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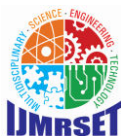
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Enactment of Hazardous Triclosan and Diethanolamine in Daily Care Shampoos Marketed in Delhi - NCR Area

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ABSTRACT: Triclosan, the antimicrobial agent marketed in Delhi-NCR area for its germ-fighting capability in personal care products, is coming under close scrutiny. In April 2010 the U.S. Food and Drug Administration (FDA) announced it is conducting a scientific and regulatory review of triclosan in FDA-regulated products, with publication of results expected in spring 2011. Triclosan is a broad-spectrum antimicrobial agent developed over 40 years ago and first introduced as a surgical scrub. Over the last 20 years its use has grown rapidly in personal care products including soap, hand sanitizer, cosmetics, and toothpaste, as well as household products such as odor-fighting socks and germ-resistant sponges, kitchenware, and bedding. One area of debate involves the hypothesis that triclosan enhances the production of chloroform, which is classified by the EPA as a probable human carcinogen.

Diethanolamine (DEA) used mostly in various cosmetic products in Delhi-NCR area and DEA-related ingredients are organic substances that function as emulsifiers to produce foam and bubbles in cosmetics. These ingredients can also be used to adjust a product's pH. In discussing the use of DEA and DEA-related ingredients in cosmetics and personal care products, it is important to understand that there are several different substances - not just one. First, DEA itself is rarely used in products. When it is used, it is added at small levels to make sure the product is not harsh when applied to the skin (adjusts the acidity).

I. INTRODUCTION

Triclosan was banned from being used in antibacterial soaps in 2016 but is still allowed in toothpaste, shampoos, and deodorants. It's a chemical antibacterial agent known to cause hormone disruptions, which can lead to cancer and affect fetal development, among other things. DEA (Diethanolamine) are emulsifiers and foam agents that reduce the surface tension between different substances so that ingredients that are water-soluble and oil-soluble can blend together. In 1998, researchers found a link between the topical application of DEA and cancer in animals during lab tests. According to the Food and Drug Administration, however, there are no proven links between the use of DEA and cancer in humans. DEA reacts quickly with preservatives to create an extremely potent carcinogen called nitrosodiethanolamine (NDEA). NDEA is easily absorbed through the skin and is linked with bladder, esophagus, liver and stomach cancer. It also prevents the uptake of choline (part of the vitamin B), required for the functioning of brain. To eliminate your exposure to NDEA, avoid these ingredients: Cocamide DEA or Cocamide Diethanolamine, DEA Lauryl Sulfate or Diethanolamine Lauryl Sulfate, Lauramide DEA or Lauramide Diethanolamine, Linoleamide DEA or Linoleamide Diethanolamine, Oleamide DEA or Oleamide Diethanolamine, and any product containing TEA or Triethanolamine.

Triclosan reacts with chlorine from the water to create chloroform, a known human carcinogen. When mixed with other ingredients, which are used for disinfection of the water, the chloroform can increase trihalomethanes, which are proven to induce cancer in laboratory animals. After decades of use in antibacterial soaps, the FDA finally banned triclosan from soap in 2016 over concerns about its long-term safety and contribution to antibiotic-resistant bacteria. However, the chemical is still permitted for use in other products, like deodorant and shampoos especially sold in Delhi area-NCR[1]

Diethanolamine is an ingredient commonly used in deodorants, as well as other personal care products. Diethanolamine is linked to cancer. Ethoxylation, the process of treating the ingredient with ethylene oxide, is used in the production of diethanolamine. 1,4-dioxane, a known carcinogen, is a by-product of ethoxylation. Diethanolamine can be spotted on labels with the term "diethanolamine" or as the abbreviation DEA. DEA can be part of complex ingredients like

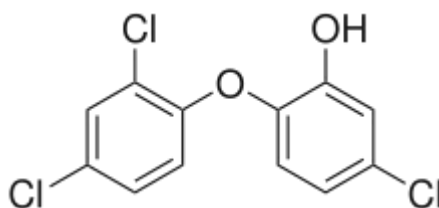
Cocamide-DEA and DEA-Cetyl Phosphate, although these complexes aren't as common in deodorants and shampoos especially sold in Delhi area-NCR.

Triclosan chemical was first registered as a pesticide with EPA in 1969, but since 1990's it is being widely used in 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. [2]

Diethanolamine, often abbreviated as DEA or DEOA, is an organic compound with the formula $\text{HN}(\text{CH}_2\text{CH}_2\text{OH})_2$. Pure diethanolamine is a white solid at room temperature, but its tendencies to absorb water and to supercool mean it is often encountered as a colorless, viscous liquid. Diethanolamine is polyfunctional, being a secondary amine and a diol. Like other organic amines, diethanolamine acts as a weak base. Reflecting the hydrophilic character of the secondary amine and hydroxyl groups, DEA is soluble in water. Amides prepared from DEA are often also hydrophilic. In 2013, the chemical was classified by the International Agency for Research on Cancer as "possibly carcinogenic to humans"

