Toxics Link
for a toxics-free world

"Disrupting Triclosan"

A potential Endocrine Disrupting Chemical found in toiletries

About Toxics Link

Toxics Link is an Indian environmental research and advocacy organization set up in 1996, engaged in disseminating information to help strengthen the campaign against toxics pollution, provide cleaner alternatives and bring together groups and people affected by this problem.

Toxics Link's Mission Statement - "Working together for environmental justice and freedom from toxics. We have taken upon ourselves to collect and share both information about the sources and the dangers of poisons in our environment and bodies, and information about clean and sustainable alternatives for India and the rest of the world"

Toxics Link has a unique expertise in areas of hazardous, medical and municipal wastes, international waste trade, and the emerging issues of pesticides, Persistent Organic Pollutants (POPs), hazardous heavy metal contamination etc. from the environment and public health point of view. We have successfully implemented various best practices and have brought in policy changes in the afore mentioned areas apart from creating awareness among several stakeholder groups.

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Abbreviations

BIS	Bureau of Indian Standard
BPA	Bisphenol-A
ENR	Enoyl-acyl carrier protein reductase enzyme
EPA	European Protection agency
ECHA	European Chemicals Agency
HPLC	High-performance Liquid Chromatographic
MAC	Maximum Authorized Concentration
PCBs	Poly Chlorinated Biphenyls
ppm	Parts per million
SIIR	Shriram Institute for Industrial Research
SAICM	Strategic Approach to International Chemical Management
SSNC	Swedish Society for Nature Conservation
WWTPs	Waste Water Treatment Plants

Foreword

In our daily life we use products like soaps, shampoo, gels, detergents, toothpaste, hand wash, packaged and processed food, all of which contain a range of chemicals some of which are beneficial while others are extremely harmful both to humans and other life forms. There are conclusive scientific evidences to suggest that many of these chemicals are highly toxic with known human health impacts. While some of these impacts are well understood and documented still there is ongoing research to bring in more conclusive evidence and establish linkage between chemicals and its impacts on human health and ecology. Triclosan, an EDC is extensively used in various personal care products like soaps, shampoo, hand wash, toothpaste, cosmetics, toys etc due to its anti bacterial properties and there is growing evidence to suggest that Triclosan can impact human health adversely. The industry is slowly recognizing and acknowledging harmful effects and working towards reducing its usage in products.

In India there is very little information about the use of Triclosan in products hence it is an important step in creating new data and information on its use in products. It is an important study that provides information to industry, consumers, academia, government and civil society to understand the extent of the problem and possibilities of reducing and regulating the use of this chemical.

The test results should open up a meaningful conversation among important stakeholders to engage in substantive discussion on the future use of this chemical in these products. The dissemination of the study findings would also set in process consumer information about endocrine disrupting chemicals and create interest in scientific institution to take up more research and generation of new data that feeds into better chemicals management and protection of human health.

SATISH SINHA
Associate Director

Introduction

1.1 About Triclosan

Triclosan [5-chloro-2-(2,4-dichlorophenoxy) phenol] is a chlorinated aromatic chemical compound (phenylether, or chlorinated bisphenol[1]) having antimicrobial and antifungal properties. Its chemical structure is a halogenated biphenyl ether which confers its chemical properties related to many toxic compounds such as Polychlorinated Biphenyls (PCBs), Polybrominated diphenyl ethers, Bispenol A and Dioxins.[2]

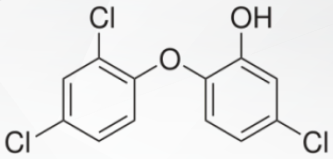


Figure 1 Chemical Structure of Triclosan

Triclosan chemical was first registered as a pesticide with EPA in 1969, but since 1990's it is being widely used in household products.[3] Triclosan is a synthetic broad spectrum antimicrobial agent which inhibits the activity of bacteria, viruses, and fungi.[4] At low doses Triclosan is bacteriostatic and at higher doses it acts as a bactericidal agent.[5] Due to its anti-biocide and anti-bacterial properties, Triclosan has been used as an important ingredient in personal care, veterinary, industrial and household products.

The expanded use of Triclosan provides a number of pathways for the compound to enter the environment and it has been detected in sewage treatment plant effluents, surface and ground water. The physio-chemical properties indicate that there is bioaccumulation and persistence potential of Triclosan in the environment. Hence, there is an increasing concern about the presence of Triclosan in the environment and its potential negative effects on human and animal health.

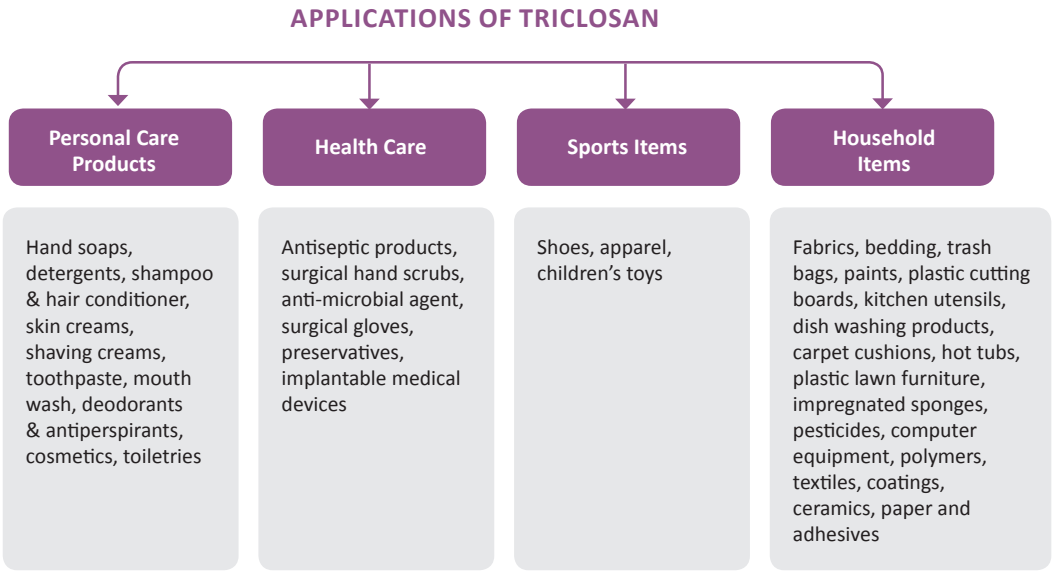
1 Ahn, K.C.; Zhao, B.; Chen, J.; Cherednichenko, G.; Sanmarti, E.; Denison, M.S.; Lasley, B.;Pessah, I.N.; Kültz, D.; Chang, D.P.Y.; et al. In vitro biologic activities of the antimicrobialstriclocarban, its analogs, and Triclosan in bioassay screens: Receptor-based bioassay screens.Environ. Health Persp. 2008, 116, 1203–1210, doi:10.1289/ehp.11200.

