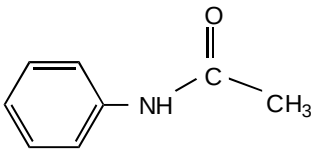
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	103-84-4
Chemical Name	Acetanilide
Structural Formula	$CH_3CONHC_6H_5$ 

RECOMMENDATIONS

The chemical is currently of low priority for further work.

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Acute toxicity of acetanilide is low since the LD50 of oral exposure in rats is 1,959 mg/kg bw.

For repeated dose toxicity, acetanilide was given by gavage at doses of 22, 67, 200, and 600 mg/kg/day to male rats for 30 days and to female rats for 39-50 days in accordance with an OECD TG 422 (combined repeated dose toxicity study with reproduction/developmental toxicity screening test). The adverse effects were red pulp hyperplasia of spleen, bone marrow hyperplasia of femur and decreased hemoglobin, hematocrit and mean corpuscular hemoglobin concentration. The LOAEL for repeated dose toxicity in rats was 22 mg/kg/day for both sexes.

Most of the *in vitro* mutagenic toxicity studies including the Ames assay, mammalian chromosomal aberration test, *Bacillus subtilus* recombination assay and SCE assay showed negative results. Regarding *in vivo* study, mammalian erythrocytes micronucleus test performed by OECD TG 474 showed negative result. Therefore acetanilide is not considered to be genotoxic. There is some evidence that this chemical is not carcinogenic in rats, mice and hamsters.

In a reproductive/developmental toxicity study performed to OECD TG 422, no treatment-related changes in precoital time and rate of copulation, impregnation, pregnancy were shown in any treated group. However, viability of offsprings at 600mg/kg bw/day and body weight of pups at 200 mg/kg/day were significantly reduced. At 600 mg/kg bw/day, four dams died and body weight was decreased at day 0 and 4 of lactation. At 200 mg/kg bw/day, there were signs of maternal toxicity (cf. repeated dose toxicity). The NOAELs for reproduction and developmental toxicity (offspring toxicity) are considered to be 200 mg/kg bw/day and 67 mg/kg bw/day, respectively.

This chemical is not irritating to skin, but slightly irritating to the eyes of rabbits. There is no information available on skin sensitization.

Environment

Physical-chemical properties of acetanilide are as follows: melting point 113.7 ºC, boiling point 304 ºC at 760

mmHg, water solubility 4g/l at 20 ºC, Log POW 1.16 at 23ºC. EQC model of fugacity level I shows that the chemical will be distributed mainly to water. Acetanilide is readily biodegradable (MITI test: 68.7 % after 14 days as BOD) and an estimated BCF of 1.56 by BCFWIN model based on log Pow (1.16) implies that bioaccumulation of acetanilide is low.

Ecotoxicity data has been generated in a limited number of aquatic species of algae (72hr-E_bC_{50}; 13.5 mg/l), daphnid (48hr-EC_{50}; is 100mg/l) and fish (96hr-LC_{50}; ≥100mg/l). No data on prolonged fish toxicity and toxicity to terrestrial organisms are available. From the acute toxicity values, the predicted no effect concentration (PNEC) of 0.135 mg/L was derived using an assessment factor of 100.

Exposure

Total production of acetanilide was about 2,300 tonnes/year in Korea as of a 1998 survey, and 196 tonnes in USA in 1998. Acetanilide is mainly used as intermediates of synthesis in pharmaceuticals and additives in hydrogen peroxide, varnishes, polymers and rubber. Although limited monitoring data indicate that non-occupational exposure may occur from the ingestion of contaminated drinking water, the most probable human exposure could be occupational exposure through dermal contact or inhalation at workplaces where acetanilide is produced or used.

In Korea, 2,320 tonnes of the chemical was used as intermediates for synthesis of pharmaceuticals. Only small amount of 120 kg was used as a stabilizer for hydrogen peroxide solution for hair colouring agents in 1998 and based on general information the content of the substance in such preparation would be very low and this human exposure is insignificant. Readily available environmental or human exposure data do not exist in Korea at the present time. And potential exposure from drinking water, food, ambient water and in the workplace is expected to be negligible because this chemical is produced in closed system in only one company in Korea.

NATURE OF FURTHER WORK RECOMMENDED

No recommendation.