II. DISCUSSION

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 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. 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. 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. Triclosan also belongs to the group of drugs, such as isoniazid (for curing tuberculosis) and diazaborine (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. 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". Triclosan was found to have estrogenic and androgenic activities in human breast cancer cells, which could potentially stimulate the growth development of cancer cells.[3]



Chemical structure of triclosan (Preferred IUPAC name : 5-Chloro-2-(2,4-dichlorophenoxy)phenol

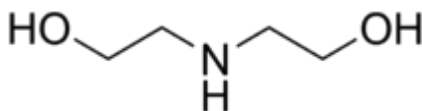
This organic compound is a white powdered solid with a slight aromatic, phenolic odor. Categorized as a polychloro phenoxy phenol, triclosan is a chlorinated aromatic compound that has functional groups representative of both ethers and phenols. Phenols often demonstrate antibacterial properties. Triclosan is soluble in ethanol, methanol, diethyl ether, and strongly basic solutions such as a 1M sodium hydroxide solution, but only slightly soluble in water. Triclosan can be synthesized from 2,4-dichlorophenol. Triclosan (TCS) was patented in 1964 by Swiss company Ciba-Geigy. The earliest known safety testing began in 1968. It was introduced the next year, mainly for use in hospitals, and was in worldwide production and use by the early 1970s.

In light of mounting evidence on the human health and ecotoxic effects of triclosan, some companies reformulated to remove it in advance of regulation: Colgate-Palmolive removed it from Palmolive Dish Soap and Softsoap in 2011 (but it remained in Colgate Total toothpaste until late 2018 or early 2019); Johnson & Johnson removed it from baby products in 2012 and all products in 2015; Procter & Gamble from all products in 2014; In 2014 it was removed from Clearasil and Avon began phasing it out; and Unilever removed it from skin care and cleansing products in 2015, and says oral care by 2017.[4]



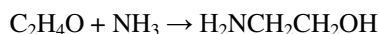
DEA is used as a surfactant and a corrosion inhibitor. It is used to remove hydrogen sulfide and carbon dioxide from natural gas.

Diethanolamine is widely used in the preparation of diethanolamides and diethanolamine salts of long-chain fatty acids that are formulated into soaps and surfactants used in liquid laundry and dishwashing detergents, cosmetics, shampoos and hair conditioners.^[5] In oil refineries, a DEA in water solution is commonly used to remove hydrogen sulfide from sour gas. It has an advantage over a similar amine, ethanolamine, in that a higher concentration may be used for the same corrosion potential. This allows refiners to scrub hydrogen sulfide at a lower circulating amine rate with less overall energy usage. DEA is a chemical feedstock used in the production of morpholine

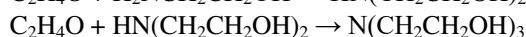


Chemical structure of diethanolamine

The reaction of ethylene oxide with aqueous ammonia first produces ethanolamine:



which reacts with a second and third equivalent of ethylene oxide to give DEA and triethanolamine:



About 300M kg are produced annually in this way.^[3] The ratio of the products can be controlled by changing the stoichiometry of the reactants.

DEA is used in the production of diethanolamides, which are common ingredients in cosmetics and shampoos added to confer a creamy texture and foaming action. Consequently, some cosmetics that include diethanolamides as ingredients contain DEA.^[5]

Preferred IUPAC name: 2,2'-Azanediyldi(ethan-1-ol)

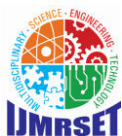
III. RESULTS

The National Capital Region (NCR) is a planning region centred upon the National Capital Territory (NCT) of Delhi in India. It encompasses Delhi and several districts surrounding it from the states of Haryana, Uttar Pradesh and Rajasthan. The NCR and the associated National Capital Region Planning Board were created in 1985 to plan the development of the region and to evolve *harmonized policies for the control of land-uses and development of infrastructure* in the region. Prominent cities of NCR include Delhi, Faridabad, Ghaziabad, Gurugram, and Noida.

The NCR is a *rural-urban* region, with a population of over 46,069,000 and an urbanisation level of 62.6%. As well as the cities and towns, the NCR contains ecologically sensitive areas like the Aravalli ridge, forests, wildlife and bird sanctuaries. The Delhi Extended Urban Agglomeration, a part of the NCR, had an estimated GDP of \$370 billion (measured in terms of GDP PPP) in 2015–16.^[6]

Marketing of daily care shampoos containing hazardous triclosan and diethanolamine. 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”. There are some chemicals which are being identified 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.^[7]

The chemical structure of Triclosan is similar to 17β-estradiol. Triclosan has many biological effects mediated via estrogen receptors. It may cause implantation failure due to their ability to mimic estrogen in humans. Triclosan was found to have estrogenic and androgenic activities in human breast cancer cells, which could potentially stimulate the growth development of cancer cells. 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. 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 endocrinedisrupting effect on thyroid hormones. 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 development. There is clear evidence that disruption of normal steroidal hormone levels, such as estrogen or testosterone, during pregnancy can lead to altered brain development. 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. 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. 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. Consumers and manufacturers may have questions about the safety of diethanolamine (DEA) and related ingredients in cosmetics. The NTP completed a study in 1998 that found an association between the topical application of DEA and certain DEA-related ingredients and cancer in laboratory animals. For the DEA-related ingredients, the NTP study suggests that the carcinogenic response is linked to possible residual levels of DEA. The NTP study did not establish a link between DEA and the risk of cancer in humans.[8]