2 Allmyr, M.; Harden, F.; Toms, L.M.L.; Mueller, J.F.; McLachlan, M.S.; Adolfsson-Erici, M.;Sandborgh-Englund, G. The influence of age and gender on Triclosan concentrations in Australianhuman blood serum. Sci. Total Environ. 2008, 393, 162–167,doi:10.1016/j.scitotenv.2007.12.006.

3 U.S. Enivronmental Protection Agency (EPA). (Triclosan Facts). Accessed 1.28.2011. Washington Toxic Coalition. Antimicrobial Products: Who Needs Them? Accessed 2.1.2011.

4 APUA, 2011. Triclosan – White paper prepared by The Alliance for the Prudent Use of Antibiotics(APUA) January 2011.

5 Yazdankhah, S. P., A. A. Scheie, E. A. HØiby, B.-T. Lunestad, E. Heir, T. Ø. Fotland, K. Naterstad & H. Kruse: Triclosan and antimicrobial resistance in bacteria: an overview. Microbial Drug Resistance 2006, 12, 83-90.



1.2 Applications of Triclosan

There are varied usages of Triclosan due to its anti-bacterial properties and it is being used as a preservative. Triclosan is a common ingredient in various anti-bacterial personal care products such as hand soaps, hand washes, dish washing soaps, liquid soaps, cosmetics, shampoos, deodorants, mouthwashes and toothpastes.[6] Further in personal care products, Triclosan also helps to preserve the products for a longer duration. Triclosan is also used to protect from bacteria, fungus, mildew, and odors in household items like toys, mattresses, toilet fixtures, fabric, paint, furniture, bedding, textiles,[7] carpets, trash bags,[8] surgical scrubs, pesticides, implantable medical devices[9] and sutures.[10] Additionally, Triclosan is also added to the surface of cutting boards, kitchen ware, and food storage containers to prevent bacterial growth[7]. It has also been used as a selective agent in molecular cloning.[11]

The figure above clearly indicates the multifarious uses of Triclosan in day to day life starting from personal care products to health care, sports related and everyday household items and equipment.

6 Kola R k, Padma R, Adul R Md, Yalavarthy P D, 2015. A review on occurrence, fate and toxicity of Triclosan. World Journal of Pharmacy & Pharmaceutical Sciences. 4 (7): 336-369.

7 Orhan M, Kut D, Gunesoglu C (2009) Improving the antibacterial activity of cotton fabrics finished with Triclosan by the use of 1,2,3,4-butanetetracarboxylic acid and citric acid. J App Poly Sci 111: 1344–1352.

8 Glaser, Aviva,2004. The Ubiquitous Triclosana common antibacterial agent exposed. Pesticides and You Vol 24 No 3 2004.

9 Bhargava, H. N., and P. A. Leonard. 1996. Triclosan: Applications and Safety. Am. J. Infect. Control. 24: 209-218.

10 Ming, X., M. Nichols & S. Rothenburger, 2007aIn vivo antibacterial efficacy of MONOCRYL plus antibacterial suture (Poliglecaprone 25 with Triclosan). Surgery Infections (Larchmt) 2007a, 8, 209-14.

11 Chuan-Wei Jang and Terry MagnusonA Novel Selection Marker for Efficient DNA Cloning and Recombineering in E. coli. PLoS One., 2013; 8(2): e57075.

The following section throws light on each of these categories where Triclosan is being used and the likely harm to environment and health because of its continuous use and constant exposure.

1.3 Triclosan in Personal Care Products

Triclosan is an anti-microbial agent marketed for its germ-fighting capability in personal care products. There has been an increased focus on the study of Triclosan because of their high production volumes and wide-spread use in personal care products. Exposure to Triclosan occurs through direct application to skin. Studies have found that the continuous exposure causes deposition of harmful chemicals in the body over time & are known to cause varied health problems that interfere with muscle functions and also alter hormone regulation.[12] Oral exposure can occur from products used in and around the mouth, as well as from hand-to-mouth contact such as toothpastes, soap, moisturizer etc. Children can have higher exposures to Triclosan because of their hand-to-mouth activities. As Triclosan is fat-soluble it does not get rapidly flushed out of the body, but rather is stored in fat and bioaccumulation in the food chain occurs thereof.[13]

12 http://articles.mercola.com/sites/articles/archive/2012/08/29/triclosan-in-personal-care-products.aspx
13 http://www.nrdc.org/health/effects/bendrep.asp

Study Rationale

Triclosan was considered a wonder chemical earlier. However, with more studies there is revelation on the extent of the ill effects of Triclosan. Therefore more countries across the globe are now looking towards ways and means of restricting the use of this chemical as far as possible. Even industries are now aware about the possible implications of Triclosan on the environment and human health and some of the major consumer products manufacturers have initiated the phasing out of Triclosan from their products.

It may be noted that the popularity of anti-bacterial consumer products has led to increased consumer use of Triclosan[14] while the continuous detection of Triclosan and its degradation in the environment and the possible impacts on human health has led to a debate on its safety, effectiveness and regulation on the application of this chemical.

2.1 Triclosan and Human Health

Scientific research has increasingly established Triclosan to have numerous adverse health effects on human health and animals. The most likely routes of exposure to Triclosan are ingestion, inhalation and absorption through the skin.[15] Further as Triclosan has the tendency of bioaccumulation in nature, it easily enters the food chain through fish or other aquatic organisms.

