

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	105-99-7
Chemical Name	Dibutyl adipate
Structural Formula	C ₄ H ₉ OOC-CH ₂ CH ₂ CH ₂ CH ₂ -COOC ₄ H ₉

CONCLUSIONS AND RECOMMENDATIONS

The chemical does not reveal any remarkable toxicity or ecotoxicity.

It is currently considered of low potential risk and low priority for further work.

SHORT SUMMARY WHICH SUPPORTS THE REASONS FOR THE CONCLUSIONS AND RECOMMENDATIONS

Dibutyl adipate is volatile liquid and production volume is less than 100 tonnes/year in 1987 - 1992 in Japan. This chemical is used as for plasticizer for resins mainly. Dibutyl adipate is readily biodegradable. Dibutyl adipate is not hydrolyzed at pH 4, but hydrolysed at 7 and 9. The half-life is a week at pH 9. Direct photodegradation is not expected because dibutyl adipate does not absorb UV light.

The potential environmental distribution of dibutyl adipate obtained from a generic fugacity model (Mackay level III) showed the chemical will be distributed mainly to water and soil. The predicted environmental concentration (PEC_{local}) of this chemical was estimated to be 4×10^{-3} mg/l from Japanese exposure scenario.

For the environment, various NOEC and LC₅₀ values were gained from test results; LC₅₀ = 3.7 mg/l (acute fish); EC₅₀ = 17 mg/l (acute daphnia); NOEC = 2.0 mg/l (algae); NOEC = 5.6 mg/l (long-term daphnia reproduction). Therefore, the chemical is considered to be moderately toxic to fish and daphnids and slightly toxic to algae. The lowest toxicity result for *Selenastrum capricornutum* (NOEC = 2.0 mg/l) was adopted for the calculation of a PNEC, applying an assessment factor of 100. Thus the PNEC of the chemical is 0.02 mg/l. Since the PEC is lower than the PNEC, environmental risk is presumably low.

As dibutyl adipate is produced in a closed system, exposure during synthesis may be excluded. This chemical is mainly used as a plasticizer for resins. There is a possibility of workplace exposure when the product is filled into barrels, with skin contact considered to be the main exposure route. Inhalation plays a minor role because the vapour pressure of this chemical is very low. Workers wear safety glasses and gloves during the filling process. Exposure levels calculated by the EU exposure model are 0.5 - 3.0 by inhalation and 0.1 - 1 mg/mg/m²/day by dermal, respectively, at production site of this chemical. There are no actual measurement data of exposure. By wearing safety equipment during filling process, the exposure level can be very low.

The chemical is contained in consumer floor wax as a. Dermal exposure of this chemical is expected during housekeeping. The exposure level was estimated to be 3.6 mg/kg bw/day for one event.

For indirect exposure via the environment, the concentration in drinking water was estimated as to be less than 4×10^{-3} mg/l from the local exposure scenario.

Although the chemical showed positive result in chromosomal aberration test *in vitro* with metabolic activation, no

genotoxic effects were observed in bacteria and no chromosomal aberration were observed *in vitro* without metabolic activation. In a combined repeat dose and reproductive/developmental toxicity screening test, salivation was observed in both sexes given 1,000 mg/kg/day. No test substance-related changes were noted in body weight gains, food consumption, findings obtained from haematology testing, blood chemical examination, urinalysis and pathological examination. For reproductive/developmental end-points, there were no adverse effects of this chemical on copulation, fertility, maintenance of pregnancy, parturition and lactation. In the 1,000 mg/kg group, pup weight on day 0 and 4 of lactation was slightly lower and viability on day 4 of lactation was decreased compared to those of the control group. However, there were no malformations which were considered to be induced by this chemical. Therefore, the NOEL was 300 mg/kg/day for repeated dose toxicity as well as 300 mg/kg/day for reproductive toxicity.

For human health, margins of safety are considered to be sufficient. Therefore, health risk is presumably low.

In conclusion, no further testing is needed at present considering its toxicity and exposure levels.

NATURE OF FURTHER WORK RECOMMENDED