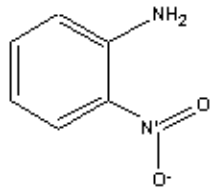
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	88-74-4
Chemical Name	2-nitroaniline
Structural Formula	

RECOMMENDATIONS

The chemical is currently of low priority for further work.

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

The results of the published studies on 2-nitroaniline did not show significant increases of methemoglobin in animals except in the inhalation study. This difference with other isomers or inducers seems to be due to the difference of chemical reactivity of the nitro substitution in position 2 compared to other substitutions. 2-Nitroaniline is metabolised *in vitro* by rabbit liver microsomes to 4-amino-3-nitrophenol. 2-nitroaniline has been shown to have an oral LD50 value of 1838 mg/kg b/w in the rat, this is the only acute effect noted. It is not irritating to skin and to the eyes, and not sensitising. In oral repeated administration a NOEL of 50 mg/kg bw/day was determined from a 9 weeks study. The major treatment-related effects are clinical signs, but not methemoglobinemia, and weight loss. In a vapour inhalation 28 day assay a NOAEL was determined at 10 mg/m^3 in rats, due to slight methemoglobinemia and haematological effects seen at 90 mg/m^3.

2-nitroaniline was shown to be non-mutagenic in relevant bacterial studies. Nonetheless, a weak mutagenic influence was reported in some studies in which tests were performed on *S. typhimurium* strains TA98 and TA1538 in presence of Hamster S9 mix or with Flavin Mononucleotide activation. Investigations of general interaction with DNA on bacteria (*E. coli*) yielded negative results, as well as *in vitro* UDS tests and *in vivo* clastogenicity tests (micronucleus i.p.) or test on the alkaline elution behaviour of the DNA. In conclusion, 2-nitroaniline is not mutagenic.

In reproduction and developmental toxicological studies, the substance caused neither teratogenic nor fertility effects, but did cause developmental effects due to pups lethality at 450 mg/kg bw /day where a maternal body weight decrease occurred. The NOAEL for developmental effects was 150 mg/kg bw/day and the maternal NOAEL was set at 50 mg /kg bw in a study according to OECD TG 422.

Environment

2-nitroaniline has been found to be non-biodegradable, even in high inoculum concentration conditions. It therefore can be considered as persistent. The highest bioconcentration factor in fish was observed to be 8, leading to the conclusion that 2-nitroaniline does not significantly bioaccumulate.

The most valid and lowest E(L)C 50 found were a LC 50 (96 hours) in *Brachydanio rerio* of 19.5 mg/l, an EC 50 (24 hours) in *Daphnia magna* of 8.3 mg/l and an EC50 (growth rate, 72 hours) in *Selenastrum capricornutum* was > 100 mg/l. The lowest result is the EC 50 (24 hours) in *Daphnia magna*. Using an extrapolation factor of 1000, a PNEC of 0.008 mg/l can be estimated for the aquatic compartment.

Exposure

Estimated worldwide production of 2-nitroaniline is 20000 to 25000 tonnes/year. The production in the E.U. was 1000 to 5000 tonnes / year in 2000 in a unique site. The use in this region is non-dispersive, as an intermediate for synthesis in chemical industry. No other use could be documented in the EU. Nevertheless, the use in metal working fluids (<10%) and dyes (<1%) which can represent about 10% of the production volume were reported but not confirmed. 2-nitroaniline is an orange massive solid at room temperature, commercialised as flakes, or melted above 71 °C. It has a low vapour pressure at room temperature (0.00368 hPa at 25 °C) which reaches 1.33 hPa at 104 °C. So when melted, a potential exposure is possible by inhalation.

The water solubility of 2-nitroaniline is 1170 mg/l at 20 °C and the measured log Pow is 1.85. Anilines are known to make covalent bonds to humic acids. Therefore 2-nitroaniline will distribute as such mainly to the water compartment in the environment, but could be covalently bound to sediments.

NATURE OF FURTHER WORK RECOMMENDED

Human Health and Environment: The recommendation that this substance is not a priority for further work is based on the use of this substance exclusively as an intermediate in a closed system.