Additionally, Triclosan has been shown to bind to both human estrogen and androgen receptors in vitro, raising concerns about its impact on the

Health Impacts of Triclosan

- Skin irritation
- Hormone disruption
- Interference with muscle function
- Contribution to antibacterial resistance
- Detrimental effects on the central nervous system
- Allergies and asthma
- Altered thyroid hormone metabolism
- Tumor development

14 http://www.ewg.org/sites/humantoxome/chemicals/chemical.php?chemid=100376

15 Calafat AM, Ye X, Wong LY, Reidy JA, Needham LL. Urinary concentrations of Triclosan in the U.S. population: 2003–2004. Environ Health Perspect. 2008; 116:303–307.

developmental and reproductive effects and also the potential cancer risks. Studies on animals also indicate that Triclosan can decrease circulating concentrations of the thyroid hormone Thyroxine (T4) in rats. Human autopsy analysis has revealed bioaccumulation of Triclosan in liver and adipose (fat) tissue. Children are most susceptible to the impact of Triclosan.[16]

Alarmingly, Triclosan has been detected in human blood, plasma and milk[17,18] in Sweden and Australia[19] and also in human urine in USA.[20] A report on exposure of Triclosan during pregnancy has revealed that it affects the fetus and was detected in 100% of maternal urine and 51% of cord blood samples after conjugate hydrolysis.[21] In a study carried out by Center for Disease Control and Prevention (NHANES study), measurable levels of Triclosan was found in 87 percent of urine samples examined in pregnant women.[22, 23]

Triclosan also belongs to the group of drugs, such as isoniazid (for curing tuberculosis) and diazoborine (experimental antibiotic) which target the enzyme enoyl reductase. Thus overuse of Triclosan may result in the development of cross-resistance to antibiotics, and thereby the emergence of bacterial strains resistant to both Triclosan and antibiotics is highly possible.[24]

2.2 Triclosan as Endocrine Disruptor

Hormones are responsible for normal growth and development of body systems such as the brain, the immune system, and the reproductive organs. Interference with these hormones during critical periods of fetal development, infancy, or childhood can result in long-lasting impacts or even permanent changes in the structure and function of these systems. ***Chemicals interfering with hormonal functions are considered as Endocrine Disruptors.***

The endocrine disruptor has been defined as an ***"exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in intact organisms or its progeny or populations"***.[25] There are some chemicals which are being identified

16 Geens, T., Neels, H., & Covaci, A. (2012). Distribution of bisphenol-A, Triclosan and n-nonylphenol in human adipose tissue, liver and brain. Chemosphere, 87(7), 796–802.

17 Allmyr M, Adolfsson-Erici M, McLachlan MS, Sandborgh-Englund G.Triclosan in plasma and milk from Swedish nursing mothers and their exposure via personal care products. Sci Total Environ. 2006 Dec 15; 372(1): 87-93.

18 Allmyr M, Harden F, Toms LM, Mueller JF, McLachlan MS, Adolfsson-Erici M, Sandborgh-Englund G. The influence of age and gender on Triclosan concentrations in Australian human blood serum.Sci Total Environ., 2008 Apr 1; 393(1): 162-7.

19 Toms LM, Allmyr M, Mueller JF, Adolfsson-Erici M, McLachlan M, Murby J, Harden FA.Triclosan in individual human milk samples from Australia.Chemosphere. 2011 Dec; 85(11):1682-6. doi: 10.1016/j.chemosphere.2011.08.009. Epub 2011 Oct 13.

20 Calafat AM, Xiaoyun Ye, Lee-Yang Wong, John A. Reidy, and Larry L. Needham, Urinary Concentrations of Triclosan in the U.S. Population: 2003–2004 Environ Health Perspect., 2008; 116(3): 303–307.

21 Benny F. G. Pycke, Laura A Geer, Mudar Dalloul, Ovadia Abulafia, Alizee M. Jenck, Rolf U HaldenHuman Fetal Exposure to Triclosan and Triclocarban in an Urban Population from Brooklyn, New York.Environmental Science and Technology (Impact Factor: 5.48). 06/2014.

22 Woodruff, T. J., Zota, A. R., & Schwartz, J. M. (2011). Environmental chemicals in pregnant women in the United States: NHANES 2003-2004. Environ Health Persp, 119(6), 878–885.

23 Latch, D.E.; Packer, J.L.; Arnold, W.A.; McNeill, K. Photochemical conversion of Triclosan to 2, 8-dichlorodibenzo-p-dioxin in aqueous solution. J. Photochem. Photobiol. A Chem. 2003, 158, 63–66, doi: 10.1016/S1010-6030(03)00103-5.

24 McMurry, L.M.; Oethinger, M.; Levy, S.B. Triclosan targets lipid synthesis. Nature 1998, 394,531–532.

25 IPCS, 2002 (WHO)

as potential endocrine disruptors and have been kept in a group known as EDCs. The issues of EDCs under consideration as a serious health issue globally and been accepted as an emerging in the Strategic Approach to International Chemical Management (SAICM).Triclosan has the tendency to interfere with hormone function, so has been categorized as an endocrine disrupting chemical or endocrine disruptor. It is lipophilic in nature, i.e., chemical generally binds to the hormone receptors and bio accumulates in the fatty tissues. Further the pharmacokinetic features of Triclosan are very similar to BPA in both humans and mice. And similar to BPA, Triclosan do alter hormonal functions in body.

The chemical structure of Triclosan is similar to 17β-estradiol[26]. Triclosan has many biological effects mediated via estrogen receptors[27]. It may cause implantation failure due to their ability to mimic estrogen in humans[28]. Triclosan was found to have estrogenic and androgenic activities in human breast cancer cells, which could potentially stimulate the growth development of cancer cells[29].

About Androgen and Estrogen

- **Androgen** - Any group of hormones that primarily influences the growth and development of the male reproductive system
- **Estrogen or Oestrogen** - Primary female sex hormone and is responsible for development and regulation of the female reproductive system and secondary sex characteristics.

