Toxics Link
for a toxics-free world

Endocrine Disruptive Chemicals (EDCs)

in Personal Care Products

A report by Toxics Link

ABOUT TOXICS LINK

Toxics Link emerged from a need to establish a mechanism for disseminating credible information about toxics in India, and for raising the level of the debate on these issues. The goal was to develop an information exchange and support organisation that would use research and advocacy in strengthening campaigns against toxics pollution, help push industries towards cleaner production and link groups working on toxics and waste issues.

Toxics Link has unique experience in the areas of hazardous, medical and municipal wastes, as well as in specific issues such as the international waste trade and the emerging issues of pesticides and POP's. It has implemented various best practices models based on pilot projects in some of these areas. It is responding to demands upon it to share the experiences of these projects, upscale some of them and to apply past experience to larger and more significant campaigns.

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Endocrine Disruptive Chemicals (EDCs)

in Personal Care Products

Abbreviations

ACC	ASEAN Cosmetics Committee
ASEAN	Association of Southeast Asian Nations
BBP	Benzyl Butyl Phthalate
BIS	Bureau of Indian Standards
CDC	Centers for Disease Control and Prevention
DEHP	di (2-ethylhexyl) phthalate
DBP	Dibutyl Phthalate
DEA	Diethanolamine
DIPA	Disopropanolamine
EC	European Commission
EDCs	Endocrine Disrupting Chemicals
EU	European Union
IPCS	International Program on Chemical Safety
MAC	Maximum authorized concentration
mg	Milligram
ng/g	Nanogram per gram
P&G	Procter & Gamble
CalEPA	The California Environmental Protection Agency
CPSIA	The Consumer Product Safety Improvement Act
USA	The United State of America
TCC	Triclocarban
UNEP	United Nations Environmental Program
USD	US Dollar
WHO	World Health Organization

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Foreword

Chemicals are an integral part of modern life today and we find increasing use of chemicals all around us. The everyday use of chemicals in food, personal care products, medicines, agriculture, products and there is hardly any sphere of life that is untouched by chemicals. Chemicals output has exponentially grown and the industry has registered high growth rate of 13-14% in last five years.

While production and consumption of chemicals continues to grow, there is also growing evidence of its impacts on environment and human health and the world increasingly recognizes this challenge and a critical need for the safe management of these chemicals over their complete lifecycle. There is increasing recognition among government and experts that health and environment are being compromised by the current arrangements in managing chemicals and chemicals laden hazardous wastes. These challenges get compounded in developing economies on account of inadequate research and related data and the inability of government to provide sound regulatory and monitoring mechanisms for handling and usage of such chemicals and waste.

Endocrine Disrupting Chemicals (EDCs) are a group of chemicals that are highly complex in their composition with diverse toxicity characteristics and far reaching impacts on human health and animals. While there is enough data and evidence on some of these chemicals about their adverse impacts on health and environment and are being recognized for long term and far reaching adverse impacts on human health especially among children. These chemicals are considered highly toxic due to its persistent properties and its ability to impact various critical endocrine functions. There are global and national efforts in regulating and controlling how we produce and use these chemicals so as to reduce its harmful impacts.

In India, there has been very little data on these chemicals hence extremely limited information and understanding among the stakeholders and citizens. These substances also con-

tinue to be used in many products and processes notably in personal care and products exclusively for use by children. The report on EDCs in personal care products is an attempt to provide basic information on some of these complex chemicals. It has made serious and honest attempt to simplify the issue and present it in a manner which can be understood by all stakeholders and can trigger a conversation on the issue. It also provides a brief glimpse on the export import flows and some of the regulatory standards that govern these chemicals.

The document is unique due to its brevity and simplicity and I hope will be important and critical in generating awareness and understanding on this complex set of chemicals.

Satish Sinha
Associate Director

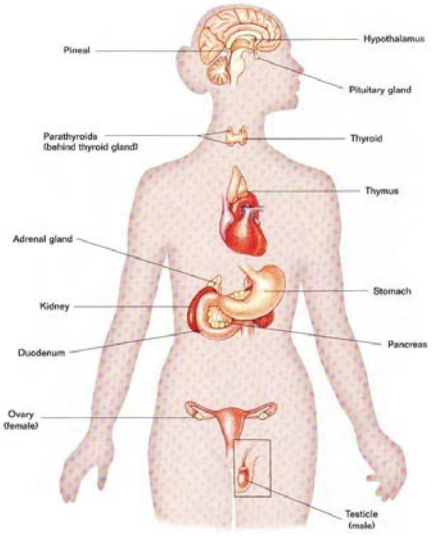
CHAPTER I

Endocrine Disrupting Chemicals – What Are They?

1.1 Introduction to the Endocrine System

The endocrine system is a complex network of glands and hormones that regulate many of the body's functions including growth, development and maturation as well as the way various organs function. *The endocrine system keeps our bodies in balance, maintaining homeostasis and guiding proper growth and development.*

The endocrine glands, including the pituitary, thyroid, adrenal, thymus, pancreas, ovaries, and testes release carefully-measured amounts of hormones into the bloodstream. These hormones act as natural chemical messengers, travelling to different parts of the body in order to control and adjust many life functions.



However, there are certain products of day to day use containing harmful chemicals which interfere with the endocrine system and cause hormone imbalance. These chemicals are known as the *Endocrine Disrupting Chemicals* (EDCs) and can impact the body's development process irrespective of whether it is the body of a human being or any other wildlife.

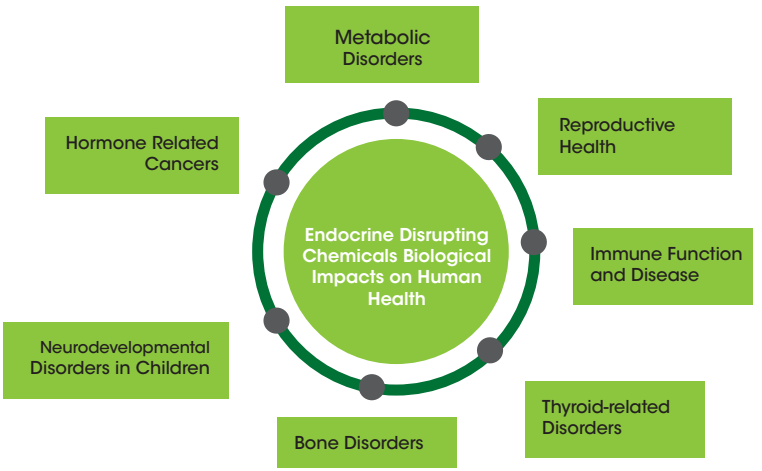
1.2 More about the Endocrine Disrupting Chemicals (EDCs)

As discussed in the earlier section, the synthetic chemicals have increasingly become integral to our lives. In the last three to four decades, dependence on synthetic chemicals has increased enormously. This is evident from the nine-fold increase in the global sale of chemicals from the year 1970 to 2001. After the impact of chemicals on human health and the environment came to the limelight, new research and studies are being initiated globally to understand the impact of chemicals on health and environment. These studies claim that some of the chemicals interrupt with the endocrine system and disrupt the hormonal system that can impact the developmental process of the human being.

