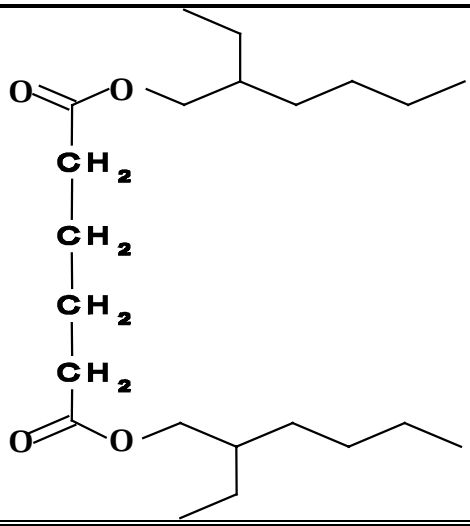
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	103-23-1
Chemical Name	Bis(2-ethylhexyl)adipate
Structural Formula	

RECOMMENDATIONS

The chemical is a candidate for further work.

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

DEHA exhibits low acute mammalian toxicity as seen by reported oral and dermal LD50s in rats of greater than 2 g/kg and no mortality in rodents exposed via inhalation for eight hours at levels up to saturation. Available data show that DEHA is not irritating to skin or eyes in animal studies and was not a dermal sensitizer in guinea pigs. Repeated-dose toxicity studies (up to 90-days) in rats and mice with DEHA in feed showed reduced body weight gains at levels of approximately 400 mg/kg and higher in rats and approximately 600 mg/kg and higher in mice (NOAELs of 189 mg/kg in rats and 451 mg/kg in mice). *In vitro* genotoxicity studies have been negative for mutations, unscheduled DNA synthesis and DNA interactions in bacterial and mammalian systems. *In vivo* genotoxicity studies have also been negative (two mouse micronucleus assays). DEHA has been evaluated for carcinogenicity in mice and rats, and there was no evidence of carcinogenicity in rats but there was evidence of liver cancer in female mice (significant incidence) and male mice (less significant). Tumors in mice were observed at high concentrations (3222 mg/kg for females and 2659 mg/kg in males). A one-generation reproductive toxicity test was performed in rats and there were no effects on reproduction although the body weight gains of pregnant dams and first generation pups was reduced at a dose level of approximately 3222 mg/kg. A developmental toxicity performed with DEHA in rats (animals treated orally via DEHA in feed on days 6-15 of gestation) demonstrated reduced maternal body weight gain at the highest dose (1080 mg/kg/d). There was evidence of pre-implantation fetal loss at the highest dose, but no gross, skeletal, or visceral abnormalities. A NOAEL for developmental toxicity was determined in rats at an estimated oral dose of 170 mg/kg/d, based on slight fetotoxicity from reduced ossification which was not statistically significant.

Environment

Experiments show that DEHA has no acute toxicity effects to aquatic organisms and a low bioaccumulation potential, and is readily degradable via abiotic (hydrolysis) and biotic processes. No acute aquatic toxic effects were noted at the apparent limit of DEHA solubility (0.0032 mg/L) and no effects were noted at concentrations several orders of magnitude greater than the solubility for most species. A chronic daphnid study did show effects at concentrations slightly above the water solubility limit. There were no effects observed at the lowest concentration tested (0.014 mg/L). An *acceptable toxic concentration* of 0.035 mg/L was derived as the geometric mean of the NOEC (0.024 mg/L) and the LOEC (0.052 mg/L). A PNEC of 0.0035 mg/L has been established (0.035 divided by an assessment factor of 10).

Tests on terrestrial organisms (earthworm) have also been performed (LC50s of >1000 mg/kg and 865 mg/kg were reported after exposures of 7 and 14 days, respectively.

Exposure

DEHA is a plasticizer used primarily in food-contact wrapping. Approximately 10,000 to 50,000 tonnes are produced each year in closed systems. It is estimated that only 25-50 individuals in the US are involved in the manufacturing and handling process. Occupational exposures are low based on production in a closed system and its low vapor pressure. The estimated exposure levels to the general population via consumer products (migration of DEHA from food wraps – estimated exposures of 117 ug/kg/d) and the environment (highest measured surface water concentration was 0.001 mg/L) are considered to be quite low in several countries.

NATURE OF FURTHER WORK RECOMMENDED

Because of the potential chronic hazard to the aquatic environment an exposure assessment is recommended with subsequent risk assessment, as appropriate.