SIDS INITIAL ASSESSMENT PROFILE

CAS No.	80-62-6
Chemical Name	Methyl methacrylate
Structural Formula	CH ₂ =CH(CH ₃)-COOCH ₃

RECOMMENDATIONS

The chemical is a candidate for further work.

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

MMA is rapidly absorbed after oral or inhalatory administration. *In vitro* skin absorption studies in human skin indicate that MMA can be absorbed through human skin. After inhalation to rats 10 to 20% of the substance is deposited in the upper respiratory tract where it is metabolised by local tissue esterases.

Acute toxicity of MMA by the oral, dermal, and inhalative routes is low as judged by tests with different species: The oral LD50 for rats, mice, and rabbits is found to exceed 5000 mg/kg bw. Acute inhalation toxicity for rats and mice is described by LC50 values of > 25 mg/l/4 hours. Acute dermal toxicity is reported for rabbits to exceed 5000 mg/kg bw. Skin and respiratory irritation are reported for subjects exposed to monomeric MMA. The substance has been shown to produce severe skin irritation when tested undiluted on rabbit skin. There are indications from studies in animals that MMA can be irritating to the respiratory system. In contact with eyes MMA has shown only weak irritation of the conjunctivae. MMA has a moderate to strong sensitising potential in experimental animals. Cases of contact dermatitis have been reported for workers exposed to the monomeric chemical. There is no convincing evidence that MMA is a respiratory sensitizer in humans.

The lead effect caused by MMA is a degeneration of the olfactory region of the nose being the most sensitive target tissue. For this effect a NOAEC of 25 ppm (104 mg/m^3) in a two-year inhalation study in rats was identified but only slight effects on the olfactory tissues have been observed at 100 ppm. Concerning systemic effects, two different valid studies have been considered for identifying a N(L)OAEL. Due to different dose selections, different values for N(L)OEALs are available. The LOEALs and the NOEALs for female rats ranges between 400 and 500 ppm and from 100 to 250 ppm respectively. In subchronic inhalation studies systemic toxic effects were seen in rats >1000 ppm, respectively in mice >500 ppm, including degenerative and necrotic lesions in liver, kidney, brain, and atrophic changes in spleen and bone marrow. These effects were not seen in chronic studies up to 1000 ppm. Oral administration to rats resulted in a NOAEL of 200 mg/kg bw/d.

MMA has *in vitro* the potential for induction of mutagenic effects, especially clastogenicity. However, this potential is limited to high doses with strong toxic effects. Furthermore, the negative *in vivo* micronucleus test and the negative dominant lethal assay indicate that this potential is not expressed *in vivo*. There is no relevant concern on carcinogenicity of MMA in humans and animals. Epidemiology data on increased tumour rates in exposed cohorts are of limited reliability and cannot be related to

MMA as the solely causal agent.

MMA did not reveal an effect on male fertility when animals had been exposed to up to 9000 ppm. From the available developmental toxicity investigations, including an inhalation study according to OECD Guideline 414, no teratogenicity, embryotoxicity or fetotoxicity has been observed at exposure levels up to and including 2028 ppm (8425 mg/m³). The available human data on sexual disorders in male and female workers cannot be considered to conclude on reproductive toxicity effects of MMA due to the uncertain validity of the studies.

Environment

In the European Union methyl methacrylate (hereafter referred to as MMA) is produced and isolated as chemical intermediate. According to industry statements for 1996, the total EU production capacity amounts to 610,000 t/a and the actual production volume to 470,000 t/a. Significant dynamics of the methacrylate-chemistry market are reported.

MMA is mainly used as an intermediate for the production of polymers. The most important polymer types are cast acrylic sheets and molding / extrusion compounds, besides emulsions, dispersions and solvent based polymers. Another significant use is the production of various methacrylate esters, which are subsequently used for polymer production. Minor amounts are distributed and used as monomer, e.g. in reactive resins, but even in these applications the MMA monomers eventually will be polymerized; the final polymerization step takes place at the site of use.