A study of male rats found that Triclosan reduced sperm count and produced degenerative damage to male reproductive tissues such as the testes, vas deferens and prostate. In the same study, Triclosan was found to disrupt androgen (male hormone) production in rats[30]. Research on rats shows that Triclosan may disrupt normal function of androgens in males and estrogen binding in females.

Metabolites (or breakdown products) of Triclosan such as chlorinated derivatives, chlorophenols and chloroform and trihalomethanes may be estrogenic, and they have the most potent endocrine-disrupting effect on thyroid hormones[31]. Triclosan has been found to disrupt sulfonation of estrogen in the placenta in sheep, which is likely to cause problems in the transport of estrogen from the placenta to the fetus. Disruption of estrogen transport to the fetus may result in abnormal

26 J. T. Wolstenholme, E. F. Rissman, and J. J. Connelly, "The role of Bisphenol A in shaping the brain, epigenome and behavior," Hormones and Behavior, vol. 59, no. 3, pp. 296–305, 2011.

27 H.-R. Lee, K.-A. Hwang, K.-H. Nam, H.-C. Kim, and K.-C. Choi, "Progression of breast cancer cells was enhanced by endocrine-disrupting chemicals, Triclosan and octylphenol, via an estrogen receptor-dependent signaling pathway in cellular and mouse xenograft models," Chemical Research in Toxicology, vol. 27, no. 5, pp. 834–842, 2014.

28 T. E. Stoker, E. K. Gibson, and L. M. Zorrilla, "Triclosan exposure modulates estrogen-dependent responsesin the female wistar rat," Toxicological Sciences, vol. 117, no. 1, pp. 45–53, 2010.

29 Gee RH, Charles A, Taylor N, Darbre PD. 2008. Oestrogenic and androgenic activity of Triclosan in breast cancer cells. J Appl Toxicol 28:78–91.

30 Kumar V, Chakraborty A, Kural MJ, Roya P. 2009. Alteration of testicular steroidogenesis and histopathology of reproductive system in male rats treated with Triclosan. Reproductive Toxicology 27:177–185.

31 Crofton KM, Paul KB, DeVito MJ, Hedge JM. 2007. Short-term in vivo exposure to the water contaminant Triclosan: Evidence for disruption of thyroxine. Environmental Toxicology and Pharmacology 24:194-197.

development[32]. There is clear evidence that disruption of normal steroidal hormone levels, such as estrogen or testosterone, during pregnancy can lead to altered brain development[33].

2.3 Triclosan and Environment

The personal care products are the major contributor to the release of Triclosan into the environment. This is because personal care products contain around 0.1% to 0.3% (w/w) Triclosan.[34]Most of these products get washed down the drain and then transported widely throughout the environment. Triclosan is one of the chemical which is frequently being detected in the stream, effluents and bio-solids of wastewater treatment plants (WWTPs) in lakes, rivers and sea water in various countries[35,36,37,38]. It is found to be degradable under aerobic conditions in WWTPs whereas only little or no removal of Triclosan occurs during anaerobic sludge digestion.

Triclosan is found at high concentrations in treated sewage sludge (also known as bio solids) that is often applied to agricultural fields as fertilizer. Because Triclosan has been shown to accumulate in earthworms living in these bio-solid-treated fields, there are concerns about these chemicals also moving into plants and wildlife.

Triclosan bio-accumulates in aquatic plants and animals and poses multiple eco-toxicity risk. The chemical also enters into the food chain from contaminated water and agricultural runoff. Triclosan is found in freshwater samples, especially in lakes and downstream from wastewater treatment plants, in concentrations known to be harmful to wildlife[39,40].

Triclosan has also been shown to interfere with the cycling of nitrogen in natural systems.[41,42] It is readily degraded in the environment via photo degradation or reaction with sunlight, with a

32 James MO, Wenjun Li W, Summerlot DP, Rowland-Faux L, Wood CE. 2009. Triclosan is a potent inhibitor of estradiol and estrone sulfonation in sheep placenta, Environ Int doi:10.1016/j.envint.2009.02.004.

33 McEwen BS. 1987. Steroid hormones and brain development: Some guidelines for understanding actions of pseudo hormones and other toxic agents. Environmental Health Perspectives 74:177-184.

34 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4454990/

35 Kumar KS, S. Priya M, Peck AM, Sajwan KS. (2010) Mass Loadings of Triclosan and Triclocarban from Four Wastewater Treatment Plants to Three Rivers and Landfill in Savannah, Georgia, USA. Arch Environ Contam Toxicol 58:275-285

36 Fair PA, Lee HB, Adams J, Darling C, Pacepavicius G, Alaee M, Bossart GD, Henry N. Muir D (2009) Occurrence of Triclosan in plasma of wild Atlantic bottlenose dolphins (Tursiopstruncates) and in their environment. Environ Pollut 157:2248-2254.

37 Chalew TEA, Halden R (2009) Environmental exposure of aquatic and terrestrial biota to Triclosan and triclocarban. J Am Water Resources Assoc 45:4-13.

38 Xie Z, Ebinghaus R, Flöser G, Caba A and Ruck W. (2008) Occurrence and distribution of Triclosan in the German Bight (North Sea). Environ Poll 156:1190-1195.

39 Brausch, J. M., & Rand, G. M. (2011). A review of personal care products in the aquatic environment: Environmentalconcentrations and toxicity. Chemosphere, 82(11), 1518–1532.

40 Venkatesan, A. K., Pycke, B. F. G., Barber, L. B., Lee, K. E., & Halden, R. U. (2012). Occurrence of Triclosan, triclocarban, and its lesser chlorinated congeners in Minnesota freshwater sediments collected near wastewater treatment plants. J Hazard Mater, 229-230, 29–35.

