

**MYTH ▶ A SMALL AMOUNT OF A CHEMICAL
CARCINOGEN IN A PERSONAL CARE
PRODUCT ISN'T DANGEROUS****FACTS ▼**

- ▶ When laboratory animals were tested with 1,4-Dioxane at the lowest parts per billion level—over the animal's lifetime—they developed cancer. [1], [2]
- ▶ The levels of 1,4-Dioxane found in many personal care products are 1,000 times higher than those found to cause cancer in laboratory animals. Based on this fact, these should not be considered "low levels" of 1,4-Dioxane. [3]
- ▶ The combined effects of lifetime exposure to 1,4-Dioxane and other carcinogens can create synergistic effects, so that levels from multiple compounds add up and even multiply to create greater risk. [3]

**MYTH ▶ ANIMAL STUDIES ARE IRRELEVANT
TO IDENTIFYING PROBABLE HUMAN
CARCINOGENS****FACTS ▼**

- ▶ Because we cannot ethically test carcinogens on a human population, the World Health Organization and most domestic & international regulatory bodies have advised that chemicals that are found to induce cancer in rodents should be considered to cause cancer in humans. [4]
- ▶ "It is also noteworthy that all known carcinogenic agents for man have been shown to be also carcinogenic in animals and frequently in the same site. Hence, common pathogenetic factors are clearly involved in the development of cancer in man and in animals." -Roy Hertz, M.D., PH.D., of the National Institutes of Health. [5], [6]

**MYTH ▶ 1,4-DIOXANE ISN'T READILY
ABSORBED THROUGH THE SKIN****FACTS ▼**

- ▶ According to a California state health official's memorandum 1,4-Dioxane "is readily absorbed through the lungs, skin and gastrointestinal tract of mammals." [7]
- ▶ The FDA has stated that, "Skin absorption studies demonstrated that dioxane readily penetrates animal and human skin from various types of vehicles."
- ▶ For example, during exposure to 1,4-Dioxane from a bath product, a person's skin is warmed, pores are opened, the skin is soaked in the contaminated water, and 1,4-Dioxane enters the bloodstream. 1,4-Dioxane is also released as a gas and is inhaled as it is trapped in the enclosed area of the bathroom or shower.

**MYTH ▶ 1,4-DIOXANE'S TOXICITY
IS QUESTIONABLE****FACTS ▼**

- ▶ US federal regulation systems (specifically, the Integrated Risk Information System) consider dioxane's potency to be equivalent or greater than many pesticides considered to be dangerous to human health. [8]
- ▶ The Environmental Protection Agency classifies 1,4-Dioxane as a "Group B2, probable human carcinogen," based on "induction of nasal cavity and liver carcinomas in multiple strains of rats, liver carcinomas in mice, and gall bladder carcinomas in guinea pigs." [1]
- ▶ The State of California's EPA lists 1,4-Dioxane on its publicly mandated annual list of chemicals known to cause cancer or reproductive toxicity. [9]
- ▶ According to the New Jersey Department of Health and Senior Services 1,4-Dioxane "should be handled as a **Carcinogen—With Extreme Caution.**" [10]
- ▶ In federally funded National Toxicology Program studies, the chemical has induced cancer in both sexes of rats and both sexes of mice. [2]
- ▶ "There is sufficient evidence for the carcinogenicity of 1,4-Dioxane in experimental animals," notes the most recent Eleventh Annual Report on Carcinogens, published by the US Department of Health and Human Services, National Toxicology Program, which lists chemicals reasonably anticipated to cause human cancer. [11]
- ▶ The federal Consumer Product Safety Commission (CSPC) reports that "the presence of 1,4-Dioxane, even as a trace contaminant, is cause for concern."
- ▶ According to the International Agency for Research on Cancer, 1,4-Dioxane is "possibly carcinogenic to humans (Group 2B)." [12]
- ▶ According to Belgian & German regulators, a massive recall of a popular line of bodycare products designed for children was mandated because the product "presents a chemical risk to children because it contains 1,4 dioxane." [13]
- ▶ According to a risk calculation performed using guidelines from the State of California's Safe Drinking Water and Toxic Enforcement Act, a single product containing 1,4-Dioxane could lead to 970 excess cancers in one million. Even if this were off by a factor of ten the risk would still be 97 excess cancers, and this remains noteworthy—especially for a cosmetic product.
- ▶ According to a California state health official's memorandum 1,4-Dioxane "is readily adsorbed through the lungs, skin and gastrointestinal tract of mammals." [14]

- ▶ Because dioxane causes cancer in animals, workers in the US have a right to some basic protections. One of these is to be informed they are handling or exposed to a cancer-causing chemical. But when it comes to our homemakers, caregivers and children who are exposed regularly if not daily to this chemical and without protective gear, manufacturers are not required by law to label it as a carcinogen due to federal regulatory loopholes in the Food Drug and Cosmetic Act.

MYTH ▶ COSMETICS ARE CAREFULLY REGULATED BY THE FDA

FACTS ▼

- ▶ The FDA does not conduct or require independent pre-market safety testing of new products or chemicals. The cosmetics and personal care products industry must provide its own safety testing.
- ▶ Companies are industry allowed to provide data to the FDA regarding the safety of their own product ingredients by funding scientific review boards comprised of doctors and toxicologists which they select. In this way, companies seeking to profit from products may influence the selection of study results submitted to the FDA submits.
- ▶ Once a product is on the market, the burden of legal proof required for its removal is extremely high.
- ▶ Since cancer and birth defects are often latent occurrences, it is difficult if not impossible to prove causation in the judicial system. Therefore, it is nearly impossible to remove a potentially dangerous product.