1.2.1 Defining Endocrine Disrupting Chemicals

Endocrine disruptors are chemicals generally known to interfere with hormone action by altering the endocrine system thus having adverse impact on the human beings and other fauna including wild life. After carefully analyzing the scientific research conducted across the globe, the International Program on Chemical Safety (IPCS), a joint program of WHO, UNEP and International Labor Organization constructed the definition of EDC: *"Endocrine disruptor as an exogenous substance or mixture that can alter the functions of the endocrine system and consequently causes adverse health effects in an intact organism or its progeny or population".* EDCs impact health in many ways and such impacts of EDCs are shown in the figure below:

Figure 1 - Biological impacts of EDCs on human health[1]



1 State of the Science of Endocrine Disrupting Chemicals- 2012 Inter-Organization Programme for the Sound Management of Chemicals

With current understanding it is evident that EDCs can have the following properties:

- EDCs are exogenous substance (synthetic or anthropogenic chemical substances widely used in modern production process and products) interfering with the hormonal system of an organism;
- Most endocrine disrupting chemicals are fat-soluble and thus can remain in the fatty tissue of an organism for long;
- As environmental contaminants, EDCs can interact with hormone receptors and mimic or antagonize the actions of endogenous hormones;
- Exposure to an EDC during critical periods of development of an organism can cause irreversible and delayed effects that do not become evident until later in life;
- Fetuses and newborns are most susceptible and the timing of exposure is more critical than its dose;
- They can have an adverse impact on wildlife as well as human beings – can cause learning disabilities, severe attention deficit disorder, cognitive and brain development problems, deformations of body (including limbs); sexual development problems, feminizing of males or masculine effects on females, etc.
- The adverse impact of EDCs could be trans-generational as well.

1.2.2 Mode and Mechanism of Actions of EDCs

There are many possible mechanisms by which EDCs may interact with the endocrine system and cause adverse effects. Endocrine disruptors may turn on, shut off, or modify signals that hormones carry, which may affect the normal functions of tissues and organs.

EDCs can interfere with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body that are responsible for normal cell metabolism.

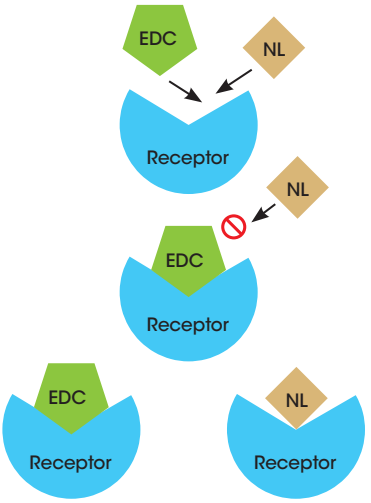
Four Points about endocrine disruption:

- Low dose matters
- Wide range of health effects
- Persistence of biological effects
- Ubiquitous exposure

More specifically EDCs can have the following effects:

- They may mimic the biological activity of a hormone by binding to a cellular receptor, leading to an unwarranted response by initiating the cell's normal response to a naturally occurring hormone at the wrong time or to an excessive extent (***agonistic effect***).
- They may bind to the receptor but not activate it. Instead the presence of the chemical on the receptor will prevent binding of the natural hormone (***antagonistic effect***)

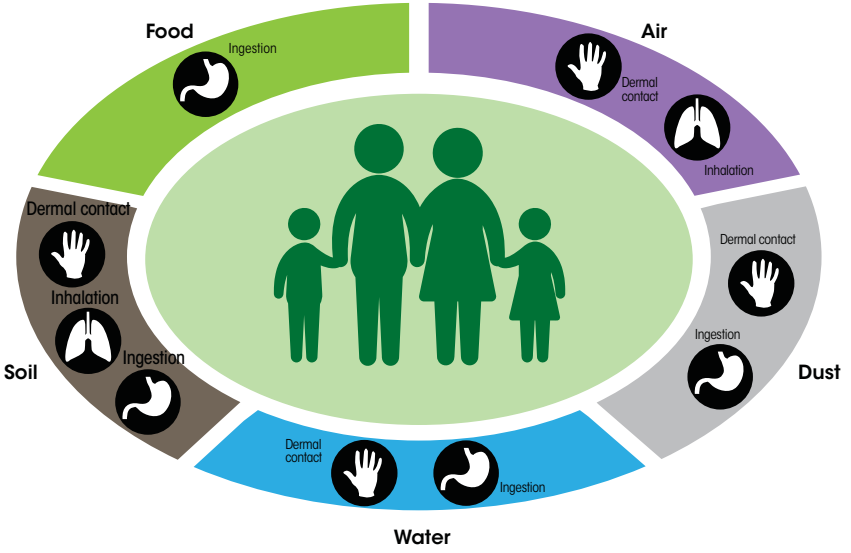
- They may ***bind to transport proteins*** in the blood, thus altering the amounts of natural hormones that are present in the circulation
- They may ***interfere with the metabolic processes*** in the body, affecting the synthesis or breakdown rates of the natural hormones



1.2.3 Sources or exposure route of EDCS

Chemicals have become an integral part of life, but there are concluding evidences that some of the chemicals have the tendency to disrupt the endocrine system. These chemicals are found in common products including toys, baby feeding bottles, plastic items, pesticides and personal care products, metals, additives or contaminants in food, and enter into the human being through the food chain or direct exposure. Further, these chemicals can transfer from a pregnant female to the developing fetus through the placenta and to offsprings from mothers' milk. Nevertheless the exposure level among the children is higher due to the hand-to-mouth activities and lack of adaptability to these chemicals.

Figure 2. Exposure routes of EDCs. The sources (water, soil, food, air and dust) illustrate pathways for human absorption of EDCs.



1.3 EDCs in Personal Care Products

Such products may include cosmetics, shampoos, deodorants, hair sprays/colors, anti-bacterial products, toothpastes, etc. Some of the chemicals are well known for their endocrine disrupting property and have been categorized as the Endocrine Disrupting Chemicals. The chemicals used in the personal care products have properties of EDCs that include Parabens, Triclosan, Triclocarbon, Phthalate, Formaldehyde releasing agents, Ethanolamines, Butylated hydrxyanisole, Propylene glycol etc.

Generally these chemicals act as antimicrobial agents, stabilizers, solvents, dispersants, lubricants, binders, emulsifying agents, suspending agents, skin penetration enhancers in the products. These chemicals are also used as anti-brittleness and anti-cracking agents in nail polishes and sealants, as anti-foaming agents in aerosols, and act as a creamy texture and foaming action in creams & face wash.

Exposure to these chemicals occurs through direct application on the skin over a period of time. Studies have found that continuous exposure to some of these chemicals lead to penetration into the skin and deposition of these harmful chemicals in the body over time thus known to cause varied health problems. Additionally, oral exposure can occur from cosmetics used in and around the mouth, as well as from hand-to-mouth contact. Children can have higher exposures to EDCs because of their hand-to-mouth activities.

The chemicals used in the personal care products are mostly fat-soluble and do not get rapidly flushed out of the body, but are stored in the fat and gradually get bio accumulated into the food chain.[2]

The present report focusses on the chemicals like Phthalates, Parabens, Triclosans, Diethniamine, Triclocarbon, Diethanolamine and their impact on health; significant research findings are available that show endocrine disrupting properties of these chemicals and therefore many countries have taken appropriate action to get rid of these chemicals from personal care products. Moreover the countries have taken affirmative measures on the use of the chemicals in the children's products.