41 Waller NJ, Kookana RS. (2009) Effect of Triclosan on microbiological activity in Australian soils. Environ Toxicol Chem 28:65-70

42 Fernandes M, Shareef A, Karkkainen M and Kookana R. (2008) The occurrence of endocrine disrupting chemicals and Triclosan in sediments of Barker Inlet, South Australia. A Report prepared for the Adelaide and Mount Lofty Ranges Natural Resources Management Board. SARDI Publication Number F2008/001026-1. South Australian Research &Development Institute (Aquatic Sciences), Adelaide. http://www.sardi.sa.gov.au

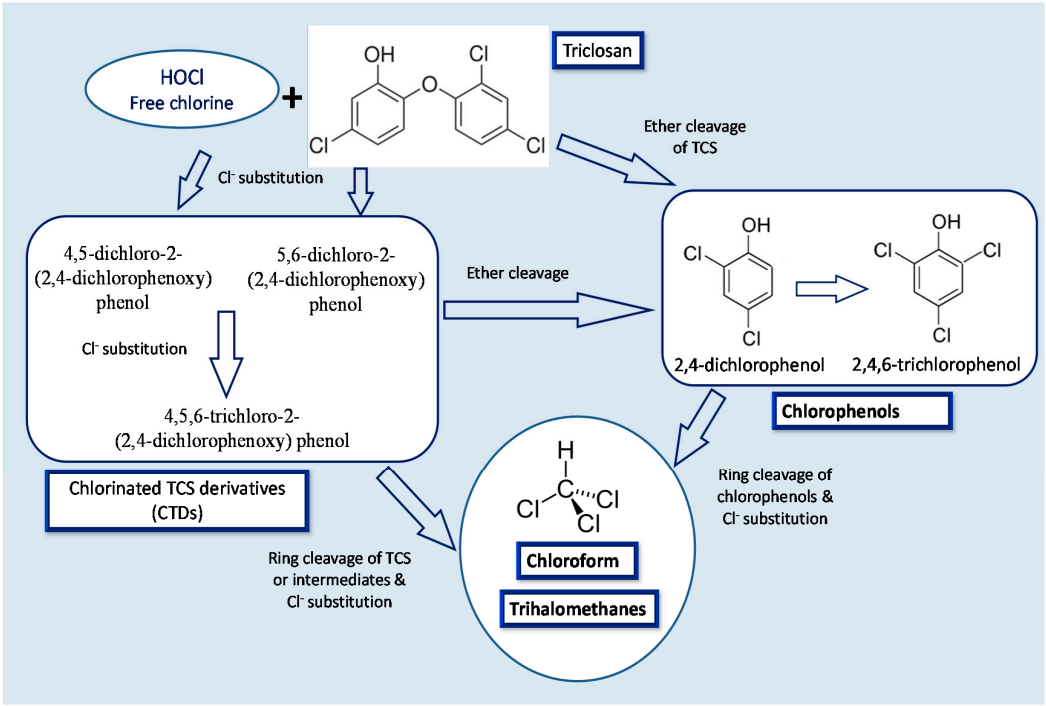


Figure 2 **Mechanisms of Triclosan conversion to its intermediate products: chlorinated Triclosan derivatives, Chlorophenols and chloroform and Trihalomethanes**

half-life of a week in aerobic and up to a month in anaerobic conditions in soil[43], forming other compounds which include chlorophenols and dioxins[44]. An atmospheric half-life of 8 hours has also been estimated based on the reaction of Triclosan with photochemical production of hydroxyl radicals. Triclosan is readily susceptible to degradation through photolysis in aqueous media with half-life that ranges from <1 h in abiotic conditions, to around 10 days in fresh water bodies.[45]

2.4 Objectives

With the above background and rationale discussed it is evident that Triclosan containing anti-bacterial consumer products like hand wash and toothpaste are the best-selling products these days, however at the same time concerns have been raised on the health and environmental impact of Triclosan. Its use makes human especially children vulnerable. Anti-bacterial liquid soaps

43 Caren C. Helbing, Catherine R. Propper, and Nik Veldhoen, 2011. Triclosan Affects the Thyroid Axis of Amphibians Toxicological Sciences 123(2): 601-602.

44 D.E. Latch, J.L. Packer, B.L. Stender, J.VanOverbeke, W.A. Arnold, K.McNeill. Aqueous Photochemistry of Triclosan: Formation of 2, 4-Dichlorophenol, 2, 8-Dichlorodibenzo-p-Dioxin, and Oligomerization Products.Environ. Sci. Technol. 2005. 24, 517-525.

45 US EPA Reregistration Eligibility Decision for Triclosan, 2008.

and toothpastes are widely used product those can cause direct oral exposure to Triclosan.[46,47]. Furthermore, research and studies have proved that Triclosan is an endocrine disrupting chemical.

India is one of the biggest and fastest growing markets of hand washes and toothpastes. At present the hand wash market stands Rs. 300 crore which has shown multiple growths since last three years. Similarly the oral care market in India is around Rs. 7000 crore. The Bureau of Indian Standards (BIS) is the standard setting body in India that sets standards to regulate the quality of these products. As per the Bureau of Indian Standards on classification of cosmetics raw materials and adjuncts Maximum Authorized Concentration (MAC) of Triclosan as preservatives in cosmetics is 0.3%. Though Triclosan has not been forbidden for the use in these products, but there are products available in the markets that have clearly labeled **"No Triclosan"**. As such studies also claim that Triclosan has no added advantages in the products hence question arises about the need to use chemicals like Triclosan in these products.

Moreover though Triclosan is being used in many of these products, there is no public information available on the possible impacts of Triclosan on human health and environment in India. Further there are no research studies available in Indian context on the Triclosan presence in the environment.

Therefore, the present study aims to create information on the use of Triclosan in few personal care products that are available in the market and are mass consumed. The study also attempts to understand the presence of Triclosan in products catering to different consumer segments and groups and also the existing regulatory frameworks and its efficacy.

Objectives of the Study

With the above research information, it is evident that the presence of Triclosan in the products for day to day use is a big concern. Accordingly, the objectives of the current study are as follows:

- To detect the presence of Triclosan in liquid soaps and toothpastes sold in Indian market
- To catalyze more studies on Triclosan in the Indian environment
- To create a niche for the policy dialogue on regulations of Triclosan

46 http://www.ama-assn.org/ama/pub/article/2036-2913.html

47 Kola R k, Padma R, Adul R Md, Yalavarthy P D, 2015. A review on occurrence, fate and toxicity of Triclosan. World Journal of Pharmacy & Pharmaceutical Sciences. 4 (7): 336-369.