DEA and DEA-related ingredients function as emulsifiers or foaming agents in cosmetics, or to adjust a product's pH (acidity). Based on information filed with FDA's Voluntary Cosmetic Registration Program, it appears that DEA and DEA-related ingredients are used much less frequently in cosmetic products than they were when the NTP completed its study. FDA believes that at the present time there is no reason for consumers to be alarmed based on the use of these substances in cosmetics. However, consumers wishing to avoid cosmetics containing DEA or DEA-related ingredients may do so by reviewing the ingredient statement that is required to appear on the outer container label of cosmetics offered for retail sale to consumers. If FDA determines that a health hazard exists, the agency will advise the industry and the public and will consider its legal options under the authority of the Federal Food, Drug, and Cosmetic Act in protecting the health and welfare of consumers.

FDA Authority Over Cosmetics

Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded

Diethanolamine is used in a number of consumer products, such as shampoos, cosmetics, and pharmaceuticals. Limited information is available on the health effects of diethanolamine.

Acute Effects: 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. (2) Animal studies indicate that exposure to diethanolamine by intravenous injections can cause increased blood pressure, pupillary dilatation, and salivation. At very high doses in animals, sedation, and coma may result. (1) Acute animal studies have shown that dermal exposure to diethanolamine may burn skin, and eye contact with the chemical may impair vision. (1) Acute animal tests in rats have shown diethanolamine to have moderate acute toxicity from oral exposure.

Chronic Effects (Noncancer): No information is available on the chronic effects of diethanolamine in humans. Animal studies have reported effects on the liver, kidney, blood, and CNS from chronic oral exposure to diethanolamine. (4,7) Skin lesions were observed in mice following daily topical administration of diethanolamine. (7) EPA has not established a Reference Concentration (RfC) or a Reference Dose (RfD) for diethanolamine.

Reproductive/Developmental Effects: No information is available on the reproductive or developmental effects of diethanolamine in humans. Animal studies have reported testicular degeneration and reduced sperm motility and count from oral exposure to diethanolamine. **Cancer Risk:** No information is available on the carcinogenic effects of diethanolamine in humans. The NTP reported an increased incidence of liver and kidney tumors in mice and no increased incidence in rats from dermal exposure to diethanolamine. (4) EPA has not classified diethanolamine for carcinogenicity.[9]



IV. CONCLUSION

The Expert Panel concluded that diethanolamine and the 16 related salts listed below are safe in the present practices of use and concentration when formulated to be nonirritating. The Expert Panel cautions that ingredients should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

- Diethanolamine
- Diethanolamine bisulfate*
- DEA-C12-13 alkyl sulfate*
- DEA-C12-15 alkyl sulfate*
- DEA-C12-13 pareth-3 sulfate*
- DEA-cetyl sulfate*
- DEA-cocoamphodipropionate*
- DEA-dodecylbenzenesulfonate*
- DEA-istearate*
- DEA-laureth sulfate
- DEA-lauryl sulfate
- DEA-linoleate
- DEA-methyl myristate sulfonate*
- DEA-myreth sulfate*
- DEA-myristate*
- DEA-myristyl sulfate*
- DEA stearate

*Were ingredients in this group not in current use to be used in the future; the expectation is that they would be used at concentrations that would be nonirritating in formulation. It is proposed in case of triclosan the following information be collected :

1. Nature of activity(ies) and types of products. For example, was triclosan used to manufacture and/or imported in cosmetics, natural health products, drugs or cleaning products.
2. Base year and quantity of triclosan used to manufacture or imported in products in that year, in kilograms.
3. Year the P2 Plan was prepared and quantity of triclosan used to manufacture or imported in products in that year, in kilograms.
4. Year the P2 Plan is expected to be implemented and the predicted quantity of triclosan to be used to manufacture or imported in products in that year, in kilograms.
5. The maximum anticipated quantity of triclosan to be used to manufacture or imported in products in any year following the implementation of the plan.
6. A description of all anticipated actions to be taken in implementing the P2 Plan. If the anticipated action includes the use of alternative substances, identification of the chemical name or common name, and CAS RN (if available) of the substance, and a description of any hazard assessments conducted.
7. A description of how the reduction target and other pollution prevention actions identified in the P2 Plan will be maintained following implementation of the plan.
8. If the person anticipates that the P2 Plan will not meet the risk management objective, an explanation of why.[10]
9. A description of what has been done to take into account the "Factors to Consider in Preparing the Plan", except those factors for which a waiver, if applicable, has been granted by the Minister of Environment.
10. Signature of the person subject to the Notice or duly authorized representative to certify that a P2 Plan has been prepared and is being implemented and that the information provided is true, accurate and complete.

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