1,4-DIOXANE

1. PUBLIC HEALTH STATEMENT

This public health statement tells you about 1,4-dioxane and the effects of exposure to it.

The Environmental Protection Agency (EPA) identifies the most serious hazardous waste sites in the nation. These sites are then placed on the National Priorities List (NPL) and are targeted for long-term federal clean-up activities. 1,4-Dioxane has been found in at least 31 of the 1,689 current or former NPL sites. Although the total number of NPL sites evaluated for this substance is not known, the possibility exists that the number of sites at which 1,4-dioxane is found may increase in the future as more sites are evaluated. This information is important because these sites may be sources of exposure, and exposure to this substance may be harmful.

When a substance is released either from a large area, such as an industrial plant, or from a container, such as a drum or bottle, it enters the environment. Such a release does not always lead to exposure. You can be exposed to a substance only when you come in contact with it. You may be exposed by breathing, eating, or drinking the substance, or by skin contact.

If you are exposed to 1,4-dioxane, many factors will determine whether you will be harmed. These factors include how much (the dose), how long (the duration), and how you come in contact with it. You must also consider any other chemicals you are exposed to and your age, sex, diet, family traits, lifestyle, and state of health.

1.1 WHAT IS 1,4-DIOXANE?

Clear liquid with faint odor	1,4-Dioxane is a clear liquid with a faint pleasant odor. It mixes easily with water.
A solvent and laboratory reagent	It is used as a solvent in the manufacture of other chemicals and as a laboratory reagent.
A contaminant	1,4-Dioxane is a trace contaminant of some chemicals used in cosmetics, detergents, and shampoos.Manufacturers now reduce 1,4-dioxane from these chemicals to low levels before these chemicals are made into products used in the home.

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1.2 WHAT HAPPENS TO 1,4-DIOXANE WHEN IT ENTERS THE ENVIRONMENT?

Found in air and water	1,4-Dioxane can be released into the air, water, and soil at places where it is produced or used as a solvent.
	In soil, 1,4-dioxane does not stick to soil particles, so it can move from soil into groundwater.
Break down	Compounds in the air can break down 1,4-dioxane into different compounds rapidly.
	In water, 1,4-Dioxane is stable and does not break down.

For more information on 1,4-dioxane in the environment, see Chapter 6.

1.3 HOW MIGHT I BE EXPOSED TO 1,4-DIOXANE?

Air	You can be exposed to 1,4-dioxane by breathing contaminated air.
	Current levels of 1,4-dioxane in air are not known. In the mid-1980s, average levels of 1,4-dioxane in air samples from the United States were about:
	 0.4 micrograms per cubic meter (μg/m³) for outdoor air 4 μg/m³ for indoor air
Water	You can be exposed to 1,4-dioxane in tap water.
	Current levels of 1,4-dioxane in water are not known. In the 1970s, the level of 1,4-dioxane in drinking water was 1 microgram per liter of water (1 μ g/L).
Consumer products	Your skin may come into contact with 1,4-dioxane when you use cosmetics, detergents, and shampoos containing 1,4-dioxane.
	During 1992–1997, the average concentration of 1,4-dioxane in some cosmetic products reportedly ranged from 14 to 79 mg/kg. In a more recent survey reported by the Campaign for Safe Cosmetics, the levels of 1,4-dioxane in cosmetic products were found to be lower (1.5–12 ppm in baby and children's products and 2–23 ppm in adult products) than in the survey done by the FDA in the 1990s.

For more information on human exposure to 1,4-dioxane, see Chapter 6.

1.4 HOW CAN 1,4-DIOXANE ENTER AND LEAVE MY BODY?

Rapidly enters your body	When you breathe air containing 1,4-dioxane, almost all of it will rapidly enter your body through your lungs. Almost all of the 1,4-dioxane in your drinking water will rapidly enter your body through the digestive tract.
Skin	Studies have found that some 1,4-dioxane can pass through skin when applied with certain preparations such as lotions, but much of it will evaporate before it can be absorbed.
Rapidly leaves your body	Once in your body, 1,4-dioxane is broken down into other chemicals. These other chemicals rapidly leave your body in the urine.

1.5 HOW CAN 1,4-DIOXANE AFFECT MY HEALTH?

This section looks at studies concerning potential health effects in animal and human studies.

The effects of 1,4-dioxane on human health depends on how much 1,4-dioxane you are exposed to and the length of exposure. The limited environmental monitoring data available suggest that the levels of 1,4-dioxane to which the general public might be exposed through contact or use of consumer products (including food), or that are normally found in environmental media, are generally significantly lower than those used in studies with experimental animals.

Short-term exposure effects	Eye and nose irritation was reported by people exposed to low levels of 1,4-dioxane for short periods of time. Exposure to very high levels may cause severe kidney and liver effects and possibly death.
Long-term exposure effects	Studies in animals have shown that breathing vapors of 1,4-dioxane affects mainly the nasal cavity and the liver and kidneys. Swallowing liquid 1,4-dioxane or contaminated drinking water, or having skin contact with liquid 1,4-dioxane also affects the liver and kidneys.

May cause cancer	Studies in workers did not indicate whether 1,4-dioxane causes cancer.
	Laboratory rats that breathed vapors of 1,4-dioxane during most of their lives developed cancer inside the nose and in the abdominal cavity; they also developed benign tumors in the liver. Laboratory rats and mice that drank water containing 1,4-dioxane during most of their lives developed liver cancer; the rats also developed cancer inside the nose. Some scientists believe that 1,4-dioxane may cause cancer by a nongenotoxic mechanism. Scientists are debating the degree to which the findings in rats and mice apply to exposure situations commonly encountered by people.
	The International Agency for Research on Cancer (IARC) has determined that 1,4-dioxane is possibly carcinogenic to humans.
	The U.S. Department of Health and Human Services (HHS) considers 1,4-dioxane as reasonably anticipated to be a human carcinogen.
	The EPA has established that 1,4-dioxane is likely to be carcinogenic to humans.

