# Bis(2-ethylhexyl) phthalate (DEHP)

117-81-7

# Hazard Summary

Bis(2-ethylhexyl) phthalate (DEHP) is used in the production of polyvinyl chloride (PVC). It exhibits low toxicity from acute (short-term) and chronic (long-term) exposures. Acute exposure to large oral doses of DEHP can cause gastrointestinal distress in humans. No information is available on the chronic, reproductive, developmental, or carcinogenic effects of DEHP in humans. Animal studies have reported increased lung weights and increased liver weights from chronic inhalation exposure to DEHP. Oral exposure has resulted in developmental and reproductive effects in rats and mice. A study by the National Toxicology Program (NTP) showed that DEHP administered orally increased the incidence of liver tumors in rats and mice. EPA has classified DEHP as a Group B2, probable human carcinogen

Please Note: The main sources of information for this fact sheet are EPA's Integrated Risk Information System (IRIS) (3), which contains information on oral chronic toxicity and the Reference Dose (RfD), and the carcinogenic effects of DEHP including the unit cancer risk for oral exposure, and the Agency for Toxic Substances and Disease Registry's (ATSDR's)Toxicological Profile for Bis(2-ethylhexyl)phthalate. (1)

### Uses

• The major use of DEHP is in the production of PVC and vinyl chloride resins, where it is added to plastics to make them flexible. (1)

### Sources and Potential Exposure

- The most probable route of exposure to DEHP is through food, with an average contribution of DEHP from food of 0.25 milligrams per day (mg/d). DEHP migrates into food from plastics during processing and storage. (1)
- Exposure to DEHP can also occur during certain medical procedures, such as blood transfusions and kidney dialysis and use of respirators. (1)
- In one study, DEHP was found in drinking water, at levels ranging from 0.04 to 30 parts per billion (ppb). (1)
- The average ambient air concentration of DEHP is very low, with < 0.002 ppb in urban areas. DEHP levels in indoor air in a newly painted room or a room with recently installed flooring could be higher than levels in the outdoor air. (1)
- Occupational exposure to DEHP may occur for those workers in factories that manufacture or use the chemical. (1)

### Assessing Personal Exposure

• Breakdown products of DEHP may be measured in urine or blood to determine exposure to DEHP. However, this test only provides a measure of recent exposure to the chemical. (1)

# Health Hazard Information

Acute Effects:

- No information is available on the acute effects of DEHP in humans via inhalation exposure. (1)
- Acute exposure to large oral doses of DEHP (5 to 10 grams) can cause gastrointestinal distress in humans. (1)
- Animal studies have noted effects on the liver and kidney and adverse effects on weight gain and food consumption from oral exposure to DEHP. (1)
- Acute animal tests in rats have shown DEHP to have low acute toxicity from oral exposure. (2)

#### Chronic Effects (Noncancer):

- No information is available on the chronic effects of DEHP in humans. (1)
- Animal studies have reported increased lung and liver weights from chronic inhalation exposure to DEHP. (1)
- Oral animal studies have reported effects on the liver from DEHP exposure. (1)
- EPA has not established a Reference Concentration (RfC) for DEHP. (3)
- The Reference Dose (RfD) for DEHP is 0.02 milligrams per kilogram body weight per day (mg/kg/d) based on increased relative liver weights in guinea pigs. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups), that is likely to be without appreciable risk of deleterious noncancer effects during a lifetime. It is not a direct estimator of risk but rather a reference point to gauge the potential effects. At exposures increasingly greater than the RfD, the potential for adverse health effects increases. Lifetime exposure above the RfD does not imply that an adverse health effect would necessarily occur.(3)
- EPA has medium confidence in the study on which the RfD was based because it utilized sufficient numbers of guinea pigs and measured multiple endpoints but only used two dose levels; medium confidence in the database because there are corroborating chronic animal bioassays; and, consequently, medium confidence in the RfD. (3)
- The California Environmental Protection Agency (CalEPA) has calculated a chronic reference exposure level of 0.01 milligrams per cubic meter (mg/m<sup>3</sup>) based on increased liver and lung weights in rats. The CalEPA reference exposure level is a concentration at or below which adverse health effects are not likely to occur. (5)

Reproductive/Developmental Effects:

- No information is available on the reproductive or developmental effects of DEHP in humans. (1)
- No reproductive or developmental effects were observed in animal studies from inhalation exposure to DEHP. (1)
- DEHP has been demonstrated to cause developmental toxicity, such as birth defects, in rats and mice from oral exposure. Reproductive effects, such as decreased fertility, proportion of pups born alive, and testicular weights and tubular atrophy, have also been noted from oral exposure to DEHP in animals. (1)

Cancer Risk:

- No information is available on the carcinogenic effects of DEHP in humans. (1)
- In the only available animal inhalation cancer study, lifetime exposure of hamsters to a very low dose of DEHP did not result in any significant increase in the incidence of tumors. However, because this is a very low dose, it is not possible to reach a conclusion as to whether or not higher concentrations might produce different results. (1)
- A study by the NTP showed that DEHP administered in the diet increased the incidence of liver tumors in rats and mice. (6)
- EPA has classified DEHP as a Group B2, probable human carcinogen. (3)
- EPA uses mathematical models, based on animal studies to estimate the probability of a person developing cancer from ingesting water containing a specified concentration of a chemical. EPA calculated an oral cancer slope factor of 0.014 (mg/kg/d)<sup>-1</sup> and an oral unit risk estimate of  $4.0 \times 10^{-7}$  (µg/L)<sup>-1</sup>. EPA estimates that, if an individual were to continuously ingest water containing DEHP at an average of 3 µg/L (0.003 mg/L) over his or her entire lifetime, that person would theoretically have no more than a one-in-a-

million increased chance of developing cancer as a direct result of ingesting water containing this chemical. Similarly, EPA estimates that ingesting water containing 30  $\mu$ g/L (0.03 mg/L) would result in not greater than a one-in-a-hundred thousand increased chance of developing cancer, and water containing 300  $\mu$ g/L (0.3 mg/L) would result in not greater than a one-in-ten thousand increased chance of developing cancer. For a detailed discussion of confidence in the potency factors, please see IRIS. (3)

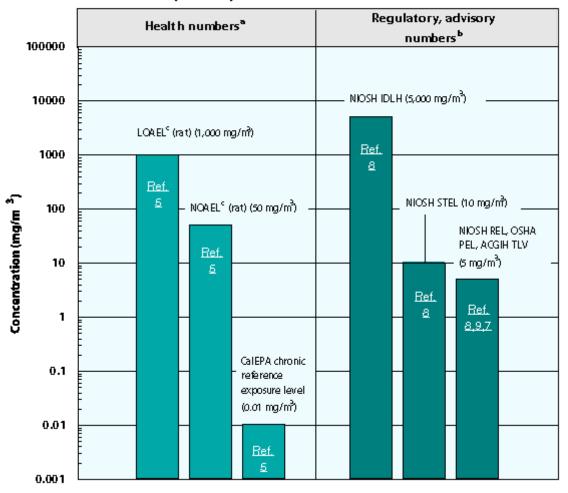
## **Physical Properties**

- Bis(2-ethylhexyl phthalate is also called di(2-ethylhexyl)phthalate or DEHP . (1)
- DEHP is a colorless liquid with almost no odor. (1)
- The chemical formula for DEHP is C H O, and the molecular weight is 390.57 g/mol. (1)
- The vapor pressure for DEHP is  $6.2 \times 10^{50}$  mm Hg at 25 °C, and it has a log octanol/water partition coefficient (log K ) of 4.2-5.11. (1)

Conversion Factors (only for the gaseous form):

To convert concentrations in air (at 25 °C) from ppm to mg/m<sup>3</sup>: mg/m<sup>3</sup> = (ppm) × (molecular weight of the compound)/(24.45). For DEHP: 1 ppm = 15.9 mg/m<sup>3</sup>.

### Health Data from Inhalation Exposure



### Bis(2-Ethylhexyl)Phthalate

ACGIH TLV -- American Conference of Governmental and Industrial Hygienists' threshold limit value expressed as a time-weighted average; the concentration of a substance to which most workers can be exposed without adverse effect.

NIOSH IDLH -- National Institute of Occupational Safety and Health immediately dangerous to life and health; NIOSH concentration representing the maximum level of a pollutant from which an individual could escape within 30 minutes without escape-impairing symptoms or irreversible health effects.

NIOSH REL--NIOSH's recommended exposure limit; NIOSH-recommended exposure limit for an 8- or 10-h timeweighted-average exposure and/or ceiling.

NIOSH STEL --NIOSH's recommended short-term exposure limit; a 15-minute TWA exposure which should not be exceeded at any time during a workday.

OSHA PEL--Occupational Safety and Health Administration's permissible exposure limit expressed as a timeweighted average; the concentration of a substance to which most workers can be exposed without adverse effect averaged over a normal 8-h workday or a 40-h workweek.

The health and regulatory values cited in this factsheet were obtained in December 1999.

ື Health numbers are toxicological numbers from animal testing or risk assessment values developed by EPA.

<sup>2</sup> Regulatory numbers are values that have been incorporated in Government regulations, while advisory numbers are nonregulatory values provided by the Government or other groups as advice. OSHA numbers are regulatory, whereas NIOSH and ACGIH numbers are advisory.

The NOAEL and LOAEL are from the critical study used as the basis for CalEPA's chronic reference exposure level.

#### Summary created in April 1992, updated in January 2000

#### References

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- 4. 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.
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- 6. National Toxicology Program. Carcinogenesis Bioassay of Di(2-ethylhexyl)phthalate (CAS No. 117-81-7) in F344 Rats and B6C3F Mice (Feed Studies). NTP TR 217. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD. 1982.
- 7. American Conference of Governmental Industrial Hygienists (ACGIH). 1999 TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents. Biological Exposure Indices. Cincinnati, OH. 1999.
- 8. National Institute for Occupational Safety and Health (NIOSH). Pocket Guide to Chemical Hazards. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. Cincinnati, OH. 1997.
- 9. Occupational Safety and Health Administration (OSHA). Occupational Safety and Health Standards, Toxic and Hazardous Substances. Code of Federal Regulations. 29 CFR 1910.1000. 1998.