About 2/3 of the total production quantity are sold to customers and not processed at the production sites.

Releases of MMA to the environment are to be expected mainly during production and processing with waste water and exhaust gas as well as during the use of water based emulsion polymers, e.g. paints and varnishes.

Residual monomeric MMA-contents, which are the basis for release estimations from different polymeric products, are reported to range between 0.005 and 1.1 %.

Direct releases to agricultural or natural soil are not expected to a relevant extent.

MMA has a water solubility of 16 g/l, a vapour pressure of 42 hPa , and a log Pow of 1.83. The environmental behavior of MMA is determined by its range of 1.1 - 9.7 hours atmospheric half life and moderate volatility. MMA is readily biodegradable. Hydrolysis is not significant at neutral and acidic pH, but increases in the upper pH range. The average K_p value of 1.0 l/kg indicates no relevant adsorption onto sediment or soil. Based on the physico-chemical properties of MMA, the air and to a much lower extent the hydrosphere are the preferred target compartments for distribution and neither relevant bioaccumulation nor geoaccumulation are expected. In waste water treatment plants 89.2 % of the substance are estimated to be removed predominately by biodegradation.

For fish, only two relevant results from acute tests are currently available. For *Lepomis macrochirus*, a 96h LC_{50} of 191 mg/l is reported, for the rainbow trout *Oncorhynchus mykiss* a LC_{50} of > 79 mg/l and a 96h NOEC of 40 mg/l.

For invertebrates acute and long-term studies on *Daphnia magna* had been conducted. The most relevant EC value is 21d NOEC = 37 mg/l; the acute study reports 48h EC₅₀ = 69 mg/l.

The most relevant study on algae has examined *Selenastrum capricornutum* according to OECD-guideline 201. The highest test concentration of 110 mg/l caused growth inhibition below 50 %, the NOEC was 110 mg/l for growth rate and 49 mg/l for biomass as endpoints.

Based on these data there is a moderate hazard concern to aquatic organisms. For derivation of the **P**redicted **No Effect Concentration** (PNEC) the lowest valid effect concentration, i.e. 37 mg/l from the long-term daphnid test, is divided by an assessment factor of 50 as proposed in the TGD for the present data basis: $PNEC_{aqua} = 740 \ \mu g/l$.

It is not possible to derive a PNEC for the atmospheric compartment due to the lack of experimental data.

Data on effects to terrestrial organisms are not available. In an indicative risk assessment for the soil compartment, the aquatic PNEC of 740 μ g/l can be used and compared to the concentration in soil pore water.

Exposure

No information.

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 conclusion: There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account:

A potential risk to the local aquatic environment is identified from wet polymerization processes by downstream users of monomeric MMA (default calculations for generic site and four out of 29 known sites). Although an improvement of exposure data would be possible for the wet polymerization scenarios, e.g. by performing effluent measurements, it is concluded that a sufficient and appropriate data basis cannot be acquired within an acceptable time frame and with acceptable efforts. Additionally, due to the dynamic methacrylate market, significant year-to-year variations of MMA tonnages used at individual sites hamper reliable PEC estimations.

On the effects side of the risk assessment data improvement would be possible because an assessment factor of 50 is used for the PNEC derivation and it might be possible to lower the PNEC by further testing, i.e. the assessment factor can be lowered to 10 if a long-term fish test is performed. But regarding the locally limited risks that are identified due to the specific scenario this kind of data improvement is not proposed by the rapporteur.

It is concluded, that local risk reduction measures have to be considered, if the MMA processing capacity exceeds 5000 t/a at one single site. It should be noted, that waste water reutilization / recycling systems are applied by some known polymerization sites, avoiding any significant MMA emission to hydrosphere. Sites applying such advanced process engineering would not require further consideration of risk reduction measures.

There is a need to limit the risks of MMA concerning skin sensitization and respiratory tract irritation at several workplaces in the chemical industry, industrial area and skilled trade and during use of casting resins. For inhalation exposure scenarios, systemic toxicity gives additional rise to concern.