Further information on the health effects of 1,4-dioxane in humans and animals can be found in Chapters 2 and 3.

1.6 HOW CAN 1,4-DIOXANE AFFECT CHILDREN?

This section discusses potential health effects in humans from exposures during the period from conception to maturity at 18 years of age.

Children are likely to have similar effects as adults	No data describe the effects of exposure to 1,4-dioxane on children or immature animals. It is likely that children would show the same health effects as adults. We do not know whether children differ from adults in their susceptibility to the effects of 1,4-dioxane.
Birth defects	We do not know whether 1,4-dioxane can harm an unborn child.

1.7 HOW CAN FAMILIES REDUCE THEIR EXPOSURE TO 1,4-DIOXANE?

Limit children's exposure to consumer products which may contain 1,4-dioxane	 1,4-Dioxane may be a contaminant in certain ingredients used in cosmetics, detergents, shampoos, and some pharmaceuticals. 1,4-Dioxane is not intentionally added, but may occur as an unintentional byproduct in some ingredients, that may be listed on the product label, including: PEG polyethylene polyethylene glycol polyoxyethylene -eth -oxynol Many products on the market today (foods, pharmaceuticals, cosmetic products, detergents, etc.) contain 1,4-dioxane in very small amounts. However, some cosmetics, detergents, and shampoos may contain 1,4-dioxane at levels higher than recommended by the FDA for other products. Families wishing to avoid cosmetics containing the ingredients listed above may do so by reviewing the ingredient statement that is required to appear on the outer container label of cosmetics offered for retail sale.
Limit exposure to contaminated drinking water	1,4-Dioxane has been detected in some drinking water supplies. Bottled water may be less likely to be contaminated with 1,4-dioxane, and consumers should contact the bottler with specific questions on potential contaminants.

1.8 IS THERE A MEDICAL TEST TO DETERMINE WHETHER I HAVE BEEN EXPOSED TO 1,4-DIOXANE?

Can be measured in blood and urine	1,4-Dioxane and its breakdown products (metabolites) can be measured in blood and urine.
	The detection of 1,4-dioxane or these metabolites cannot be used to predict the kind of health effects that might develop from that exposure.
	The tests need to be conducted within days after exposure because 1,4-dioxane and its metabolites leave the body fairly rapidly.

For more information on the different substances formed by 1,4-dioxane breakdown and on tests to detect these substances in the body, see Chapters 3 and 7.

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1.9 WHAT RECOMMENDATIONS HAS THE FEDERAL GOVERNMENT MADE TO PROTECT HUMAN HEALTH?

The federal government develops regulations and recommendations to protect public health. Regulations *can* be enforced by law. The EPA, the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA) are some federal agencies that develop regulations for toxic substances. Recommendations provide valuable guidelines to protect public health, but *cannot* be enforced by law. The Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health (NIOSH) are two federal organizations that develop recommendations for toxic substances.

Regulations and recommendations can be expressed as "not-to-exceed" levels, that is, levels of a toxic substance in air, water, soil, or food that do not exceed a critical value that is usually based on levels that affect animals; they are then adjusted to levels that will help protect humans. Sometimes these not-to-exceed levels differ among federal organizations because they used different exposure times (an 8-hour workday or a 24-hour day), different animal studies, or other factors.

Recommendations and regulations are also updated periodically as more information becomes available. For the most current information, check with the federal agency or organization that provides it.

Levels in drinking water set by EPA	The EPA has determined that exposure to 1,4-dioxane in drinking water at concentrations of 4 mg/L for one day or 0.4 mg/L for 10 days is not expected to cause any adverse effects in a child.
Levels in workplace air set by OSHA	OSHA set a legal limit of 100 ppm 1,4-dioxane in air averaged over an 8-hour work day.
Levels set by NAS	The National Academy of Sciences (NAS) established a maximum specification of 10 ppm for 1,4-dioxane in the ingredient polysorbate, a food additive.

Some regulations and recommendations for 1,4-dioxane include the following:

	FDA considered 10 ppm to be an acceptable limit for 1,4-dioxane during its evaluation of a spermicide, N-9, in a contraceptive sponge product.
	FDA also set a limit on 1,4-dioxane at 10 ppm in approving glycerides and polyglycerides for use as excipients in products such as dietary supplements.
	FDA keeps a record of raw materials and products contaminated with 1,4-dioxane.

1.10 WHERE CAN I GET MORE INFORMATION?

If you have any more questions or concerns, please contact your community or state health or environmental quality department, or contact ATSDR at the address and phone number below.

ATSDR can also tell you the location of occupational and environmental health clinics. These clinics specialize in recognizing, evaluating, and treating illnesses that result from exposure to hazardous substances.

Toxicological profiles are also available on-line at www.atsdr.cdc.gov and on CD-ROM. You may request a copy of the ATSDR ToxProfiles[™] CD-ROM by calling the toll-free information and technical assistance number at 1-800-CDCINFO (1-800-232-4636), by e-mail at cdcinfo@cdc.gov, or by writing to:

Agency for Toxic Substances and Disease Registry Division of Toxicology and Environmental Medicine 1600 Clifton Road NE Mailstop F-62 Atlanta, GA 30333 Fax: 1-770-488-4178

Organizations for-profit may request copies of final Toxicological Profiles from the following:

National Technical Information Service (NTIS) 5285 Port Royal Road Springfield, VA 22161 Phone: 1-800-553-6847 or 1-703-605-6000 Web site: http://www.ntis.gov/