SIDS INITIAL ASSESSMENT PROFILE

CAS No.	107-64-2
Chemical Name	Dioctadecyldimethylammonium chloride
Structural Formula	$(n\text{-}C_{18}H_{37})_2N^+(CH_3)_2Cl^-$

CONCLUSIONS AND RECOMMENDATIONS

The substance is currently of low priority for further work.

SHORT SUMMARY WHICH SUPPORTS THE REASONS FOR THE CONCLUSIONS AND RECOMMENDATIONS

Exposure

Dimethyldioctadecylammonium chloride (DODMAC) as an isolated substance is not produced or used in a commercial range. DODMAC is the major component in the technical product ditallowdimethylammonium chloride (DHTDMAC). The alkyl chains of this compound consist of 60-70% C18-chains, so the proportion of DODMAC is about 42% related to the total content of dialkyldimethylammonium compounds. The actual production volume was estimated at 5,004 t in 1996 and 5,651 t in 1997. DHTDMAC is used as fabric softener, as additive in car washing agents and cosmetics, to activate organic clays (bentonites), in sugar refining, as anti-static and disinfection agent, corrosion inhibitor and wood impregnation. The use of DHTDMAC as fabric softener has been strongly diminished in the last years in several EU countries. Releases of DODMAC into the environment occur during production, processing to and use of activated bentonites and due to the use as fabric softener and in hair conditioners and car washing agents via household sewage. Exposure of the terrestrial compartment is expected due to sludge application. DODMAC has been detected in drinking water received from bank filtrate and surface water.

Hazards to the Environment

DODMAC is not readily biodegradable. Its removal in wwtps (ca. 95%) is mainly due to ad-sorption onto sludge. For the degradation in soil and sediment a half-life of 500 d resp. 5000 d was derived. Based on the molecular structure, no abiotic degradation (e.g. hydrolysis, photolysis) under environmental conditions is expected.

No data for the vapour pressure are available. Based on the molecular structure, no volatility is expected.

Both DODMAC and DHTDMAC have to be considered as nearly insoluble in water.

However, the compounds form stable dispersions in water containing unilamellar or multilamellar particles such as vesicles. Both substances can also form mixed aggregates with other substances, e.g. anionic tensides or humic substances. DODMAC adsorbs onto both the mineral and the organic fraction of soil and sediments. For the assessment, a value of 10,000 l/kg dw is used for both Kp_{sed} and Kp_{soil}.and of 16,800 l/kg dw for Kp_{susp}.

From a bioaccumulation study with fish a BCF of 13 was derived. For the sediment-dwelling organisms *Lumbriculus variegatus* a BSAF (biota sediment accumulation factors) of 0.28 was found and for *Tubifex tubifex* a value of 0.78. From these values it can be concluded that DODMAC has a low bioaccumulation potential.

Short- and long-term tests are available with fish, invertebrates and algae using both laboratory water and river water. As it is assumed that tests with river water are more relevant these values are used for the environmental hazard assessment.

The most sensitive aquatic species to DODMAC is the algae *Selenastrum capricornutum*: in river water tests, a 5d-NOEC = 62 µg/l was determined, while in laboratory water, the 96 h-NOEC was 6 µg/l. From a long-term test with *Daphnia magna* a 21d-NOEC for reproduction of 380 µg/l in river water was derived. In an embryo-larval test with *Pimephales promelas* a 33d-NOEC of 230 µg/l in river water was found. With an assessment factor of 10 a $PNEC_{riverwater}$ of 6.2 µg/l was derived from the NOEC for Selenastrum capricornutum.

In long-term tests with sediment organisms the following effect values were obtained:

Chironomus riparius: 24d-NOEC = 876 mg/kg dw
Lumbriculus variegatus: 28d-NOEC = 5000 mg/kg dw
Tubifex tubifex: 28d-NOEC = 1515 mg/kg dw; 28d-EC_{10} = 550 mg/kg dw
Caenorhabditis elegans: 72h-NOEC = 1350 mg/kg dw

A PNECsed of 55 mg/kg dw was derived from the EC_{10} for *Tubifex* using an assessment factor of 10.

From effect values with terrestrial organisms a PNECsoil of 20 mg/kg was derived.

Human Health

Human data on the acute toxicity and on local irritation/corrosion caused by DODMAC are not available. In rats, the substance exhibited only low acute toxicity with oral LD_{50} > 2000 mg/kg bw, dermal LD_{50} > 200 mg/kg bw and inhalation LC_{50} > 180 mg/l/1 hour.

Pure DODMAC causes serious damage to the eyes but only moderate irritation to the skin of rabbits. Data on respiratory irritation is not available. Technical grade DODMAC, however, has proven to be corrosive to the skin of rabbits because of a high content of isopropanol.

DODMAC enhances the allergic potency of other chemical substances, but does not seem to cause skin sensitization by itself as judged on the basis of tests with relevant concentrations of DODMAC.

There is no information on health effects in humans following repeated exposure to DODMAC via any route. Following repeated oral exposure of 500 mg/kg bw/d of DODMAC to rats degeneration of adrenal cortex was induced. Comparable lesions in the adrenals were also seen after 500 mg/kg bw/d DHTDMAC, additional effects were reticuloendothelial hyperplasia and accumulation of foamy macrophages of mesenteric lymph nodes and increased incidence of chronic liver inflammation. No adverse effects were reported up to 100 mg/kg bw/d DODMAC (NOAEL). After repeated dermal application to rabbits, local irritation but no systemic toxic effects were observed up to 40 mg/kg bw/d (NOAEL). A systemic LOAEL was not determined. There is no information on effects after prolonged inhalation exposure to rodents.

DODMAC showed negative results in bacterial mutation tests and in an *in vitro* chromosomal aberration test. There is no evidence of a genotoxic potential of the substance. No data is available on carcinogenic effects of DODMAC or DHTDMAC. There are no data from mutagenicity studies which give concern regarding carcinogenicity of both substances.

There is no human data on the reproductive toxicity of DODMAC. In an oral study on rats according to OECD Guideline 421 a dose of 500 mg/kg bw/d led to impaired reproductive performance in combination with clear signs of general toxicity. Based on the reduced mating, fertility and gestation indices a NOAEL for reproductive toxicity of 125 mg/kg/d can be estimated.

No specific human population at risk could be identified within the general population.

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 at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.