# SIDS INITIAL ASSESSMENT PROFILE

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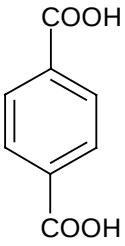
| **CAS No.** | 100-21-0 |
| **Chemical Name** | Terephthalic acid |
| **Structural Formula** |  |



## RECOMMENDATIONS

The chemical is currently of low priority for further work.

## SUMMARY CONCLUSIONS OF THE SIAR

### Human Health

Results from repeated dose and acute toxicity studies via the oral, dermal and inhalation routes indicate that terephthalic acid is of low order of toxicity, and it is non-irritating to the skin and eyes. A 15 week oral repeat dose study in rats reported a LOAEL of 3837 mg/kg b.w./day for male rates and 4523 mg/kg/day for female rats. The NOAEL is 1220 mg/kg b.w./day for male rats and 1456 mg/kg b.w./day for female rats. Repeated exposure inhalation studies up to 10 $mg/m^3$ (6 hours/day, 5 days/week) using rats or guinea pigs showed no adverse effects, except for mild respiratory irritation in one study with rats.

The primary adverse effect of high doses of terephthalic acid to rats is almost completely restricted to the urinary tract. These effects include formation of bladder calculi, and inflammatory changes and hyperplasia of the bladder epithelium. These urinary changes did not occur when exposure was by inhalation. Rats fed terephthalic acid (greater than 2%) 1000 mg/kg b.w./day for two years developed bladder calculi, bladder hyperplasia, and bladder tumors.

It is believed that the calculi injure the bladder epithelium and induce cell proliferation, which is probably a critical factor in the induction of bladder tumors by terephthalic acid. Bladder calculi cannot occur unless the solubility of the stone components is exceeded (i.e., unless the product of the concentrations of $Ca^{++}$ and terephthalate in urine exceeds the solubility product of the calcium-terephthalate complex). Based on urinary solubility of Ca-terephthalate, normal human urine would become saturated with Ca-terephthalate at a terephthalic acid concentration of approximately 8 to 16 mM. Assuming that the average volume of urine excreted by humans is 1.5 liters/day, the amount of terephthalic acid that would have to be absorbed to produce the minimum saturating concentration of terephthalic acid is 2400 mg/day. It is unlikely that humans would ingest enough TPA to induce bladder calculi, and this therefore is of little concern to human health.

Terephthalic acid is not a reproductive toxicant; however, in a one-generation reproduction feeding study, postnatal developmental effects were observed in rats (LOAEL and NOAEL approximately equivalent to 1120 mg/kg b.w./day and 280 mg/kg b.w./day respectively). The adverse effects observed in the offspring appear to be the result of

maternal toxicity and the formation of renal and bladder calculi in the weanling animals. No developmental effects were seen in rats when the exposure was by inhalation (NOAEC 10 mg/$m^3$, the highest dose tested). Terephthalic acid is not genotoxic. Terephthalic acid did not induce an increase in micronucleated polychromatic erythrocytes (micronuclei) in male or female mice *in vivo*.

**Environment**

Terephthalic acid (TPA) is non-toxic to aquatic organisms at concentrations lower than its water solubility (15 mg/l at 10$^o$C). Tests were performed with a more soluble sodium salt. The values for fish acute toxicity ranged from a 96-hour $LC_0$ of greater than 500 mg/l to a 96-hour $LC_{50}$ ranging from 798 to 1640 mg/l. The $EC_{50}$ for *Daphnia* was greater than 982 mg/l and the 96-hour NOEC for *Scenedesmus subspicicatus* was greater than 1000 mg/l. Using the lowest reported $LC_{50}$ value of the three base set tests, a PNEC value of 8 mg/l is calculated. TPA is not expected to bioaccumulate. It is subject to hydroxy radical oxidation in the atmosphere, and biodegrades in soil and surface water under aerobic conditions. Detection of terephthalic acid in air and water samples has been in the low ppt range.

**Exposure**

Terephthalic acid is an industrial chemical intermediate, and occupational exposures are low. In 1993, the worldwide production was estimated to be 17 to 21 million tonnes. Manufacture of polyester fibers and films accounts for a majority of TPA use. End products of polyester fiber may include yarns for carpet, apparel, fill fibers for consumer products, and industrial filaments. PET containers, the next major use, are used for a wide variety of food and beverage packaging and in other food contact uses.

## NATURE OF FURTHER WORK RECOMMENDED

No further work is recommended.