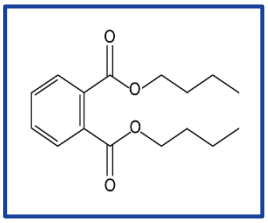
SUMMARY

Background: Di-*n*-butyl phthalate (DBP) is a chemical used in consumer products such as food packaging, inks, nail polish, and personal care products. Humans are primarily exposed to DBP via contaminated food throughout their lifetime, including during pregnancy and early childhood. NTP studied the effects of lifetime exposure to DBP in male and female rats (with exposure starting in utero) and male and female mice (with exposure starting in adolescence) to identify potential toxicity or cancer-related outcomes.



Methods: Pregnant rats were fed diets containing 300, 1,000, 3,000, or 10,000 parts per million (ppm) DBP throughout pregnancy and while nursing their offspring, and then groups of 50 male and 50 female offspring continued the same diet as their mothers for 2 years. The same group sizes of male and female mice were fed diets containing 1,000, 3,000, or 10,000 ppm DBP for 2 years beginning in adolescence. Control animals were fed diets with no chemical added (0 ppm DBP). At the end of each study, tissues from more than 40 sites from every animal were examined for signs of disease.

Results: In male rats, neoplasms (which can include benign or malignant growths) were observed in the pancreas at a marginally higher incidence as the concentration of DBP in the diet increased. Neoplasms were not observed in female rats or male and female mice. Other effects observed in male rats exposed to DBP included malformations and noncancerous tissue abnormalities in the reproductive tract. Likewise, male mice exhibited noncancerous tissue abnormalities in the reproductive tract. Noncancerous tissue abnormalities were also observed in the liver of male and female rats and mice, the pituitary gland of male rats, and the kidney of female mice.

Conclusions: *NTP uses a four-point scale to rate the level of evidence that a substance has the ability to cause cancer in laboratory animals. Under the conditions of these 2-year feed studies, there was equivocal (uncertain) evidence that DBP has the ability to cause pancreatic cancer in male rats and no evidence that it has the ability to cause cancer in female rats or in male or female mice. Exposure to DBP increased noncancerous tissue abnormalities in the male reproductive tract of rats and mice, liver of male and female rats and mice, pituitary gland of male rats, and kidney of female mice.*