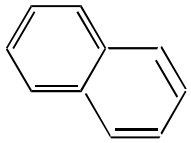
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	91-20-3
Chemical Name	Naphthalene
Structural Formula	

CONCLUSIONS AND RECOMMENDATIONS

The chemical is a candidate for further work.

SHORT SUMMARY WHICH SUPPORTS THE REASONS FOR THE CONCLUSIONS AND RECOMMENDATIONS

Western European production capacity for naphthalene in 1985 was 282,000 tonnes. Around 70% is used in the manufacture of phthalic anhydride. It is also used in the production of mothballs, azo dyes, naphthalene sulfonic acids and alkylated naphthalene solvents. Naphthalene and its alkyl homologues are the major constituents of creosote used for timber treatment. Tar containing naphthalene is also used in some specialist paints and waterproof membranes. Environmental releases of naphthalene from production and use are likely to be small in comparison to releases from combustion sources, particularly motor vehicle exhausts.

In the atmosphere, naphthalene reacts with hydroxyl radicals and has a half-life of approximately 1 day. Experimental results on biodegradability indicate that naphthalene may be easily degraded under aerobic and denitrifying conditions, particularly when acclimated microorganisms are present, with concentrations falling below measurable levels in 8-12 days. Measured soil organic carbon-water partition coefficients indicate moderate sorption to soils. Bioconcentration factors of ~300 have been measured in fish.

The toxicity of naphthalene has been tested on a wide range of fish and aquatic invertebrate species. The majority of results from short-term tests lie in the range 1-10 mg/l. From longer-term studies, NOECs of 0.12 and 0.45 mg/l for fish, and 0.6 and 0.22 mg/l for invertebrates have been determined. (There are some indications from other less clear tests of effects down to 10 µg/l.) Test results for algae appear to show short-term effects at lower concentrations than those from longer-term tests. Thus growth was affected at 400 µg/l over 3 days, but 10 day EC_{50} values for biomass were 33 and 25 mg/l.

Following a detailed risk assessment in the European Union, this chemical is currently considered of low priority for further work for the environment (but see note under summary of further work).

There is no information on the effects of naphthalene following acute inhalation or dermal exposure in humans. Acute oral exposure to naphthalene causes haemolytic anaemia, which may be fatal. There is little quantitative human acute toxicity information available, although severe haemolytic anaemia, which may have proved lethal in the absence of clinical intervention, was reported in a female who had ingested approximately 6 g naphthalene (estimated to be equivalent to approximately 120 mg/kg, assuming a 50 kg youth). Studies in rodents have indicated that the toxic effects of naphthalene seen in these species are different from those in humans. No conclusions can be drawn regarding the irritant properties of naphthalene from studies in humans; data from animal studies indicate that it is only a slight skin and eye irritant. Despite widespread use, the absence of reports in humans appears to indicate

that naphthalene in not a skin or respiratory sensitiser. In animal skin sensitisation studies, negative results were obtained in both an inadequate maximisation study and a briefly reported Buehler study.

For repeated exposures via the oral route general signs of toxicity and death were observed in rats and rabbits at doses of 700 mg/kg/day and above. A NOAEL of 53 mg/kg/day was identified in mice (14 and 90 days). Signs of nasal inflammation were observed in a 90-day inhalation study in rats at 58 ppm. In mice signs of respiratory tract inflammation were noted at 10 ppm (LOAEL). No adverse effects were observed in rats following dermal application at a dose of 1000 mg/kg/day.

Naphthalene has given reproducible negative results in bacterial mutation assays, and was apparently negative in an *in vitro* UDS assay available in abstract form only. It was found to be clastogenic in CHO cells in the presence, but not in the absence, of S9; and sister chromatic exchanges were produced *in vitro* in the presence and absence of S9. This activity is not expressed *in vivo* as evidenced by the two negative micronucleus tests. However, a confirmatory *in vivo* study in a second tissue is recommended to remove uncertainty as to whether or not naphthalene has the potential to exhibit its genotoxic potential *in vivo*.

In the most useful animal carcinogenicity study available, female mice showed an increase in the incidence of benign tumours (alveolar/bronchiolar adenomas), to which this species is prone, following inhalation exposure to naphthalene. Although some uncertainty remains concerning the genotoxic potential *in vivo* of naphthalene, the neoplasia seen in mice lies on a background of inflammatory changes in the tissues affected and is thus considered to be a result of chronic tissue injury, and therefore arising via a non-genotoxic mechanism.

No animal studies have specifically investigated fertility. However, in a two-year carcinogenicity study mice showed no histopathological changes in the gonads or accessory sex organs following inhalation of 30 ppm naphthalene. Naphthalene only produces fetotoxicity at maternally toxic doses in animals, and does not produce developmental toxicity at maternally subtoxic doses.

A detailed risk assessment in the European Union has identified occupational health risks from mothball manufacture. Exposure of infants to textiles (clothing/bedding) that have been stored for long periods with naphthalene moth repellent also raises significant concern. There is documented evidence for the development of severe haemolytic anaemia resulting from such use, although there is no quantitative information available on the level or duration of exposure to naphthalene in these cases.

NATURE OF FURTHER WORK RECOMMENDED

SIAM 5 recommendations:

- Surveillance programme has been proposed for workers in the production of mothballs.
- Actual exposure data during damp-proof laying.
- An additional *in vivo* genotoxicity test is recommended as post-SIDS testing.
- Risk management measures should be considered concerning the exposure of infants to textiles that have been stored for long periods with naphthalene moth repellent.

[Supplementary information post-SIAM: It is recommended that Member States consider a national environmental risk assessment for use in grinding wheel manufacture.]