MYTH ▶ THE CONTAMINATION OF PRODUCTS WITH 1,4-DIOXANE IS AN ISOLATED OCCURRENCE

FACTS ▼

- ▶ Cosmetics contaminated with 1,4-Dioxane might also have traces of formaldehyde, nitrosamines, phthalates and other contaminants. [15] According to David Steinman, author of *Safe Trip to Eden: Ten Steps to Save Planet Earth from the Global Warming Meltdown*: "I can go into any store and at least half if not more than three fourths of the products with suspect ingredients will actually be found to contain a number of known and suspected carcinogens."

MYTH ▶ CLEANING UP 1,4-DIOXANE CHEMICALS WOULD BE COST-PROHIBITIVE TO COMPANIES AND CONSUMERS

FACTS ▼

- ▶ There are many inexpensive and effective alternatives to ethoxylation and to the ingredients implicated in the creation of 1,4-Dioxane in widespread use among many leading personal care products.
- ▶ For example, laboratory studies show 1,4-Dioxane is non-existent in the variety of products produced and certified under the USDA National Organic Program.
- ▶ According to the FDA Cosmetic Handbook, the cost of removing or "vacuum stripping" out this chemical carcinogen after it has been created is extremely low, and the raw materials are readily available. [16]

REFERENCES

- [1] "1,4-Dioxane (1,4-Diethyleneoxide). Hazard Summary—Created in April 1992; Revised in January 2000." US Environmental Protection Agency. www.epa.gov/ttn/atw/hlthef/dioxane.html
- [2] "Bioassay of 1,4-Dioxane for possible carcinogenicity (CAS No. 123-91-1)." National Toxicology Program, TR-80.
- [3] Reif, A.E. "Synergism in carcinogenesis." *J Natl Cancer Institute*, 1984 Jul; 73(1): 25-39.
- [4] Fitzhugh, O.G., et al. "Chronic oral toxicity of aldrin and dieldrin in rats and dogs." *Fd. Cosmet. Toxicol.*, 1964; 2: 551-562; Walker A.I.T., et al. "The toxicology and pharmacodynamics of dieldrin: two year oral exposure of rats and dogs," *Toxicol. Appl. Pharmacol.*, 1960; 15: 345-373; National Cancer Institute, Bioassay of Chlordane for Possible Carcinogenicity, Carcinogenesis Technical Report Series #8, 1977; Japanese Research Institute for Animal Science and Biochemistry and Toxicology, Thirty Month Chronic Toxicity and Tumorigenicity Tests in Rats with Chlordane Technical, Confidential Report to Velsicol Chemical Co., December 1983.
- [5] Hertz, R. "The problem of possible effects of oral contraceptives on cancer of the breast." *Cancer*, December 1969: 1140-1145.
- [6] Hertz, R. "The estrogen-cancer hypothesis with special emphasis on DES." In *Origins of Human Cancer*, edited by H.H. Hiatt, J.D. Watson, and J.A. Winston, pp. 1665-1682. Vol. 4 of Cold Spring Harbor Conference on Cell Proliferation. Cold Spring Harbor Laboratory, 1977.
- [7] Spath, D.P., op cit.
- [8] "1,4-Dioxane (1,4-Diethyleneoxide). Hazard Summary—Created in April 1992; Revised in January 2000." www.epa.gov/ttn/atw/hlthef/dioxane.html Compare with oral slope factor for another probable human carcinogen, captan: "Captan. Hazard Summary—Created in April 1992; Revised in January 2000." www.epa.gov/ttnatw01/hlthef/captan.html
- [9] "Chemicals Known to the State to Cause Cancer or Reproductive Toxicity." 12/8/06. www.oehha.ca.gov/prop65/prop65_list/files/P65single120806.pdf
- [10] "Hazardous Substance Fact Sheet." NJ Department of Health and Senior Services. www.state.nj.us/health/eoh/rtkweb/0789.pdf
- [11] *Report on Carcinogens*, op cit.
- [12] "1,4-Dioxane (Group 2B)." Int'l Agency for Research on Cancer. Vol. 71, 1999: 589.
- [13] www.ec.europa.eu/consumers/dyna/rapex/create_rapex.cfm?rx_id=99
- [14] Spath, D.P. "1,4-Dioxane Action Level." 3/24/98. Memorandum from Spath, Chief of the Division of Drinking Water & Environmental Management, Dept. of Health Services, 601 N. 7th St., Sacramento, CA 95814 to George Alexeff, Deputy Director for Scientific Affairs, Office of Environmental Health Hazard Assessment. www.oehha.ca.gov/water/pals/pdf/PAL14DIOXAN.pdf
- [15] Steinman, D. & Epstein, S. *The Safe Shopper's Bible*. New York, NY: Macmillan, 1995, pp. 190-196.
- [16] *Cosmetic Handbook*, op cit.
- [17] Gouveia-Vigeant, T. & Tickner, J. "Toxic chemicals and childhood cancer: A review of the evidence." Lowell Center for Sustainable Production, Univ. of Massachusetts Lowell, One University Avenue, Lowell, MA 01854. www.sustainableproduction.org/downloads/Child%20Canc%20Exec%20Summary.pdf
- [18] US Food & Drug Administration, Center for Food Safety & Applied Nutrition, FDA/IAS* Booklet: 1992 *Cosmetic Handbook*. www.cfsan.fda.gov/~dms/cos-hdb3.html

—Adopted From The Campaign For Safe Cosmetics



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