SIDS INITIAL ASSESSMENT PROFILE

CAS No.	101-77-9
Chemical Name	4,4'-Methylenedianiline (MDA)
Structural Formula	H ₂ C H ₂ C NH ₂

RECOMMENDATIONS

The chemical is a candidate for further work.

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

MDA is of moderate acute toxicity to rats: LD50oral 350-450 mg/kg, LD50dermal 1000 mg/kg and LC50inhalation >0.837 mg/l (this concentration exceeds the highest attainable concentration at room temperature). Target organs are liver and kidney (and eye in cats and dogs). MDA is slightly irritating to rabbit skin and causes mild to moderate irritation to the eyes of rabbits. Human evidence indicates that MDA is a skin sensitizer.

MDA has been shown to cause mutations both in vitro and in vivo, and to be carcinogenic. Chronic oral MDA administration to rats and mice results in tumours of the liver and thyroid, (non-neoplastic LOAEL 9 and 10 mg/kg bw/d, male and female rats, respectively). However, the available human data did not clearly demonstrate carcinogenic activity. Developmental or fertility data in animals or humans does not exist.

Environment

MDA has a log Kow of 1.59, a water solubility of 1.25 g/l and a vapour pressure of 2.87X10-8hPa. MDA is not expected to be volatile and to undergo hydrolysis. MDA is inherently biodegradable in industrial WWTPs, degradation in municipal WWTPs cannot be deduced from the actual database. The major transformation pathway in the hydrosphere is probably photolysis. MDA forms covalent bounds with the organic matter of sediments and soils. As the reaction product with humic acids is only poorly biodegraded, its accumulation in sediments has to be expected.

MDA is expected to be of low bioaccumulation potential in fish, however, accumulation of reaction products with humic substances in sediment dwelling organisms may occur, although effects data for this end point do not exist.

The following data were selected as lowest acute and long-term effect values for each algae, daphnia and fish: *Scenedesmus subspicatus:* 72h-EC50 = 11 mg/l, 72h-EC10 = 0.3 mg/l; *Moina macrocopa:* 24h-EC50 = 2.3 mg/l, 14d-NOEC = 0.15 mg/l; *Oryzias latipes* 48h-LC50 = 32 mg/l. With an assessment factor of 50, a PNEC of 3 μ g/l was derived from the 14d-NOEC for *Moina macrocopa*.

Release of MDA to the environment during production is mainly via waste water. No significant releases into the atmosphere and soils are expected.

Exposure

In 1993 the production volume of MDA was in the region of 430,000 tons. 4,4'-Methylenedianiline (MDA) is produced both as single compound and as the major component of a technical mixture with a varying content of triand polynuclear amines. More than 99% of the total production volume of MDA are used as an intermediate for the production of Methylenediphenyldiisocyanate (MDI), which is further processed to polyurethanes. Maximum 4000t MDA, per annum are used as hardners for epoxy resins and adhesives, intermediate in the manufacture of highperformance polymers and processing to 4,4'-Methylenebis(cyclohexaneamine). Significant releases of MDA into the environment occur only during production.

NATURE OF FURTHER WORK RECOMMENDED

This substance has been agreed in the European Union Risk Assessment program under Regulation EEC/793/93 with the following conclusions. The risk assessment shows that there is a need for specific measures to limit the risks for workers and consumers.

The toxicity of the reaction product of MDA with humic acids on sediment organisms is unknown. Thus no PNECsed could be estimated, and a risk assessment for this sub-compartment is not possible. A test on *Lumbriculus variegatus* with pre-incubated MDA should be performed.