Sampling & Methodology

3.1 Sampling

Eleven samples of liquid soap and eleven samples of toothpastes were randomly collected from Delhi-NCR region. Some of these products were solely meant for use by kids as being claimed by manufacturers. The sample included observed known brands. Most of the samples collected have been labeled Triclosan. The samples were sent to **Shriram Institute for Industrial Research (SIIR)**[48], New Delhi for quantitative analysis of Triclosan.

3.2 Methodology

A High-Performance Liquid Chromatographic (HPLC) based customized method was used by the SIIR Lab (SOP-SRI/FF/52 (HPLC)) for the determination of Triclosan in personal care products. As indicated below the methodology includes sample preparation, processes such as preparation of mobile phase, UV detection and sample analysis.

Sample Preparation

It was accomplished by a simple liquid extraction with the same solvent system as used in mobile phase to perform required HPLC technique.

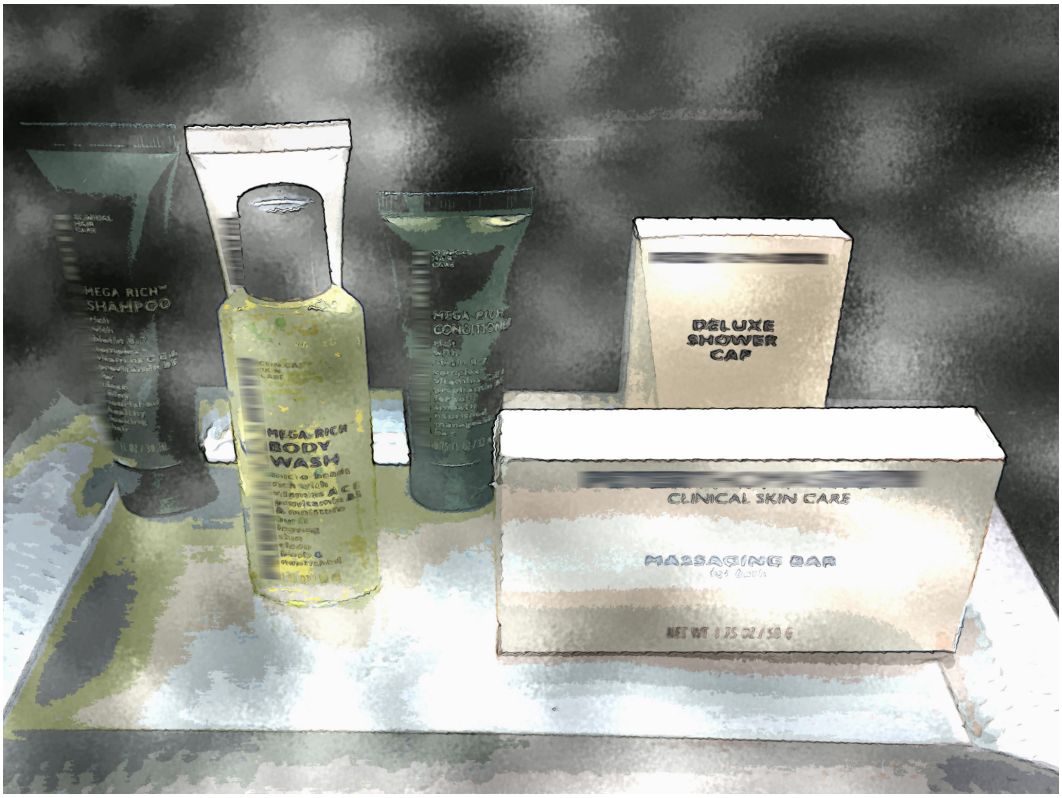
48 Shriram Institute for Industrial Research (SIIR), 19, University Road, Delhi-110007

Process of samples

- Mobile phase: Acetonitrile – TEA phosphate
- UV Detection: 230, 254 and 280 nm
- When HPLC/MS analysis was carried out, TEA phosphate was replaced by TEA acetate in the mobile phase under same conditions

Sample analysis:

Accurately weighed quantity of the cosmetic sample was treated with 9.0 ml of the mobile phase under ultrasonication at 60^{0}C for 15 min. After cooling, the solution/suspension was filtered through a 0.2 µm RC15 filter using a syringe; then 1 ml of the internal standard stock solution was added to the filtrate and the solution diluted to 10 ml with the mobile phase. The resulting sample solution was subjected to HPLC analysis.



Results

This test results indicate that most of the liquid soaps and toothpastes available in Indian market contain Triclosan irrespective of the manufacturers. Out of the twenty two samples analyzed sixteen samples (72.8%) samples contained Triclosan.

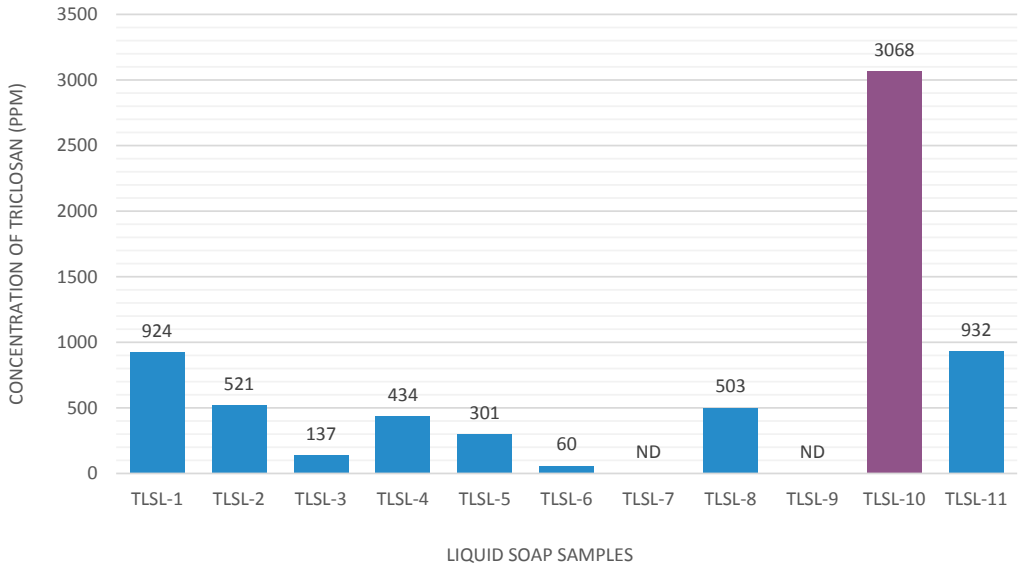
4.1 Results in Liquid Soap

- The maximum concentration of Triclosan was found to be 3068 ppm. (0.3068%)
- In all samples except one, Triclosan concentration was found to be below 0.3% as given in BIS standards for cosmetics raw materials & adjuncts IS 4707(part2): 2009

