

1. PUBLIC HEALTH STATEMENT

This public health statement tells you about di(2-ethylhexyl) phthalate (DEHP) and the effects of exposure.

The Environmental Protection Agency (EPA) identifies the most serious hazardous waste sites in the nation. These sites make up the National Priorities List (NPL) and are the sites targeted for long-term federal cleanup activities. DEHP has been found in at least 737 of the 1,613 current or former NPL sites. However, the total number of NPL sites evaluated for DEHP is not known. As more sites are evaluated, the sites at which DEHP is found may increase. This information is important because exposure to DEHP may harm you and because these sites may be sources of exposure.

When a substance is released from a large area, such as an industrial plant, or from a container, such as a drum or bottle, it enters the environment. This release does not always lead to exposure. You are 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 DEHP, many factors determine whether you'll be harmed. These factors include the dose (how much), the duration (how long), and how you come in contact with it. You must also consider the other chemicals you're exposed to and your age, sex, diet, family traits, lifestyle, and state of health.

1.1 WHAT IS DEHP?

DEHP, which is an abbreviation for di(2-ethylhexyl) phthalate, is a manufactured chemical that is commonly added to plastics to make them flexible. Other names for this compound are dioctyl phthalate (DOP) and bis(2-ethylhexyl) phthalate (BEHP). (Note that di-n-octyl phthalate, however, is the name for a different chemical.) Trade names used for DEHP include Platinol DOP, Octoil, Silicol 150, Bisoflex 81, and Eviplast 80. DEHP is a colorless liquid with almost no odor. It does not evaporate easily, and little will be present in the air even near

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sources of production. It dissolves more easily in materials such as gasoline, paint removers, and oils than it does in water. It is present in many plastics, especially vinyl materials, which may contain up to 40% DEHP, although lower levels are common. DEHP is present in plastic products such as wall coverings, tablecloths, floor tiles, furniture upholstery, shower curtains, garden hoses, swimming pool liners, rainwear, baby pants, dolls, some toys, shoes, automobile upholstery and tops, packaging film and sheets, sheathing for wire and cable, medical tubing, and blood storage bags. Additional information on the properties of DEHP and its uses is found in Chapters 4 and 5.

1.2 WHAT HAPPENS TO DEHP WHEN IT ENTERS THE ENVIRONMENT?

DEHP can enter the environment through releases from factories that make or use DEHP and from household items containing it. Over long periods of time, it can move out of plastic materials into the environment. Therefore, DEHP is widespread in the environment; about 291,000 pounds were released in 1997 from industries. It is often found near industrial settings, landfills, and waste disposal sites. A large amount of plastic that contains DEHP is buried at landfill sites. DEHP has been found in groundwater near waste disposal facilities.

When DEHP is released to soil, it usually attaches strongly to the soil and does not move very far away from where it was released. When DEHP is released to water, it dissolves very slowly into underground water or surface waters that contact it. It takes many years before DEHP in buried or discarded materials disappears from the environment. Because DEHP does not evaporate easily, normally very little goes into the air. DEHP in air will bind to dust particles and will be carried back down to earth through gravity and rain or snow. Indoor releases of DEHP to the air from plastic materials, coatings, and flooring in home and work environments, although small, can lead to higher indoor levels than are found in the outdoor air.

DEHP can break down in the presence of other chemicals to produce mono(2-ethylhexyl)-phthalate (MEHP) and 2-ethylhexanol. Many of the properties of MEHP are like those of DEHP, and therefore its fate in the environment is similar. In the presence of oxygen, DEHP in water and soil can be broken down by microorganisms to carbon dioxide and other simple

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chemicals. DEHP does not break down very easily when deep in the soil or at the bottom of lakes or rivers where there is little oxygen. It can be found in small amounts in fish and other animals, and some uptake by plants has been reported. You will find additional information on the fate of DEHP in the environment in Chapters 5 and 6.

1.3 HOW MIGHT I BE EXPOSED TO DEHP?

You can be exposed to DEHP through air, water, or skin contact with plastics that have DEHP in them. Food may also contain DEHP, but it is not certain how much.

It is not clear, but it is likely that a little DEHP is transferred by skin contact with plastic clothing or other articles that contain DEHP. Exposure through this route is expected to be low since plastic articles of clothing, like raincoats, do not have direct contact with your skin, and transfer is probably very low even if they do touch you.

You may be exposed to DEHP through drinking water, but it is not known how common this is. If you drink water from a well located near a landfill or waste site, you may be exposed to higher-than-average levels of DEHP.

You can breathe in DEHP that has been released to the environment. The average air level of DEHP is very low, less than 2 parts of DEHP per trillion parts of air (ppt) in cities and industrial areas. DEHP levels in the indoor air in a room with recently installed flooring could be higher than levels in the outdoor air. Workers in factories that make or use DEHP also breathe in higher-than-average levels of this compound.

