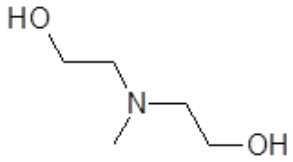
SIDS INITIAL ASSESSMENT PROFILE

CAS No(s).	105-59-9
Chemical Name(s)	Ethanol, 2.2'-(methylimino)bis- (MDEA)
Structural Formula(s)	

SUMMARY CONCLUSIONS OF THE SIAR

Physical-chemical Properties

2.2'-(Methylimino)bisethanol (MDEA) is a liquid with a melting point of -21.3 °C at 1013 hPa (measured), a boiling point of 243.3 °C at 1013.3 hPa (measured) and an extrapolated vapour pressure of 0.0031 hPa at 20 °C. The measured octanol-water partition coefficient (log K_{ow}) is -1.08 at 25 °C and pH 10.1 and the water solubility is > 1000 g/L at 20 °C (measured). The measured pKa value of the protonated form of MDEA in water was 8.52 (25 °C).

Human Health

MDEA is readily absorbed from the skin and distributed to internal organs. Metabolic processes play an important role in the elimination of this compound. The main route of excretion after dermal exposure is through the urine. Absorption from the gastrointestinal tract is also expected based on the low molecular weight of the substance.

Single exposures of rats to saturated vapour atmospheres of MDEA did not result in mortality or other signs of local or systemic toxicity in tests similar to OECD TG 403; LC_{50} values were not determined. Dermal LD_{50} values for rabbits of > 2000 mg/kg bw have been calculated from studies similar to OECD TG 402; sluggishness, unsteady gait, emaciation and prostration were noted after application of undiluted MDEA but surviving animals recovered during the observation period. Oral (gavage) LD_{50}'s for rats were >= 1945 mg/kg bw in studies similar to OECD TG 401; staining, lacrimation (some bloody), diarrhea, postural changes, sluggishness, and prostration were observed, but surviving animals recovered post dosing. After oral gavage, bronchitis and bronchiectasis was noted in surviving animals.

MDEA was not irritating to the skin in a study similar to OECD TG 404, but skin irritation (with some necrosis in females) was seen in the 90-day dermal repeated-dose study. MDEA is a moderate eye irritant based on results of a study similar to OECD TG 405. Signs of respiratory irritation have not been reported in acute vapour inhalation studies.

In a study similar to OECD TG 406 (skin sensitisation; guinea pig maximization procedure), MDEA produced sporadic irritation but did not produce dermal sensitization in guinea pigs.

In a study similar to OECD TG 411, 10 rats/sex/dose were administered MDEA at 0, 100, 250 and 750 mg/kg bw/day under occlusive cover for 6 hours/day, 5 days/week for 90 days. MDEA produced moderate to severe irritation at the site of treatment at the highest two doses, characterized by desquamation, excoriation, ulceration, necrosis, eschar, acanthosis, hyper- and parakeratosis, fibrosis, and dermatitis. No systemic effects were observed. The NOAEL was 100 mg/kg bw/day for local effects and 750 mg/kg bw/day (the highest dose tested) for systemic toxicity.

MDEA did not induce gene mutations in bacteria or mammalian cells *in vitro* in studies similar to OECD TG

471 or 476, respectively, or induce micronuclei *in vivo* in a study similar to OECD TG 474. Based on these results, MDEA is not considered to be genotoxic. No data are available for the carcinogenicity of MDEA.

In an OECD TG 421 oral gavage study, male and female rats were administered MDEA at 0, 100, 300 and 1000 mg/kg bw before and during mating (both sexes) and during gestation and for 4 days of lactation (females). The NOAEL for general, systemic toxicity was 100 mg/kg bw/day for the F_0 parental male and female rats based on decreased body weights at the higher doses. The NOAEL for reproductive toxicity was 300 mg/kg bw/day based on increased duration of gestation. The NOAEL for developmental toxicity was 300 mg/kg bw/day, based on litter loss, insufficient lactation behaviour (less or no milk in the stomach) and reduced viability index and reduced postnatal offspring weight gain. In a prenatal developmental OECD 414 dermal study, pregnant rats were administered 0, 250, 500 or 1000 mg/kg bw under occluded patches for 6 hours/day on gestation days 6 to 15. No increase in the total number of malformations or variations (external, visceral, or skeletal) was observed. The NOAEL for maternal toxicity in rats was 250 mg/kg bw/day based on severe dermal irritation. The NOAEL for developmental toxicity was 1000 mg/kg bw/day (the highest dose tested).