Table 1 - **Concentration of Triclosan (ppm) in Liquid Soaps**

Liquid Soap	Concentration of Triclosan (ppm)
TLSL-1	924
TLSL-2	521
TLSL-3	137
TLSL-4	434
TLSL-5	301
TLSL-6	60
TLSL-7	ND
TLSL-8	503
TLSL-9	ND
TLSL-10	3068
TLSL-11	932

Graph 1 - Graphical representation of Triclosan concentration in Liquid Soaps



The figure above indicates that in TLSL-7 & TLSL-9 concentration is below detection limit i.e.25 ppm and alarmingly high in TLSL-10.

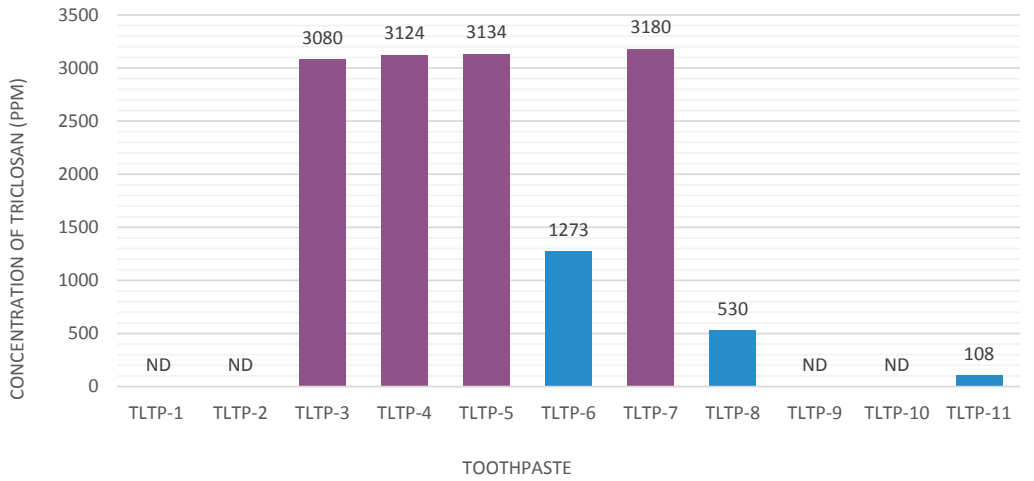
4.2 Results in Toothpaste

- The maximum concentration of Triclosan was found to be 3180 ppm
- 63.6% samples contain Triclosan while in rest of the samples Triclosan was not detected
- Out of 63.6% samples, in 36.4% samples Triclosan was found to be above BIS standard IS 4707 (part2):2009 i.e., 3000 pm
- Out of four kid's samples, Triclosan was not detected in 3 samples while in one sample Triclosan concentration was found to be 108 ppm which is much below as per BIS standard i.e., 3000 ppm

Table 2 – Concentration of Triclosan (ppm in Toothpastes)

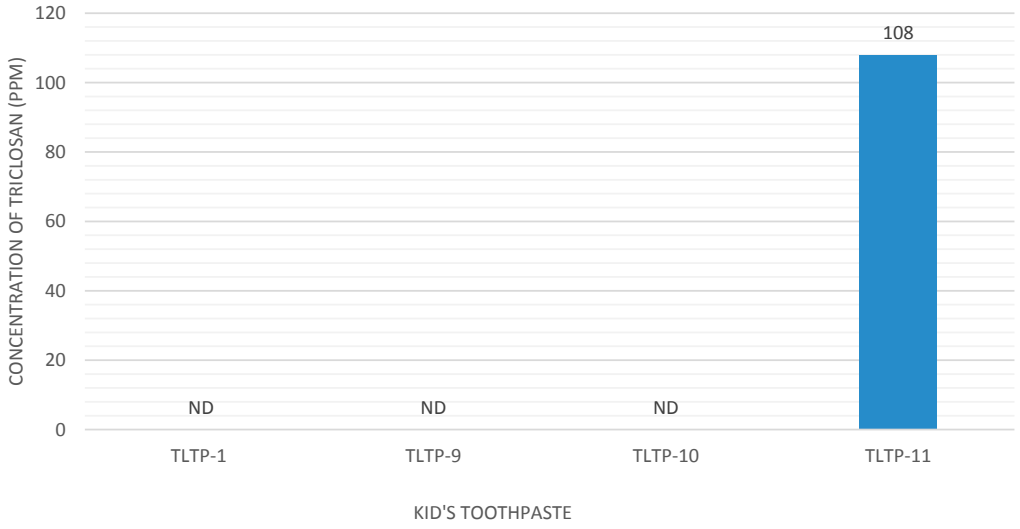
Toothpaste	Concentration of Triclosan (ppm)
TLTP-1	ND
TLTP-2	ND
TLTP-3	3080
TLTP-4	3124
TLTP-5	3134
TLTP-6	1273
TLTP-7	3180
TLTP-8	530
TLTP-9	ND
TLTP-10	ND
TLTP-11	108

Graph 2 - Graphical representation of Triclosan concentration in Toothpastes



The figure above indicates that in TLTP-1, TLTP-2, TLTP-9 & TLTP-10 concentration is below detection limit i.e. 25 ppm, while it is alarmingly high for TLPT-3, TLPT-4, TLPT-5 and TLPT-7.