2 http://www.nrdc.org/health/effects/bendrep.asp

The average daily total personal paraben exposure is estimated to be

76 mg

with cosmetics and personal care products accounting for

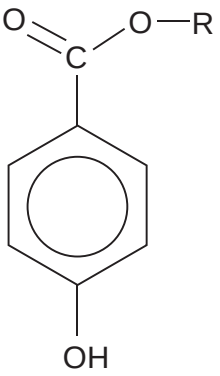
50 mg, 25 mg

from pharmaceutical products

CHAPTER II

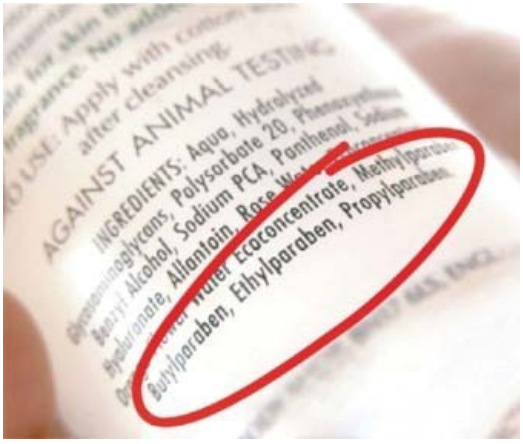
Types of Endocrine Disrupting Chemicals

2.1 Parabens



Parabens are man-made chemicals often used in small amounts as preservatives in cosmetics, pharmaceuticals, foods, and beverages. Often more than one paraben is used in a single product. The chemical composition of Parabens is esters of para-hydroxybenzoic acid and commonly includes **Methyl paraben, Ethyl paraben, Propyl paraben** and **Butyl paraben.**

Though Parabens are also available naturally and can be extracted from the plants, however the commercially used Parabens are synthetically produced through Industrial process. These compounds, and their salts, are used in cosmetic products for their anti-bactericidal and fungicidal properties. It has been estimated that 75 to 90 percent of cosmetics contain Parabens.[3]



3 Winter, R. *A Consumer's Dictionary of Cosmetic Ingredients*, 7th ed. New York: Three Rivers Press, 2009

2.1.1 Uses of Parabens

- Shampoos
- Moisturizers
- Shaving gels
- Personal lubricants
- Hair spray/mousse/gel
- Spray tanning solution
- Cleansers
- Makeup
- Toothpaste
- Topical/parenteral pharmaceuticals

2.1.2 Health Impacts

Parabens are widely used as antimicrobial preservatives in personal care and consumer products, food and pharmaceuticals. Due to their ubiquity, human beings are constantly exposed to these chemicals.

They can easily penetrate into the skin and can be absorbed through skin, blood and digestive system.[4] The average daily total personal paraben exposure is estimated to be 76 mg, with cosmetics and personal care products accounting for 50 mg, 25 mg from pharmaceutical products, and 1 mg from food.[5]

After dermal uptake, Parabens are hydrolyzed and conjugated and excreted in urine. Despite high total dermal uptake of Paraben and metabolites, little intact Paraben can be recovered in the blood and urine. Paraben metabolites may play a role in the endocrine disruption seen in experimental animals but further studies are needed to determine levels of Parabens and metabolites. Overall, the estrogenic burden of Parabens and their metabolites in blood may exceed the action of endogenous estradiol in childhood and the safety margin for Propyl Paraben is very low when compared with worst-case exposure to NOAELs from experimental studies in rats and mice.[6]

The estrogenic properties displayed by Parabens appear to increase with increasing chain length. Parabens may also interfere with male reproductive functions. Studies conducted by the U.S. Centers for Disease Control and Prevention (CDC) find four different Parabens in human urine samples, indicating exposure despite very low levels in products.[7] A study conducted by Barr et al. in 2012 found parabens in almost 100% of breast samples from breast cancer patients.[8, 9]

4 U.S. FDA. Parabens. http://www.fda.gov/Cosmetics/ProductandIngredientSafety.
5 http://www.grimalt.net/wp-content/uploads/2013/04/parabens-2013.pdf
6 http://www.sciencedirect.com/science/article/pii/S089062381000078X
7 Ye et al., (2007). Temporal stability of the conjugated species of bisphenol A, parabens, and other environmental phenols in human urine. J. Exposure Science and Environmental Epidemiology, 17(6):567-572.
8 http://www.ncbi.nlm.nih.gov/pubmed/22237600
9 http://healthandenvironmentonline.com/2013/06/17/parabens-endocrine-disruptors-in-cosmetics-and-food/

Parabens have also been detected in human tissues and bodily fluids, but it is the discovery of these chemical compounds in the breast tissue of patients with breast cancer that has raised public concern over their use. It is hypothesized that the estrogenic properties of parabens may play a role in breast cancer development. However, studies investigating the health effects of parabens are conflicting. At this point, there is an insufficient amount of data suggesting serious consequences from paraben use and exposure to warrant drastic avoidance measures or government regulations.[10] The European Commission on Endocrine Disruption has listed Parabens as Category 1 priority substances, based on evidence that they interfere with hormone function.[11]

2.1.3 Parabens in Environment

Parabens from the products are also released into the environment. The chemicals have been detected in the urban streams into which treated or untreated effluent from wastewater treatment plants flows.[12] Further, these chemical compounds have also been found in the rivers and drinking water sources.[13] Parabens have also been detected in soil from the agricultural fields, possibly from irrigation or use of the fertilizer. The studies have been shown the presence of these chemicals in dust.[14]

2.1.4 Regulations

Parabens have been established as endocrine disrupting chemicals, so the countries have adopted stringent regulations to contain the use of Parabens in the personal care products. Netherland is one of the first countries that has banned the use of Parabens in personal care products intended for children younger than 3 years of age in 2011.

The European Commission (EC) has banned five Parabens in all cosmetics and personal care products considering the health concern of the human beings from April 2014. These banned Parabens are Isopropyl paraben, Isobutyl paraben, Phenyl paraben, Benzyl paraben, and Pentyl paraben. In addition, they are proposing to lower the allowed maximum concentrations of butyl-and propyl paraben as well as to prohibit these in leave-on cosmetics designed for application in the nappy area and in cosmetics intended for children under 3 years of age.

10 Kirchhof MG, de Gannes GC. (2013)., The health controversies of parabens., Skin Therapy Lett. 18(2):5-7.

11 DHI Water and Environment. Study on Enhancing the Endocrine Disrupter Priority List with a Focus on Low Production Volume Chemicals. Revised Report to

12 Yamamoto H, Tamura I, Hirata Y, et al. Aquatic toxicity and ecological risk assessment of seven parabens: individual and additive approach. Sci Total Environ. 2011 Dec;410–411:102–11

13 Pedrouzo M, Borrull F, Marce RM, et al. Ultra-high-performance liquid chromatography-tandem mass spectrometry for determining the presence of eleven personal care products in surface and wastewaters. J Chromatogr A. 2009 Oct; 1216(42):6994–7000.

14 Ramirez N, Marce RM, Borrull F. Determination of parabens in house dust by pressurised hot water extraction followed by stir bar sorptive extraction and thermal desorption-gas chromatography-mass spectrometry. J Chromatogr A. 2011; 1218(37):6226–31.

In Jan 2015 the Association of Southeast Asian Nations' (ASEAN) Cosmetics Committee (ACC) decided to ban the use of five parabens as preservatives in cosmetics. These are: isopropyl paraben, isobutyl paraben, phenyl paraben, benzyl paraben, and pentyl paraben.

In India, the standard making agency Bureau of Indian Standards (BIS) in its standard IS-4707 (Part 2) for cosmetics raw materials & adjuncts, maximum authorized concentration (MAC) for parabens are esters of para-hydroxybenzoic acid in cosmetic products is 0.4% for single paraben and 0.8% for mixture of parabens.