DEHP also can enter your body during certain medical procedures, and medical exposures are likely to be greater than any environmental exposures. Blood products that are stored in plastic bags and used for transfusions contain from 4.3 to 1,230 parts of DEHP per million parts of blood (ppm). Other plastic medical products also release DEHP. Flexible tubing used to administer fluids or medication can transfer DEHP to the patient. The plastic tubing used for kidney dialysis frequently contains DEHP and causes DEHP to enter the patient's blood. DEHP

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also is present in the plastic tubing of respirators and is carried from it to the lungs. Additional information concerning sources of exposure to DEHP is found in Chapter 6.

1.4 HOW CAN DEHP ENTER AND LEAVE MY BODY?

DEHP enters your body when you eat food or drink water containing this material or when you breathe in contaminated air. Small amounts of DEHP might enter your body by skin contact with plastics, but scientists are fairly certain that very little enters this way. Most DEHP that enters your body in food, water, or air is taken up into the blood from the intestines and lungs. DEHP can be introduced directly into your bloodstream if you get a blood transfusion, receive medicines through flexible plastic tubing, or have dialysis treatments.

After DEHP is ingested, most of it is rapidly broken down in the gut to MEHP and 2-ethylhexanol. Breakdown is much slower if DEHP enters your blood directly by way of a transfusion. Although some MEHP is absorbed into the bloodstream from the gut, MEHP is poorly absorbed, so that much of ingested DEHP leaves the body in the feces. The compounds that do enter the blood travel through the bloodstream to your liver, kidneys, testes, and other tissues, and small amounts might become stored in your fat and could possibly be secreted in breast milk. Most of the DEHP, MEHP, and 2-ethylhexanol leaves your body within 24 hours in the urine and feces. Additional information on the uptake, metabolism, and excretion of DEHP is found in Chapter 3.

1.5 HOW CAN DEHP AFFECT MY HEALTH?

To protect the public from the harmful effects of toxic chemicals and to find ways to treat people who have been harmed, scientists use many tests.

One way to see if a chemical will hurt people is to learn how the chemical is absorbed, used, and released by the body; for some chemicals, animal testing might be necessary. Animal testing might also be used to identify health effects such as cancer or birth defects. Without laboratory animals, scientists would lose a basic method to get information needed to make wise decisions

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to protect public health. Scientists have the responsibility to treat research animals with care and compassion. Laws today protect the welfare of research animals, and scientists must comply with strict animal care guidelines.

DEHP, at the levels found in the environment, is not expected to cause adverse health effects in humans. A man who voluntarily swallowed 10 g (approximately 0.4 ounces) of DEHP had stomach irritation and diarrhea. Most of what we know about the health effects of DEHP comes from studies of rats and mice that were given DEHP in their food, or the DEHP was placed in their stomach with the aid of a tube through their mouth. In most of these studies, the amounts of DEHP given to the animals were much higher than the amounts found in the environment. Rats and mice appear to be particularly sensitive to some of the effects of DEHP. Thus, because certain animal models may not apply to humans, it is more difficult to predict some of the health effects of DEHP in humans using information from these studies.

Breathing DEHP does not appear to have serious harmful effects. Studies in rats have shown that DEHP in the air has no effect on lifespan or the ability to reproduce. As mentioned previously, almost no DEHP evaporates into air. You probably will not have any health effects from skin contact with DEHP because it cannot be taken up easily through the skin.

Short-term oral exposures to levels of DEHP much higher than those found in the environment interfered with sperm formation in mice and rats. These effects were reversible, but sexual maturity was delayed when the animals were exposed before puberty. Short-term exposures to low levels of DEHP appeared to have no effect on male fertility.

Studies of long-term exposures in rats and mice have shown that high oral doses of DEHP caused health effects mainly in the liver and testes. These effects were induced by levels of DEHP that are much higher than those received by humans from environmental exposures. Toxicity of DEHP in other tissues is less well characterized, although effects in the thyroid, ovaries, kidneys, and blood have been reported in a few animal studies. The potential for kidney effects is a particular concern for humans because this organ is exposed to DEHP during dialysis and because structural and functional kidney changes have been observed in some exposed rats.

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Since changes in the kidneys of long-term dialysis patients might be due to the underlying kidney disease, and kidney changes have not been consistently seen in animals exposed to DEHP, the significance of the rat kidney changes is not clear.

Humans absorb and breakdown DEHP in the body differently than rats and mice. Therefore, many of the effects seen in rats and mice after exposures to DEHP might not occur in humans and higher animals like monkeys (primates). More information on the health effects of DEHP is found in Chapters 2 and 3.

No studies have evaluated the potential for DEHP to cause cancer in humans. Eating high doses of DEHP for a long time resulted in liver cancer in rats and mice.

The Department of Health and Human Services (DHHS) has determined that DEHP may reasonably be anticipated to be a human carcinogen. EPA has determined that DEHP is a probable human carcinogen. These determinations were based entirely on liver cancer in rats and mice. The International Agency for Research on Cancer (IARC) has recently changed its classification for DEHP from “possibly carcinogenic to humans” to “cannot be classified as to its carcinogenicity to humans,” because of the differences in how the livers of humans and primates respond to DEHP as compared with the livers of rats and mice.

