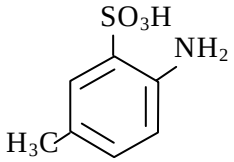
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	88-44-8
Chemical Name	4-Aminotoluene-3-sulfonic acid
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

From the outcome of a single dose administration reported in a preliminary examination of a 28-Day Repeat Dose Toxicity study [OECD TG407], the oral LD50 in rats is considered to be greater than 2000 mg/kg in both sexes. This substance was not corrosive or irritant to human skin.

In the 28-Day Repeated Dose Toxicity study [OECD TG407], this substance was administrated to male and female rats at 0, 100, 300, 1000 mg/kg/day dose by gavage. At 1000 mg/kg/day in males, a decrease of white blood cell count, total cholesterol and urine pH, also an enlargement of cecum were observed. At 1000 mg/kg in females, an increase of GPT and a decrease of glucose, also an enlargement of cecum were observed. All of those changes recovered within 14 days after cessation of the treatment. No other dose-dependent histopathological changes were observed in any dose groups. No changes in mortality, behavior or toxic effects on the body weight and food consumption were observed in any dose levels and in any sexes. The NOAEL for both sexes is considered to be 300 mg/kg/day.

This substance was not mutagenic in bacteria up to 5,000 ug/plate [OECD TG471, TG472] and 10,000 ug/plate. A chromosomal aberration test tested up to 1.9 mg/mL (10mM) [OECD TG473] was negative except in the 6hr short-term test in the presence of an exogenous metabolic activation system. The positive response in the 6 hr short term test was based on the low pH, because the induction of chromosomal aberration was diminished after adjustment of the pH to a neutral range. The result of an unscheduled DNA synthesis up to 187 mg/L was negative. Furthermore, an *in vivo* micronucleus test was negative. Overall, this substance can be considered to be not genotoxic *in vitro* and *in vivo*.

In a Preliminary Reproduction Toxicity Screening Test [OECD TG421], this substance was administrated to male and female rats at 0, 100, 300, 1000 mg/kg/day dose by gavage for 48 days in males and 41 – 46 days (from 14 days before mating to 3 days after parturition) in females. No compound-related dose effects were observed in the copulation index, fertility index, gestation length, number of corpora lutea or implantations, implantation index, gestation index and maternal behavior. As for pups, there were no significant differences in number of offspring or live offspring, sex ratio, the live birth index, the viability index or the body weight. No pups with malformations were found in any groups. No changes in clinical signs and necropsy findings were observed in offspring. From those results, the NOAEL for reproductive and developmental toxicity is considered to be 1000 mg/kg/day.

Environment

This substance is soluble in water (6.0 g/L at 20°C) and the vapor pressure is low (< 0.00052 Pa at 100°C) [OECD TG104]. This substance was not readily biodegradable (0% after 14 days on BOD) [OECD TG301C] and is stable to

hydrolysis in water at pH 4, 7 and 9 [OECD TG111]. The bioconcentration potential is low (BCF < 4 (0.2 mg/L) and < 0.4 (2 mg/L)) [OECD TG305C]. The log Pow is –0.67 at 25°C [OECD TG107]. This substance, if released into the atmosphere, will react with photochemically produced hydroxyl radical and decrease with a half-life of 4.5 hours. The pKa value of this substance is 3.28. It is present as a zwitterion under environmental condition. The behavior of this substance in the environment is considered to be similar to a weak acid.

The fugacity model (Mackay level III) suggests that if released to water, the majority of the substance would remain in the water compartment and, if released into air or soil, ca.50% would distribute to both water and the soil compartment.

In an acute toxicity test to fish, the LC50 was greater than 10 mg/L (*Oryzias latipes*, 96hr limit test) [OECD TG203].
In an acute toxicity test to daphnia, the EC50 was greater than 10 mg/L (*Daphnia magna*, 48hr limit test) [OECD TG202].
In an acute toxicity test to algae, the EC50 was greater than 10 mg/L (*Selenastrum capricornutum*: 0 – 72 hr biomass, and 24 – 72 hr growth rate) [OECD TG201].
In a chronic toxicity test to daphnia, the NOEC was 3.2 mg/L (*Daphnia magna*, 21 days reproduction) [OECD TG211] and in a chronic toxicity test to algae, the NOEC was 10 mg/L (*Selenastrum capricornutum*: 0 – 72 hr biomass, and 24 – 72 hr growth rate) [OECD TG201].

Exposure

The production volume of this substance in 2001 is estimated to be 2,000 - 3,000 metric tonnes/year in Japan and ca.18,000 metric tonnes/year in the world. The production countries are Japan, Korea, P.R. China, United Kingdom and U.S.A. In total there are about 20 manufacturing sites and about 55 use sites in the world.

This substance is produced in closed systems, and the packing process is performed in semi-closed or open systems. The user may use it in semi-closed systems. The only recognized use is as an industrial intermediate in the synthesis of organic pigments (Pigment Red 57 and its metal salts). These pigments are utilized in ink, paint, stationery goods, cosmetic goods and for the coloring of resin, fiber, leather, paper, rubber, etc. The concentration of the non-reacted parent substance in pigments is not known, but the consumer exposure is thought to be insignificant. There are no known direct uses of this substance in any consumer product. In the case of cosmetic goods (lip stick, etc.), regulations are in place in each region, for example the content of the substance in the colouring agent must be less than 0.2 % in the USA. Therefore, the possibility of consumer exposure from cosmetic goods is considered to be low.

Because of its use limited to the pigment industry and its low vapor pressure, the release of this substance into air and soil is very low. The concentration of this substance in effluent water from waste water treatment plant of manufacturer in Japan is less than 0.009 mg/L. The total emission from manufacturer's site through water in Japan is calculated to be less than 5 kg/year.

Based on the use and the properties of the substance, only occupational exposure by inhalation and dermal routes need to be considered.

RECOMMENDATION

The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

This chemical is currently of low priority for further work because of its low hazard potential.