government, was established in 2006 to address the poor oral health and extensive oral health inequalities among children in Scotland. It focused on getting all children brushing their teeth at least twice a day for at least two minutes with a fluoride toothpaste. Continued availability of high-quality fluoride toothpaste is essential to the success of this and similar programmes.

III. Estimation of the impact of a SAS ban

Despite the widespread availability of affordable and effective fluoride toothpastes in the EU market since the 1980s, caries is still the most prevalent condition. The condition persists among children, teenagers, and adults across Europe. With an ageing population and persistent health inequalities, we now see a slower decline or even an increase in caries prevalence in several countries.

Currently, about 80% of toothpastes on the EU market are formulated with SAS as an abrasive system. Therefore, a ban on SAS in toothpastes would have a devastating effect on oral health and other linked general health issues.

a) Increase in caries rates

Caries remains present in Europe and using an effective fluoride toothpaste remains part of all major oral health strategies. Limiting EU market availability of the most effective toothpastes, as a result of a ban on SAS, would have serious implications for caries prevalence. It would particularly affect the most vulnerable populations in Europe which is totally unacceptable.

b) Economic cost

As previously noted, dental caries has a significant economic cost¹⁸. The indirect costs mainly stem from lost economic productivity due to absences from work. Vujicic and Listl³⁹ researched this issue, relying on previously published estimates of the global burden of disease for oral conditions and the global economic impact of dental diseases. They separated out the specific contribution of caries to work out the economic cost of caries worldwide. According to the most recent analysis available, and under the aforementioned assumption that 45% of the economic burden of dental disease can be attributed to caries, the global economic burden of caries is estimated to be 245 billion USD. This includes an estimated 161 billion USD in direct caries treatment costs and an estimated 84 billion USD in indirect productivity losses. Applying these calculations to Europe, we can expect a similar pattern, and therefore significantly higher costs than reported earlier.

An increase of caries following a ban of SAS, whether due to reduced effectiveness of non-SAS-based toothpastes or due to increased toothpaste costs or supply issues, would have a serious economic impact.

c) Lower accessibility and affordability of effective toothpastes

If SAS can no longer be used in toothpaste formulation, toothpaste manufacturers will be required to develop, clinically test, and manufacture reformulated toothpastes. This will require expertise, time, and resources to produce new clinically effective formulations that are equal or superior to the current ones.

Inevitably the extra R&D costs of reformulation will be passed onto the consumer and impact accessibility and affordability of the toothpaste. People experiencing social deprivation (who also experience the highest caries prevalence) will be disproportionately affected.

Such an outcome is totally unacceptable from a public health perspective, as the focus on health inequalities is a key target of health policy (both in Europe but also globally) as evidenced by the recent World Health Assembly resolution on health inequalities⁴⁰.

IV. Conclusions

A ban on SAS in toothpastes would seriously impact public health in Europe and have economic implications beyond direct health care costs.

- 1) Although preventable, caries is responsible for the largest burden of all non-communicable diseases. Oral diseases are the third most expensive conditions in the European Union, following diabetes and cardiovascular diseases.
- 2) Toothbrushing with an effective and affordable fluoride toothpaste is responsible for the global decline in caries incidence over the last few decades, and a key public health strategy for achieving future reductions in caries.
- 3) Toothpaste formulations seek to find the right balance between abrasiveness and cleaning whilst also ensuring that fluoride and other active ingredients are sufficiently bioavailable to deliver their respective benefits.
- 4) Approximately 80% of effective fluoride toothpastes in the EU are currently formulated with SAS and there are no readily available alternatives.
- 5) Replacement of all SAS-based toothpastes by other formulations would create an unprecedented increase in tooth decay prevalence in the EU. This is not only detrimental to the oral health of the European population but would be accompanied by an increase in the direct and indirect costs of caries.

A ban on SAS in toothpastes would have serious negative health impact and considerable cost implications for the community affecting the wider European economy. This is totally unacceptable from both public health and economic perspectives. Therefore, we would like the Commission to reconsider its approach to SAS in toothpastes.

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Appendix

Appendix 1

Estimated productivity losses due to dental diseases in EU-28 countries (2015)¹⁸

Country	Productivity losses (absolute total) US\$	Productivity losses (per capita) US\$
Austria	1.654.770.610	193,4
Belgium	1.860.990.582	164,15
Bulgaria	184.293.536	25,72
Croatia	184.821.920	43,63
Cyprus	64.593.054	71,77
Czech Republic	675.873.042	64,19
Denmark	1.028.472.160	181,71
Estonia	69.701.192	52,96
Finland	927.504.754	169,5
France	8.300.250.640	129,26
Germany	14.072.152.710	172,27
Greece	794.561.445	72,7
Hungary	384.660.000	39,02
Ireland	783.034.912	168,43
Italy	4.865.123.266	79,83
Latvia	96.103.637	47,44
Lithuania	128.862.738	44,16
Luxembourg	103.186.993	183,93
Malta	21.539.914	50,44
Netherlands	3.546.651.840	209,43
Poland	1.646.086.910	43,31
Portugal	816.302.411	78,46
Romania	616.513.310	31,04
Slovakia	206.603.111	38,09

Slovenia	186.408.126	90,36
Spain	3.817.396.150	82,28
Sweden	1.420.012.521	143,74
United Kingdom	8.382.382.380	129,08
Total	56.838.853.864	112,04