Paraben free products are available in market. Clariant, a pigment and preservative manufacturer, has released the Paraben-Free alternative to cosmetics preservatives.

2.1.5 Information on Exports-Imports

India exported isopropyl paraben item worth USD 12,082 in 2014. United States is the only buyer of the isopropyl paraben item. India exported Benzyl paraben (bp) worth USD 30,788 with total quantity of 1,500. United Kingdom is the largest buyer of Benzyl paraben bp accounting for exports worth USD 11,941 followed by the United States and Switzerland which imported benzyl paraben (bp) worth USD 10,849 and USD 7,997 respectively.

2.1.6 Alternatives to Parabens

Sodium benzoate, Dehydroacetic acid, Benzoic acid and Potassium sorbate are in use as alternative preservatives to parabens along with natural extracts such as Grapefruit seed extract, Thymol, Cinnamaldehyde, Allyl isothiocyanate, Citric acid, Ascorbic acid and Rosemary extract.

Research Studies:

a. **Mei-Fei Yueha, Koji Taniguchib, Shujuan Chena, Ronald M. Evansc, Bruce D. Hammockd,1, Michael Karinb, and Robert H. Tukeya, 2014. The commonly used antimicrobial additive triclosan is a liver tumor promoter. PNAS, 111 (48): 17200–17205. www.pnas.org/cgi/doi/10.1073/pnas.1419119111.**

Abstract

Using the procarcinogen diethyl nitrosamine (DEN) to initiate tumorigenesis in mice, it was discovered that TCS substantially accelerates hepatocellular carcinoma (HCC) development, acting as a liver tumor promoter. TCS-treated mice exhibited a large increase in tumor multiplicity, size, and incidence compared with control mice. TCS mediated liver regeneration and fibrosis preceded HCC development and may constitute the primary tumor-promoting mechanism through which TCS acts. These findings strongly suggest there are adverse health effects in mice with long-term TCS exposure, especially on enhancing liver fibrogenesis and tumorigenesis, and the relevance of TCS liver toxicity to humans should be evaluated.

b. **Pycke BF, Geer LA, Dalloul M, Abulafia O, Jenck AM, Halden RU, 2014. Human fetal exposure to triclosan and triclocarban in an urban population from Brooklyn, New York. Environ Sci Technol. 014;48(15):8831-8. doi: 10.1021/es501100w. Epub 2014 Jul 15.**

Abstract

The concentrations of triclosan, triclocarbon, and its human metabolites (2′-hydroxy-TCC and 3′-hydroxy-TCC) as well as the manufacturing byproduct (3′-chloro-TCC) were determined as total concentrations after conjugate hydrolysis in maternal urine and cord blood plasma from a cohort of 181 expecting mother/infant pairs in an urban multiethnic population from Brooklyn, NY. Liquid chromatography tandem mass spectrometry was used for study which was conducted in 2007-09. TCS was detected in 100% of urine and 51% of cord blood samples after conjugate hydrolysis.

c. **Wolff MS et al., 2007. Pilot Study of Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols in Girls, Environmental Health Perspectives, 115 (1): 116-121.**

Abstract

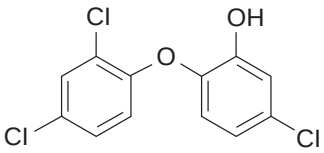
In this study 25 urinary analytes representing 22 separate agents from three chemical families: phytoestrogens, phthalates, and phenols were measured. Wide spectrums of hormonally active exposure biomarkers were detectable and variable among young girls, with high maximal concentrations (> 1,000 µg/L) found for several analytes. Exposures occur chiefly from the diet and from household or personal care products.

d. **Mary S. Wolff et al., 2010. Investigation of Relationships between Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols and Pubertal Stages in Girls. Environmental Health Perspectives, 118(7):1039-1046.**

Abstract

Weak hormonally active xenobiotic agents investigated in this study had small associations with pubertal development, mainly among those agents detected at highest concentrations. Small inverse associations were seen for triclosan with pubic hair development.

2.2 Triclosan



Triclosan [5-chloro-2-(2,4-dichlorophenoxy) phenol; TCS] is a phenylether, or chlorinated bisphenol. It is having antimicrobial and antifungal properties used in wide range of consumer products.[15] It possesses multiple properties in various concentrations, in high concentrations, it acts as a biocide with multiple cytoplasmic and membrane targets,[16] whereas in lower concentrations Triclosan has bacteriostatic property and targets bacteria by inhibiting fatty acid synthesis. Due to these properties it has been used as an important ingredient in the personal care products.

2.2.1 Uses of Triclosan

- Antiseptic soaps
- Cosmetics
- Deodorant
- Detergents
- Toothpastes
- Mouthwash
- Hair products

2.2.2 Health Impacts

Triclosan is a well-known chemical for its endocrine disrupting properties. Triclosan is lipophilic in nature, so the chemical generally binds and bio accumulates in the fatty tissues. As it is very commonly used in the personal care products, it can penetrate into the skin[17] and has the tendency to interfere with hormone function, so has been categorized as an endocrine disrupting chemical.[18]

Evidence does suggest that Triclosan can affect aquatic wildlife and the hormonal systems of mice. It may impact male and female hormones like testosterone and estrogen, and may also affect thyroid systems, which regulate weight and metabolism.[19]

Triclosan has been shown to bind to both human estrogen and androgen receptors in vitro, raising concerns about its impact on the developmental and reproductive effects and also a potential cancer risk. The animal studies have also found that it can decrease circulating concentrations of the thyroid hormone Thyroxine (T4) in rats. The children are the most susceptible to the impact of Triclosan.

15 Courtney, K.D.; Moore, J.A. Teratology studies with 2, 4, 5-trichlorophenoxyacetic acid and 2, 3, 7, 8-tetrachlorodibenzo-P-dioxin. Toxicol. Appl. Pharmacol. 1971, 20, 396–403.

16 Russell AD (May 2004). "Whither triclosan?". J. Antimicrob. Chemother. 53 (5): 693–5. doi:10.1093/jac/dkh171. PMID 15073159

17 Calafat, A. "Urinary Concentrations of Triclosan in the U.S. Population: 2003-2004." _Environ Health Perspect _116, 3(Mar 2008):303-307.

18 Gee, RH et al. "Oestrogenic and androgenic activity of triclosan in breast cancer cells." Appl Toxicol.28, 1 (Jan 2008):78-91.

19 http://www.breastcancerfund.org/clear-science/radiation-chemicals-and-breast-ancer/triclosan.html

In a study carried out by the Centers for Disease Control and Prevention (NHANES study), 75 percent of samples were found to have significant levels of Triclosan and its metabolites. Higher levels were found in young adults and more affluent adults.[20] A parallel NHANES study examining chemical levels in pregnant women found measurable levels of triclosan in 87 percent of urine samples examined.[21]

Human autopsy analysis reveals that triclosan bio accumulates in liver and adipose (fat) tissue, but not in brain tissue, the three tissue types examined.[22]

The recent studies have detected Triclosan in human breast milk (at levels of 20–300 ng/g), blood samples (at ranges of 0.01–38 ng/ml)[23,24,25,26] and in the urine of 61% of girls aged 6–8 years.