MDEA possesses properties indicating a hazard for human health (eye irritation, some severe skin irritation and systemic toxicity following repeated exposure, reproductive toxicity at high doses). Adequate screening-level data are available to characterize the human health hazard for the purposes of the OECD Cooperative Chemicals Assessment Programme.

Environment

MDEA is expected to be hydrolytically stable in the natural environment. The majority of MDEA will exist as a cation in water at environmentally relevant pH (pH 5-8). It should be noted, however, that EPISuite predicts environmental fate endpoints for MDEA in its uncharged form. Therefore, there will be some differences between predicted and actual results.

In the atmosphere, indirect photo-oxidation by reaction with hydroxyl radicals is predicted to occur with a half-life of 1.3 hours. In an OECD TG 301A ready biodegradablity test, 96 % biodegradation was observed after 18 days. Similar results were obtained in an inherent biodegradability test (OECD TG 302B) and a Kombi test although in an OECD TG 301C ready biodegradability test, 7% biodegradation was observed after 28 days. In a ready test with natural seawater according to OECD TG 306 the substance was not readily biodegradable (15% in 63 days). MDEA is considered readily biodegradable under aerobic conditions in freshwater compartments and not readily biodegradable in marine environment..

A level III fugacity model calculation with equal and continuous distributions to air, water and soil compartments suggests that MDEA will distribute mainly to the soil (62%) and water (37.9%) compartments with minor distribution to the air and sediment compartment (<0.1%). A pH corrected Henry's law constant at pH 7 of 2.56 x 10^{-7} Pa m³/mol at 25 °C (estimated) suggests that volatilization of MDEA from the water phase is not expected to be high.

MDEA is not expected to bioaccumulate in the aquatic environment based on an estimated BCF value of 3.16.

The following acute toxicity test results have been determined for aquatic species:

Fish

[*Leuciscus idus*]	96 h LC_{50} = 1466 mg/L (nominal; static)
[*Leuciscus idus*]	96 h LC_{50} > 1000 — 2200 mg/L (nominal; static)
[*Cyprinodon variegatus*]	96 h LC_{50} > 1000 mg/L (nominal; semi-static)
[*Pimephales promelas* fry]	96 h LC_{50} = 1170 mg/L (nominal; static)

Invertebrates

[*Daphnia magna*]	48 h LC_{50} = 233 mg/L (nominal; static)
[*Daphnia magna*]	48 h LC_{50} = 230 mg/L (nominal; static)

Algae

[*Desmodesmus subspicatus*]	72 h ErC_{50} = 175.7 mg/L (growth rate; nominal)
	72 h EbC_{50} = 55.0 mg/L (area under growth curve; nominal)
[*Skeletonema costatum*]	72 h ErC_{50} = 410 mg/L (growth rate method; nominal)

72 h EbC_{50} = 110 mg/L (area under growth curve; nominal)

MDEA has a low hazard profile for the environment. **The chemical is readily biodegradable in fresh water and is not expected to bioaccumulate. Adequate screening-level data are available to characterize the hazard to the environment for the purposes of the OECD Cooperative Chemicals Assessment Programme.**

Exposure

In the Sponsor Country (USA), production volume was 22,680 to < 45,360 tonnes in 2005. MDEA can be used as an intermediate. MDEA is used mainly in the construction industry. Other applications of MDEA include use as an additive in lubricants and coatings. Potential exposure routes for workers include dermal and inhalation. In its use as lubricants/coatings, there may be consumer uses. Exposure would be by the dermal and/or inhalation routes.