Graph 3 - **Graphical representation of Triclosan concentration in Kid's Toothpastes**



Conclusion and Recommendation

The study was an attempt to get an understanding of Triclosan uses in toiletries available in the local market and to catalyze the process of further studies with regard to Triclosan as well as to establish dialogue at a policy level in India. Based on our key findings and analysis the conclusion and recommendations are elaborated in the following sections.

5.1 Conclusion

The lab results indicate that Triclosan is being used in hand wash and toothpaste sold in Indian market. Though the concentration of Triclosan is relatively low in hand washes however high concentration of Triclosan has been found in most of the toothpaste samples. And in most of the toothpaste samples the level of Triclosan is much above the prescribed limit of BIS standard of 3000 ppm. However, Triclosan has not been detected in most of the toothpaste samples meant for children. Also as a matter of fact some of the toothpaste and hand wash samples do not contain Triclosan at all.

Now the question arises, whether Triclosan is at all required for hand wash and toothpaste when Triclosan is found to be controversial due to its EDC properties. An important fact came during the selection of the samples that some of the products have been labeled as Triclosan free. Further the results also prove that some of the products do not contain Triclosan, thus may not be a necessary ingredient and can be replaced with other alternatives.

Perencevich et al. 2001, in their study named "National and regional assessment of the antibacterial soap market: a step toward determining the impact of prevalent antibacterial soaps, published in American Journal of Infection Control in 2001 mentioned in a survey of brand name soaps available in the U. S., that 76% of liquid soaps and 29% of bar soaps were "antimicrobial", containing either Triclosan. Among these, 100% of antimicrobial liquid soaps and 16% of antimicrobial bar

soaps contained Triclosan.[49] The research studies also claim that anti-bacterial soaps containing Triclosan are not much effective at preventing disease than traditional soap products. Soaps containing typical concentrations of Triclosan (0.2%or 0.3%) are not much effective than plain soap in reducing bacterial populations.[50]

Most importantly the major personal care product manufacturers like Johnson and Johnson, Procter and Gamble have announced the phase out of Triclosan from their products. . In the developing world, many countries are in the process of either phasing out or restricting the use of Triclosan due to growing concern as EDCs and its impact on aquatic life.

Further a study of Human Health risk based prioritization of Endocrine Disrupting Chemicals in water: A perspectives by Arun Kumar IIT, Delhi has identified Triclosan as a potential EDC in wastewater.[51] So there is a possibility that Triclosan can be one of the sources for pollution in water bodies in India as there are very limited ETPs available for wastewater treatment.

5.2 Recommendations

Considering the above studies and various perspectives, it is thus recommended that the stakeholders like Bureau of Indian Standards, Research institutions, Industries and Policymakers need to play a critical role in getting rid of the use of this chemical and minimize its health and environmental impacts.

Role of Bureau of Indian Standards (BIS)

The BIS needs to check and come out with the limit on Triclosan use in various products and monitor the levels against the standards that it sets. BIS also needs to create more data on Triclosan presence in other consumer personal care products.

Research Agenda on Triclosan and its impacts on ecosystem

Triclosan is a proven harmful chemical and its very commonly used in personal care products available in Indian markets. However hardly any research studies are available in India on Triclosan in the environment and likelihood damage it will cause to the ecosystem. So more research studies and data are needed to understand the overall scenario of Triclosan and that will perhaps help the policymakers to look for a suitable solution to the issue.

49 Perencevich, E. N., M. T. Wong & A. D. Harris: National and regional assessment of the antibacterial soap market: a step toward determining the impact of prevalent antibacterial soaps. American Journal of Infection Control 2001, 29, 281-3.

50 Aiello AE, Larson EL, Levy SB. 2007. Consumer Antibacterial Soaps: Clinical Infectious Diseases 45(2):137-147.

51 http://web.iitd.ac.in/~arunku/files/CEL899_Y13/Human%20Health%20Risk-based%20Prioritization%20of%20EDC_Kumar.pdf

Issue of Labeling

Triclosan is proved to be a harmful chemical hence mandatory labeling provisions on the use of this chemical in products is recommended. Apart from personal care products, Triclosan is also being used in other products, so labeling should also be extended to those products also.

Adoption of Good Practices by the Manufacturers

It is an established fact that Triclosan may not be a necessary ingredient in toiletries and other consumer products. However knowing the fact that Triclosan is a harmful chemical and alternatives are available, manufacturers are still using the chemical in their products. Though some of the manufacturers have started to phase out these products voluntarily, more manufacturers should come forward to phase out this harmful chemical from their products.

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Annexure

Regulation of Triclosan

The European Commission restricted Triclosan to a maximum concentration of 0.2% in mouthwashes and 0.3% in other cosmetic products such as toothpastes, hand soaps and face powders. However at present time, Triclosan is coming under close scrutiny. The European Union announced in June 2015 that the anti-bacterial pesticide, Triclosan, is toxic and bio accumulative and will be phased-out for hygienic uses and replaced by more suitable alternatives. According to the European Chemicals Agency (ECHA), "No safe use could be demonstrated for the proposed use of Triclosan." The ECHA opinion states that, "Risk was identified for both surface water and for the non-compartment specific effects relevant to the food chain (secondary poisoning).

The US EPA regulates the antimicrobial uses of Triclosan when used as a bacteriostat, fungistat, mildewstat, and deodorizer. However, when Triclosan is used in products intended for contact with the human body (i.e., personal care products such as soaps, antiseptics and toothpaste) or in food or food wrappers, it is regulated by the Food and Drug Administration[52]. Minnesota is the first state of USA that has banned the use of Triclosan in most retail consumer hygiene products.

In Australia maximum Triclosan permissible limit in cosmetic is 0.3%. In Japan, Triclosan is included in the Standards for Cosmetics (as established by the Pharmaceutical Affairs Law, 1960), which sets a maximum allowable concentration of 0.1% Triclosan in cosmetic products (Ministry of Health and Welfare Notification No. 331, 2000).

As per BIS standards for cosmetics raw materials & adjuncts, in India maximum authorized concentration (MAC) of Triclosan as preservatives in cosmetics is 0.3%.

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