2.2.3 Triclosan in Environment

Triclosan is one of the chemical which is frequently being detected in the stream, effluents and bio- solids of wastewater treatment plants and in lakes, rivers and sea water in various countries.[27, 28, 29,30] Triclosan bio accumulates in aquatic plants and animals and poses multiple eco-toxicity risk. The chemical also enters into the food chain from the 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 harm-

20 Calafat, A., Ye, X., Wong, L.-Y., JA, R., & LL, N. (2008). Exposure of the U.S. population to bisphenol A and 4-tertiary-octylphenol. Environ Health Persp, 116, 2003–2004.

21 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.

22 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.

23 Adolfsson-Erici, M., Pettersson, M., Parkkonen, J., and Sturve, J. (2002). Triclosan, a commonly used bactericide found in human milk and in the aquatic environment in Sweden. Chemosphere 46, 1485–1489.

24 Allmyr, M., Adolfsson-Erici, M., McLachlan, M. S., and Sandborgh-Englund, G. (2006). Triclosan in plasma and milk from Swedish nursing mothers and their exposure via personal care products. Science Total Environ. 372, 87–93.

25 Hovander, L., Malmberg, T., Athanasiadou, M., Athanassiadis, I., Rahm, S., Bergman, A., and Wehler, E. K. (2002). Identification of hydroxylated PCB metabolites and other phenolic halogenated pollutants in human blood plasma. Arch. Environ. Contam. Toxicol. 42, 105–117.

26 Wolff, M. S., Teitelbaum, S. L., Windham, G., Pinney, S. M., Britton, J. A., Chelimo, C., Godbold, J., Biro, F., Kushi, L. H., Pfeiffer, C. M., et al. (2007). Pilot study of urinary biomarkers of phytoestrogens, phthalates, and phenols in girls. Environ. Health Perspect. 115, 116–121.

27 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

28 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.

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

30 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.

ful to wildlife.[31, 32] Triclosan is readily degraded in the environment via photo degradation or react with sunlight, forming other compounds, which include chlorophenols and dioxins.

2.2.4 Regulations

Many research studies claim the health impact and EDCs properties of the chemical, the countries have taken appropriate regulations to restrict the use of Triclosan in various products. In 2014 the European Commission has 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. In Australia maximum Triclosan permissible limit in cosmetic is 0.3%. Minnesota is the first state of USA that has banned the use of Triclosan in most retail consumer hygiene products.

In Jan 2015 the Association of Southeast Asian Nations' (ASEAN) Cosmetics Committee (ACC) has decided to restrict 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.

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

The industries have also taken voluntary action to phase out Triclosan from their products. Johnson & Johnson has voluntarily removed Triclosan from baby products and all the personal care products; Proctor and Gamble has also announced to remove Triclosan from all its products by 2014.

2.2.5 Information on Exports-Imports[33]

India exported Triclosan worth USD 35,620,324 in the last financial year. United States is the largest buyer of Triclosan followed by Brazil and United Kingdom. In June 2015 India exported Triclosan of USD 907,827. India imported Triclosan worth USD 155,138. Germany is the largest supplier of Triclosan accounting for imports worth USD 103,481 followed by Thailand.

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

32 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.

33 https://www.zauba.com/importanalysis-triclosan/hs-code-29095090-report.html

2.2.6 Alternatives to Triclosan

There are several chemicals used today in "antibacterial" personal care and hygiene products which are toxic to the human body. According to the Centers for Disease Control and Prevention (CDC), vigorous hand washing in warm water with plain soap for at least 10 seconds is sufficient to fight germs in most cases, even for healthcare workers. For extra assurance, use of an alcohol- or peroxide-based hand sanitizer product is a good option.[34] There are some common natural alternatives to Triclosan such as Neem *(Azadirachta indica)* and Clove *(Syzygium aromaticum)*.

Research Studies:

a. **Mei-Fei Yueha, Koji Taniguchib, Shujuan Chena, Ronald M. Evansc, Bruce D. Hammockd,1, Michael Karinb, and Robert H. Tukeya, 2014. The commonly used antimicrobial additive triclosan is a liver tumor promoter. PNAS, 111 (48): 17200–17205. www.pnas.org/cgi/doi/10.1073/pnas.1419119111.**

Abstract

Using the procarcinogen diethyl nitrosamine (DEN) to initiate tumorigenesis in mice, it was discovered that TCS substantially accelerates hepatocellular carcinoma (HCC) development, acting as a liver tumor promoter. TCS-treated mice exhibited a large increase in tumor multiplicity, size, and incidence compared with control mice. TCS mediated liver regeneration and fibrosis preceded HCC development and may constitute the primary tumor-promoting mechanism through which TCS acts. These findings strongly suggest there are adverse health effects in mice with long-term TCS exposure, especially on enhancing liver fibrogenesis and tumorigenesis, and the relevance of TCS liver toxicity to humans should be evaluated.

b. **Pycke BF, Geer LA, Dalloul M, Abulafia O, Jenck AM, Halden RU, 2014. Human fetal exposure to triclosan and triclocarban in an urban population from Brooklyn, New York. Environ Sci Technol. 014;48(15):8831-8. doi: 10.1021/es501100w. Epub 2014 Jul 15.**

Abstract

The concentrations of triclosan, triclocarbon, and its human metabolites (2′-hydroxy-TCC and 3′-hydroxy-TCC) as well as the manufacturing byproduct (3′-chloro-TCC) were determined as total concentrations after conjugate hydrolysis in maternal urine and cord blood plasma from a cohort of 181 expecting mother/infant pairs in an urban multiethnic population from Brooklyn, NY. Liquid chromatography tandem mass spectrometry was used for study which was conducted in 2007-09. TCS was detected in 100% of urine and 51% of cord blood samples after conjugate hydrolysis.

34 http://www.nurseweek.com/features/98-10/soap.html

c. **Wolff MS et al., 2007. Pilot Study of Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols in Girls, Environmental Health Perspectives, 115 (1): 116-121.**

Abstract

In this study 25 urinary analytes representing 22 separate agents from three chemical families: phytoestrogens, phthalates, and phenols were measured. Wide spectrums of hormonally active exposure biomarkers were detectable and variable among young girls, with high maximal concentrations (> 1,000 µg/L) found for several analytes. Exposures occur chiefly from the diet and from household or personal care products.

d. **Mary S. Wolff et al., 2010. Investigation of Relationships between Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols and Pubertal Stages in Girls. Environmental Health Perspectives, 118(7):1039-1046.**

Abstract

Weak hormonally active xenobiotic agents investigated in this study had small associations with pubertal development, mainly among those agents detected at highest concentrations. Small inverse associations were seen for triclosan with pubic hair development.

2.3. Phthalates

Phthalates or phthalate esters are esters of phthalic (1, 2-benzendicarboxylic acid) acid and are mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity). Phthalates are commonly being used in the personal care products as skin moisturizers, skin softeners, skin penetration enhancers, stabilizers, dispersants and lubricants, binders, emulsifying agents, solvents and suspending agents. Phthalates are also used as anti-brittleness and anti-cracking agents in nail polishes and sealants, as anti-foaming agents in aerosols.[35, 36]

2.3.1 Uses of Phtalates

- Fragrances
- Shampoo
- Hairspray
- Shaving creams & lotions
- Cosmetics

35 H. J. Koo and B. M. Lee, Estimated exposure to phthalates in cosmetics and risk assessment, J. Toxicol. Env. Health A, 67, 1901–1914 (2004).

36 Cosmetic ingredient review, Annual review of cosmetic ingredient safety assessments 2002/2003, Int. J. Toxicol., 24(suppl. 1), 1–102 (2005).

