



Title	Triclosan In Toothpaste
Requestor	Principal Director of Oral Health, Ministry of Health Malaysia
Reason For Request	To ascertain the safety and effectiveness of triclosan in toothpaste as an active ingredient added in oral hygiene product

1. INTRODUCTION

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether) is a non-ionic, broad spectrum, antimicrobial agent that is used as an ingredient added to many consumer products intended to reduce or prevent bacterial contamination. It is added to some toothpaste, antibacterial soaps, body washes and some cosmetics [1]. Due to its low toxicity, potency, absence of demonstrable side effects and compatibility with toothpaste and mouth rinse, triclosan is suitable to be incorporated into many over-the-counter (OTC) oral hygiene products. However, recently, there have been issues raised by the public regarding the safety and side effects of triclosan in cosmetic products, particularly the carcinogenic effect. A video about Colgate Total said to have caused cancer was widely shared among netizen, creating doubt and controversial among the public.

2. METHODS

Literature was searched through electronic databases which included Ovid interface: Ovid MEDLINE in process and other non-indexes citations 1946 to present, EBM reviews - Cochrane Central Register of Controlled Trails Jun 2016, EBM Reviews – Cochrane database of Systematic Review 2005 to June 2016, Embase 1998 to 2016. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the reference of retrieved articles. The search strategy used these terms either singly or in various combinations: safety, effectiveness, cost, triclosan, toothpaste, oral hygiene, oral health, cancer and consumer product. The search was limited to human, animal health in-vivo and in-vitro and the last search was conducted on 8 August 2019.

3. RESULTS

a. Safety

Food & Drug Administration (FDA) of the United State of America had raised this issue and conducted researches to investigate this matter. In 1997, FDA reviewed extensive data about triclosan in Colgate Total toothpaste. The evidence showed that triclosan in the product was effective in preventing gingivitis [2,3]. However, Colgate-Palmolive need to submit laboratory reports annually to FDA for continuous monitoring [3]. At present, the usage of triclosan-incorporated Colgate Total toothpaste is permitted in the USA.

For other products, such as over-the-counter (OTC) consumer antiseptic products, FDA has not received evidence that triclosan provides a benefit to human health. At this time, FDA doesn't have evidence that triclosan in OTC consumer antibacterial soaps and body washes provides any benefit over washing with regular soap and water. A final rule was issued for further details information in 2017 [4].

The long term effects of usage of triclosan-containing toothpaste on thyroid function are currently unknown. Triclosan is structurally similar to thyroid hormones and reductions in serum thyroid hormone levels have been observed in animal studies following oral administration of triclosan. A study conducted by Cullinan *et al.* concluded that triclosan incorporated toothpaste had no detectable effect on thyroid function and is safe for usage [5]. A systematic review conducted in 2013 had concluded that there was also no evidence of any harmful effects associated with the use of triclosan/copolymer toothpastes in studies up to three years in length [3].

To date, there are no conclusive evidence of the relationship between triclosan and cancer. Mohammad A. Alfihli & Myon-Hee Lee (2019) in their study concluded that dose and time dependence is an important factor in determining the eventual denouement of triclosan [6]. More human based *in-vivo* and *in-vitro* epidemiological studies need to be conducted to determine the relationship [7].

b. Effectiveness

A systematic review has been conducted to assess the effects of using toothpaste containing triclosan plus copolymer, in comparison to those without triclosan. It was concluded that there was a 22% reduction in plaque, 22% reduction in gingivitis, 48% reduction in bleeding gums and a 5% reduction in tooth decay pertaining to the usage of triclosan incorporated toothpaste [3]. The review concluded that toothpastes containing triclosan/copolymer, in addition to fluoride, reduced plaque, gingival inflammation, gingival bleeding and coronal caries when compared with fluoride toothpastes without

triclosan/copolymer. A recent study by Al Habashneh et al in 2017 found that twice daily brushing with toothpaste containing 0.3% triclosan and polyvinyl methyl ether and maleic acid copolymer provides a more effective level of plaque control and gingival health with no effect on decreasing dentin hypersensitivity [8].

d. Regulations in Malaysia

In Malaysia, toothpastes and mouth rinses are categorised under cosmetic products. All cosmetic products need to be notified according to the Guidelines for Control of Cosmetics Products in Malaysia issued by National Pharmaceutical Regulatory Agency (NPRA) in 2015. According to these guidelines (as stated in 'Annex VI' no.25), the maximum authorized concentration of triclosan in any toothpastes, hand soaps, body soaps, shower gels, deodorants, face powders, blemish concealers, nail-cleaning products, shampoo, hair conditioner and facial cleanser is 0.3%, whereas in mouth rinses, is 0.2%. The ingredients and its concentration must also be labelled on the packaging [9]. Thus, any oral hygiene products that adhere to this regulation are legal to be used in Malaysia.

c. Cost

The data on cost benefit of triclosan incorporated in oral hygiene products is not included in this paper.

4. CONCLUSION & RECOMMENDATIONS

In conclusion, oral hygiene products, especially toothpaste and mouth rinse that contain triclosan are safe to use. Evidences also showed that toothpastes containing triclosan/copolymer, in addition to fluoride, is effective in reducing plaque, gingival inflammation, gingival bleeding, and coronal caries. The concentration of triclosan permitted by NPRA for toothpaste and mouth rinse is 0.3%, and 0.2% respectively. There was no evidence relating triclosan to the carcinogenic effect, particularly in *in-vivo* studies. This review shows that current levels of triclosan in oral hygiene products such as toothpaste and mouth rinse can be safely use by the public. However, Oral Health Programme, Ministry of Health will monitor closely the current studies and evidence related to triclosan from time to time.

Reference:

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Date: 08.08.2019