1.6 HOW CAN DEHP AFFECT CHILDREN?

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

Children can be exposed to DEHP if they eat food or drink water contaminated with DEHP or if they breathe in the chemical from ambient or indoor air. Small children can also be exposed by sucking on or skin contact with plastic objects (toys) and pacifiers that contain DEHP, as well as by ingestion of breast milk containing DEHP. Children also can be exposed to DEHP if they undergo certain medical procedures that require the use of flexible tubing such as that used to

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administer fluids or medication to the patient. However, there is no conclusive evidence of adverse health effects in children exposed to DEHP in any of these ways.

In studies of pregnant mice and rats orally exposed to large doses of DEHP, effects on the development of the fetus, including birth defects and even fetal death, were observed. Researchers observed alterations in the structure of bones and of parts of the brain, and in the liver, kidney, and testes of the young animals. These harmful effects suggested that DEHP or some of its breakdown products passed across the placenta and reached the fetus. Therefore, humans exposed to sufficiently high levels of DEHP during pregnancy could possibly have babies with low birth weights and/or skeletal or nervous system developmental problems, but this is not certain. Studies in animals also have shown that DEHP or some of its breakdown products can pass from mother to babies via the breast milk and alter the development of the young animals. This could also happen in humans because DEHP has been detected in human milk.

We do not know whether children differ from adults in their susceptibility to health effects from DEHP. However, studies suggest that young male animals are more susceptible than older ones to the adverse effects of DEHP on the sex organs.

More information regarding children's health and DEHP can be found in Section 3.7, Children's Susceptibility.

1.7 HOW CAN FAMILIES REDUCE THE RISK OF EXPOSURE TO DEHP?

If your doctor finds that you have been exposed to significant amounts of DEHP, ask whether your children might also be exposed. Your doctor might need to ask your state health department to investigate. As discussed in Section 1.8, tests for DEHP only provide a measure of recent exposure to the chemical.

DEHP is used in many products that are made from plastic, but especially a plastic known as polyvinyl chloride (PVC) or vinyl. When it is found in products, DEHP is at a higher level when

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that product is new. Less is found in products that are old. Items made from PVC include many plastic toys, some plastic furniture, car and furniture upholstery, shower curtains, some garden hoses, tablecloths, and some flooring (vinyl flooring). Not all PVC products contain DEHP, but it is found in many products. Because DEHP might be in some toys, there is a concern that children chewing on such toys might be exposed. One study has shown that DEHP can go from plastics to laboratory-simulated saliva.

1.8 IS THERE A MEDICAL TEST TO DETERMINE WHETHER I HAVE BEEN EXPOSED TO DEHP?

The most specific test that can be used to determine if you have been exposed to DEHP is the measurement of MEHP and other breakdown chemicals in your urine or blood. This test only provides a measure of recent exposure, since DEHP is rapidly broken down into other substances and excreted from your body. You also could be tested for another breakdown product (phthalic acid), but this test would not be specific for DEHP. One or 2 days after exposure, your feces could be tested for the presence of DEHP metabolites. These tests are not routinely available through health care providers. More information on medical tests for DEHP is found in Chapters 3 and 7.

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. Federal agencies that develop regulations for toxic substances include the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA). Recommendations provide valuable guidelines to protect public health but cannot be enforced by law. Federal organizations that develop recommendations for toxic substances include the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health (NIOSH).

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

Recommendations and regulations are also periodically updated as more information becomes available. For the most current information, check with the federal agency or organization that provides it. Some regulations and recommendations for DEHP include the following:

Several federal guidelines regulate DEHP in consumer products, drinking water, and the work environment. FDA limits the types of food packaging materials that can contain DEHP. EPA limits the amount of DEHP in drinking water to 6 parts of DEHP per billion parts of water (6 ppb). EPA requires that spills of 100 pounds or more of DEHP to the environment be reported to the agency. The average concentration of DEHP in workplace air is limited by OSHA to 5 milligrams of DEHP per cubic meter (mg/m^3) of air over an 8-hour workday. The short-term (15-minute) exposure limit is $10 \text{ mg}/\text{m}^3$. The guidelines established by the American Conference of Governmental Industrial Hygienists (ACGIH) for the workplace are the same as the OSHA regulations. More information on government regulations pertaining to DEHP is found in Chapter 8.

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

Agency for Toxic Substances and Disease Registry
Division of Toxicology
1600 Clifton Road NE, Mailstop E-29
Atlanta, GA 30333
Web site: <http://www.atsdr.cdc.gov>

* Information line and technical assistance

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Phone: 1-888-42-ATSDR (1-888-422-8737)

Fax: 1-404-498-0057

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

* To order toxicological profiles, contact

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Phone: 1-800-553-6847 or 1-703-605-6000