2.3.2 Health Impacts

Phthalates and their metabolites have been found potentially harmful for human and environment due to their hepatotoxic, teratogenic, and carcinogenic characteristics.[37] There is high possibility of dermal absorption of Phthalates via the skin. Higher possibility of exposure can occur from cosmetics that are left on the skin for extended period of time. Topical exposure to Phthalate esters in cosmetic products may contribute to the observed urinary levels of mono-esters (metabolites of phthalate esters) in humans[38]. However infants and young children are more vulnerable to the potential adverse effects of Phthalates given their increased dosage per unit body surface area, metabolic capabilities, and developing endocrine and reproductive systems.[39]

Phthalates have potential toxic effects to the developing endocrine and reproductive systems. High doses have been shown to change hormone levels and cause birth defects.[40] Main et al found that phthalate exposure through breast milk was associated with abnormal reproductive hormone levels in 3-month-old infants, suggesting that early human exposures may have an adverse impact on endocrine homeostasis.[41] Phthalate also can causes anti-androgenicity in adult men.[42]

2.3.3 Phthalates in Environment

Phthalates are also very commonly found in the environment. Butyl Benzyl Phthalate (BBP), di (2-ethylhexyl) phthalate (DEHP), and Dibutyl Phthalate (DBP) elicit the most toxicity to terrestrial organisms, fish, and aquatic invertebrates.[43, 44] Eco-toxicity studies with these phthalates showed adverse effects to aquatic organisms with a broad range of endpoints and at concentrations that coincide with measured environmental concentrations.

Studies have demonstrated that phthalates with shorter ester chains like DMP, DEP, DBP, DPP, and BBP can be readily biodegraded and mineralized. On the other hand, phthalates with

37 Matsumoto M, Hirata-Koizumi M, Ema M (2008) Potential adverse effects of phthalic acid esters on human health: a review of recent studies on reproduction. Regul Toxicol Pharm 50:37–49

38 National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, NPT-CERHR Expert Panel Report on Di-n-Butyl Phthalate, October 2000.

39 Sheela Sathyanarayana, Catherine J. Karr, Paula Lozano, Elizabeth Brown, Antonia M. Calafat, Fan Liu and Shanna H. Swan. Antonia. Baby Care Products: Possible Sources of Infant Phthalate Exposure. Pediatrics 2008;121;260-268

40 Third National Report on Human Exposure to Environmental Chemicals, (PDF) U.S. CDC, July 2005.

41 Main KM, Mortensen GK, Kaleva MM, et al. Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in infants three months of age. Environ Health Perspect. 2006;114(2):270–276

42 Albert, O.; Jegou, B. (2013). "A critical assessment of the endocrine susceptibility of the human testis to phthalates from fetal life to adulthood". Human Reproduction Update 20 (2): 231. doi:10.1093/humupd/dmt050. PMID 24077978

43 Staples, C. A.; Adams, W. J.; Parkerton, T. F.; Gorsuch, J. W.; Biggingers, G. R.; Reiner, K. H. 1997. Aquatic Toxicity of Eighteen Phthalate Esters. Environ. Toxicol. Chem. 1997, 16 (5), 875–891.

44 EC. 2008a. European Commission. European Union Risk Assessment Report Bis(2-Ethylhexyl) Phthalate (DEHP), CAS-No. 117-81-7. Vol. 80; EUR 23384EN; Office for Official Publications of the European Communities: Luxembourg, 2008.

longer ester chains, such as Dicyclohexyl phthalate, Dihexyl phthalate (DHP), Dioctyl phthalate (DOP), and Di-2-ethylhexyl phthalate (DEHP) are less susceptible to biodegradation.[45, 46]

2.3.4 Regulations

In spite of the varied usages of Phthalates, the chemical has been regulated for its impact on health and environment. In India Dibutyl phthalate (DBP), Di (2-ethylhexyl) phthalate (DEHP), Bis(2-Methoxyethyl) phthalate, Isopentyl phthalate, and Benzyl butyl phthalate (BBP) are restricted in raw materials of cosmetics under the Bureau of Indian Standards of IS 4707(Part 2): 2009.

The Consumer Product Safety Improvement Act (CPSIA) USA had banned the use DEHP, DBP and BBP in cosmetics in 2008. The US Consumer Product Safety Commission has issued a notice of proposed rulemaking to expand the ban on phthalates in Section 108 of the Consumer Product Safety Improvement Act.

The EU has classified DEHP, BBP & DBP as Category 2 reproductive toxins and prohibited their use in cosmetics.[47] Australia has prohibited the use, sale and supply of cosmetics containing the phthalate DEHP from 2011.

Procter & Gamble (P&G) had announced to remove phthalates form all of its products including the personal care products from 2014.

2.3.5 Information on Exports-Imports[48]

India is not a producer of Phthalates and largely depends on the import from the US and EU. India imported Dibutyl phthalate worth USD 32,774. United States is the largest supplier of Dibutyl phthalate accounting for imports worth USD 27,560 followed by Germany which exported Dibutyl phthalate worth USD 5,214. India exported Dibutyl phthalate drums worth USD 532 only. Tanzania is the only buyer of Dibutyl phthalate drums.

45 Wang JL, Chen LJ, Shi HC, Qian Y (2000) Microbial degradation of phthalic acid esters under anaerobic digestion of sludge. Chemosphere 41:1245–1248

46 Chang BV, Yang CM, Cheng CH, Yuan SY (2004) Biodegradation of phthalate esters by two bacteria strains. Chemosphere 55:533–538

47 Scientific Committee on Consumer Products, Health & Consumer Protection Directorate-General, European Commission, Opinion on phthalates in cosmetic products, http://ec.europa.eu/health/ph_risk/ committees/04_sccp/docs/sccp_o_106.pdf.

48 https://www.zauba.com/exportanalysis-phthalate-report.html

Research Studies:

a. **Jessica La Rocca, Alexandra M. Binder, Thomas F. McElrath, and Karin B. Michels, 2015. First-Trimester Urine Concentrations of Phthalate Metabolites and Phenols and Placenta miRNA Expression in a Cohort of U.S. Women. http://dx.doi.org/10.1289/ehp.1408409**

Abstract

The objective of this study was to determine if prenatal exposure to multiple EDCs is associated with changes in miRNA expression of human placenta, and if miRNA alterations are associated with birth outcomes. By assessing gene ontology enrichment, it was determined that the potential mRNA targets of these microRNAs predicted in silico were associated with several biological pathways, including the regulation of protein serine/threonine kinase activity. Overall, these results suggest that prenatal phenol and phthalate exposure is associated with altered miRNA expression in placenta, suggesting a potential mechanism of EDC toxicity in humans.

b. **Main KM, Mortensen GK, Kaleva MM, et al. Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in infants three months of age. Environ Health Perspect. 2006;114(2):270–276**

Abstract

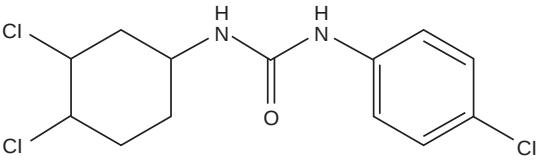
Study investigated whether phthalate monoester contamination of human breast milk had any influence on the postnatal surge of reproductive hormones in newborn boys as a sign of testicular dysgenesis. Data on reproductive hormone profiles and phthalate exposures in newborn boys are in accordance with rodent data and suggest that human Leydig cell development and function may also be vulnerable to perinatal exposure to some phthalates. Findings of studies are also in line with other recent human data showing incomplete virilization in infant boys exposed to phthalates prenatally.

c. **Carl-Gustaf Bornehag, Fredrik Carlstedt, Bo AG. Jönsson, Christian H. Lindh, Tina K. Jensen, Anna Bodin, Carin Jonsson, Staffan Janson, Shanna H. Swan, 2015. Prenatal Phthalate Exposures and Anogenital Distance in Swedish Boys. Environmental Health Perspectives, 123(1): 101-107.**

Abstract

The objective of this study was to examine the associations between prenatal phthalate exposure and AGD in Swedish infants. AGD was measured in 196 boys at 21 months of age, and first-trimester urine was analyzed for 10 phthalate metabolites of DEP (diethyl phthalate), DBP (dibutyl phthalate), DEHP, BBzP (benzylbutyl phthalate), as well as DiNP and creatinine. DDiNP is associated with a shorter AGD in boys at the age of 21 months, which is of concern because AGD has been related to male genital birth defects and impaired reproductive function in adult males.

2.4. Triclocarbon



Triclocarban, also known as TCC or 3,4,4′-trichlorocarbanilide, is an antibacterial agent commonly used in the personal care products like soaps and lotions for which it was originally developed. Research study suggests that it is similar in its mechanism to Triclosan and is active predominantly against gram-positive bacteria.[49]

Triclocarbon is used globally as an antimicrobial active ingredient in bar soaps. However, a study comparing the health effects of hand washing with antibacterial soap containing Triclocarbon and regular soap found no difference in the effectiveness at preventing infections between the two types of soap.[50] So the intention of use of Triclocarbon in the soap has been challenged. In December 2013, the Food and Drug Administration required all companies to prove within a year that Triclocarbaon is not harmful to consumers.

2.4.1 Uses of Triclocarbon

It is used globally in a wide range of personal cleansing products.

- Soaps
- Deodorants
- Detergents
- Cleansing lotions
- Wipes
- Hand wash

2.4.2 Health Impacts

The properties of the Triclocarbon are more or less similar to that of Triclosan, so has the potency to cause harm to the human health. Triclocarban has also been described as an endocrine disruptor that is described by scientists as unique in its modes of action. Triclocarban enhance the gene expression of other steroid hormones, including androgens, estrogens, and cortisol.[51,52]

49 McDonnell G, Russell AD. Antiseptics and disinfectants: activity, action, and resistance. Clin Microbiol Rev. 1999;12:147–179.

50 Stephen P Luby, Mubina Agboatwalla, Daniel R Feikin, John Painter, Ward Billhimer MS, Arshad Altaf, and Robert M Hoekstra, "Effect of handwashing on child health: a randomised controlled trial," Lancet, July 16-22, 2005.

51 Ki Chang Ahn, Bin Zhao, Jiangang Chen, Gennady Cherednichenko, Enio Sanmarti, Michael S. Denison, Bill Lasley, Isaac N. Pessah, Dietmar Kültz, Daniel P.Y. Chang, Shirley J. Gee, and Bruce D. Hammock, "In Vitro Biologic Activities of the Antimicrobials Triclocarban, Its Analogs, and Triclosan in Bioassay Screens: Receptor-Based Bioassay Screens", Environmental Health Perspectives,2010.

52 Jump up, Bill Lasley, "Triclocarban androgen- and estrogen receptor assays" Presentation at 3rd annual Pacific Southwest Organic Residuals Symposium, University of California-Davis, 2008.

Human exposure to TCC contained in commercial personal care soaps that are frequently used may enhance the activity of endogenous sex steroid hormones, suggesting that TCC as an EDC may affect male reproductive systems. In females, because the breast can be exposed to antimicrobial TCC-containing products such as soap and deodorants applied to the underarm and breast area, TCC amplification of E2-induced ER activity may harm patients with ER-positive breast cancer.

2.4.3 Triclocarban in Environment

Most of these products get washed down the drain, where they enter our waterways and are then transported widely throughout the environment. Triclocarban are found in high concentrations in sediments and sewage sludge where they can persist for decades. In the environment, antibacterial compounds could disrupt aquatic ecosystems and pose a potential risk to wildlife.[53]

2.4.4 Regulations

In India under the Bureau of Indian Standards of IS 4707(Part 2): 2009 i.e. raw materials of cosmetics, Triclocarban is allowed only in rinse-off products and maximum authorized concentration (MAC) as antimicrobial agent in the finished product is 1.5% of the product while allowed MAC as preservative is 0.2% only. Some of the major companies like Johnson & Johnson, Procter & Gamble, Colgate-Palmolive, and Avon have begun phasing out chemical use due to health concerns.[54]

Research Studies:

a. **Pycke BF, Geer LA, Dalloul M, Abulafia O, Jenck AM, Halden RU, 2014. Human fetal exposure to triclosan and triclocarban in an urban population from Brooklyn, New York. Environ Sci Technol. 014;48(15):8831-8. doi: 10.1021/es501100w. Epub 2014 Jul 15.**

Abstract

The concentrations of triclosan, triclocarbon, and its human metabolites (2′-hydroxy-TCC and 3′-hydroxy-TCC) as well as the manufacturing byproduct (3′-chloro-TCC) were determined as total concentrations after conjugate hydrolysis in maternal urine and cord blood plasma from a cohort of 181 expecting mother/infant pairs in an urban multiethnic population from Brooklyn, NY. Liquid chromatography tandem mass spectrometry was used for study which was conducted in 2007-09. Urinary levels of TCC are reported here for the first time from real-world exposures during pregnancy, showing a median concentration of 0.21 µg/L. Urinary concentrations of TCC correlated

53 http://www.nrdc.org/living/chemicalindex/triclosan.asp

54 Westervelt, Amy, http://www.theguardian.com/sustainable-business/avon-remove-triclosan-product-cosmetic-chemicals.

well with its phase-I metabolite ∑-2′-hydroxy-TCC) and the manufacturing byproduct ∑-3′-chloro-TCC C, and ∑-2′-hydroxy-TCC correlated strongly with ∑-3′-hydroxy-TCC.

b. **Ki Chang Ahn et. al., 2008. In Vitro Biologic Activities of the Antimicrobials Triclocarban, Its Analogs, and Triclosan in Bioassay Screens: Receptor-Based Bioassay Screens. Environmental Health Perspectives, 116 (9): 1203-1210**

Abstract
In this study, researchers assessed the activity of TCC, its analogs, and TCS in in-vitro nuclear-receptor–responsive and calcium signaling bioassays. TCC enhanced hormone-dependent induction of ER- and AR-dependent gene expression but had little agonist activity, suggesting a new mechanism of action of endocrine-disrupting compounds. These observations have potential implications for human and animal health. Further investigations are needed into the biological and toxicological effects of TCC, its analogs, and TCS.

2.4.5 Information on Exports-Imports[55]

India exported Triclocarban worth USD 1,658. United States is the largest buyer of triclocarban accounting for exports worth USD 1,656 followed by Poland. Average price of triclocarban per unit is USD 16.54. India imported triclocarban worth USD 658,394. China is the largest supplier of triclocarban accounting for imports worth USD 614,210 followed by Mexico and United States which exported triclocarban worth USD 43,970 and USD 215 respectively. Average price of triclocarban per unit is USD 10.45.

2.4.6 Alternatives to Triclocarban:

Triclocarban has a very limited use in the products so there are hardly any alternatives available to replace Triclocarbon.

2.5. Di-Ethanolamine

Diethanolamine, often abbreviated as DEA or DEOA, is an organic compound with the formula $HN(CH_2CH_2OH)_2$. DEA is used in the production of Diethanolamides, which is a common ingredient in cosmetics and shampoos added to confer a creamy texture and foaming action. In cosmetics Diethanolamides are present as cocamide diethanolamine, lauramide diethanolamine, linoleamide diethanolamine and oleamide diethanolamine. These compounds may contain 4–33% diethanolamine, and are present in cosmetics at concentrations of < 0.1–50%.[56]

55 https://www.zauba.com/importanalysis-triclocarban-report.html

56 Dea L (1986). 7 Final Report on the Safety Assessment of Cocamide DEA, Lauramide DEA, Linoleamide DEA, and Oleamide DEA. Int J Toxicol, 5: 415–454.

2.5.1 Uses of Di-Ethanolamine

Diethanolamine is used in:[57,58]

- Soaps
- Shampoos
- Detergents
- Cleaners
- Polishers
- Cosmetics

2.5.2 Health Impacts

The health concerns of DEA have been well documented. DEA and its compounds cause mild to moderate skin and eye irritation.[59] Diethanolamine are known for causing occupational Asthmagens.[60] Acute inhalation exposure to Diethanolamine in humans may result in irritation of the nose and throat, and dermal exposure may result in irritation of the skin.[61] The International Agency for Research on Cancer (IARC) Monograph[62] concluded that small excesses were observed for cancers at various sites, in particular the stomach, oesophagus and larynx.

DEA can react with other ingredients in the cosmetic formula to form an extremely potent carcinogen called nitrosodiethanolamine (NDEA). NDEA is readily absorbed through the skin and has been linked with stomach, esophagus, and liver and bladder cancers. The studies in animals have also reported effects on the liver, kidney, blood, and CNS from chronic oral exposure to Diethanolamine.[63]

The California Environmental Protection Agency (CalEPA) has established a chronic reference exposure level of 0.02 milligrams per cubic meter (mg/m^3) for Diethanolamine based on effects on the blood in rats. Animal studies have reported testicular degeneration and reduced sperm motility and count from oral exposure to Diethanolamine.

57 U.S. Department of Health and Human Services. Hazardous Substances Data Bank (HSDB, online database). National Toxicology Information Program, National Library of Medicine, Bethesda, MD. 1993.

58 California Environmental Protection Agency (CalEPA). Air Toxics Hot Spots Program Risk Assessment Guidelines: Part III. Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels. SRP Draft. Office of Environmental Health Hazard Assessment, Berkeley, CA. 1999.

59 Turkoglu M. and Sakr A. "Evaulation of irritation potential of surfactant mixtures." Int J Cosmet Sci. 21, 6 (Dec 1999):371-82.

60 Association of Occupational and Environmental Clinics. Description of the AOEC Exposure Code System. 2010. Available: http://www.aoecdata.org/ [accessed 17 January 2012]

61 New Jersey Department of Health. Hazardous Substance Fact Sheet on Diethanolamine. New Jersey Department of Health, Trenton, NJ. 1989.

62 IARC (2000). Some industrial chemicals. IARC Monogr Eval Carcinog Risks Hum, 77: 1–529. PMID:11236796

63 California Environmental Protection Agency (CalEPA). Air Toxics Hot Spots Program Risk Assessment Guidelines: Part III. Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels. SRP Draft. Office of Environmental Health Hazard Assessment, Berkeley, CA. 1999.

2.5.3 Di-Ethanolamine in Environment

Though the DEA can cause adverse impact on the health, however there are no evidences of DEA on the environment as such. DEA is biodegraded in water & soil as the half-life of the chemical is very less. Moreover DEA may leach to the soil when present in high concentrations.

2.5.4 Regulations

The European Commission prohibits DEA in cosmetics because of concerns on the formation of carcinogenic nitrosamines[64]. Diethanolamine (DEA) is unacceptable for use in cosmetics in Canada. This is because DEA and similar compounds like disopropanolamine (DIPA) can form harmful nitrosamines that may be linked to cancer.[65] In India Diethanolamine is banned in raw material of cosmetics under the Bureau of Indian Standards of IS 4707(part2): 2009. In 1979 the FDA ordered industry to eliminate NDEA from their products.

2.2.5 Information on Exports-Imports details[66]

India imported Diethanolamine pure worth USD 4,819,140 with total quantity of 3,159,282. kg Germany is the largest supplier of Diethanolamine pure accounting for imports worth USD 4,420,622 followed by Belgium and Russia which exported pure Diethanolamine worth USD 370,029 and USD 28,489 respectively.

Research Studies:

a. **Robin E. Dodson, Marcia Nishioka, Laurel J. Standley, Laura J. Perovich, Julia Green Brody, and Ruthann A. Rudel, 2012. Endocrine Disruptors and Asthma-Associated Chemicals in Consumer Products. Environmental Health Perspectives, 120 (7): 935-943.**

Abstract
We analytically quantified endocrine disruptors and asthma-related chemicals in a range of cosmetics, personal care products, cleaners, sunscreens, and vinyl products. We also evalu¬ated whether product labels provide information that can be used to select products without these chemicals. We selected 213 commercial products representing 50 product types. We tested 42 composited samples of high-market-share products, and we tested 43 alternative products identi¬fied using criteria expected to minimize target compounds. Analytes included parabens, phthalates, bisphenol A (BPA), triclosan, ethanolamines, alkyl phenols, fragrances, glycol ethers, cyclosiloxanes, and ultraviolet (UV) filters.

64 European Commission. 2011. CosIng. Available: http://ec.europa.eu/consumers/cosmetics/cosing [accessed 7 September 2011].
65 http://www.hc-sc.gc.ca/cps-spc/cosmet-person/labelling-etiquetage/ingredients-eng.php#a4.3
66 https://www.zauba.com/importanalysis-di-ethanolamine-report.html

CHAPTER III

Way Forward

There are established facts that Endocrine Disruptive Chemicals in personal care products can cause serious damage to the health and environment. Further, these chemical residues can enter to the environment mainly through runoff water and can enter into the food chain. However there is very limited information available on the health impact in our country.

Thus the need of the hour is to:

- Create scientific epidemiological data linking the impact of chemicals of personal care products with the human being and environment with special attention to the children.
- Generate awareness on the negative impacts of such chemicals on the endocrine system causing health concerns for human beings as well as fauna and wildlife prompting consumers "to think about it" prior to purchasing such products.
- Engage with manufacturers, importer and exporter to reduce or phase out the use of such chemicals from the products.
- Engage with the Government and with relevant stakeholders at the national and global level to bring out the policies to restrict the usage of such chemicals.
- Promote and popularise alternatives those are available and share information on these chemicals
- Undertake further research on alternatives that can be made available to people as well as manufacturers.

India imported Diethanolamine pure worth

USD 4,819,140

with total quantity of 3,159,282 kg

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U.S. FDA. Parabens. http://www.fda.gov/Cosmetics/ProductandIngredientSafety.

http://www.grimalt.net/wp-content/uploads/2013/04/parabens-2013.pdf

http://www.sciencedirect.com/science/article/pii/S089062381000078X

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http://www.ncbi.nlm.nih.gov/pubmed/22237600

http://healthandenvironmentonline.com/2013/06/17/parabens-endocrine-disruptors-in-cosmetics-and-food/

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