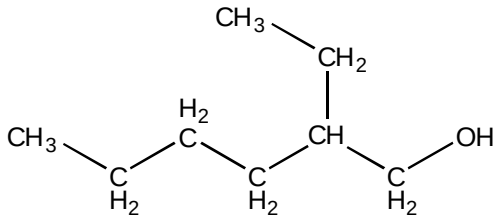
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	104-76-7
Chemical Name	2-Ethylhexanol
Structural Formula	

CONCLUSIONS AND RECOMMENDATIONS

This chemical is a candidate for further work.

SHORT SUMMARY WHICH SUPPORTS THE REASONS FOR THE CONCLUSIONS AND RECOMMENDATIONS

1.7 millions tonnes of 2-Ethylhexanol (2EH) was produced in 1992 worldwide. 2EH is predominantly used as raw material (intermediate) in the synthesis of platicizers, hexyl esters and acrylates and has other uses e.g. in paints.

2EH is classified as “inherently biodegradable”, and may have a high potential to bioaccumulate in aquatic organisms. 2EH is of moderate acute toxicity to aquatic animals and plants (L(E)C50 within 11.5-44mg/l). Data on chronic toxicity on aquatic animals is not available.

Calculations based upon chemical/physical data indicate that 2EH will migrate to the water compartment. 2EH will only degrade slowly in water, and is expected to be persistent in ground water. 2EH will degrade in the air.

Information is not available on degradation in soil.

The potential exposure of the local aquatic environment around the factory site is considered to be low if the waste water is effectively treated. It is unclear if the use of WWTP adapted to 2EH satisfactorily reduces the concentration of 2EH in the sludge and effluent. Without proper treatment of waste water the PEC/PNEC (>1) indicates a possible risk to the aquatic environment. Monitoring data indicates that such an exposure does occur.

2EH was moderately irritating to rabbit skin and a moderate-to-severe irritant to the eye in rabbits. A sensitization study is not available.

2EH is rapidly and extensively absorbed via the gastrointestinal tract in rats and rabbit. Percutaneous absorption through rat skin is low. Observed toxicity via p.o. and inhalation routes indicates that 2EH/metabolites are distributed to several organs. Target organs include liver, kidney and stomach. The excretion of 2EH/metabolites following p.o. administration is rapid and extensive occurring mainly via the urine in rat and rabbit.

Acute oral studies (rat, mouse, guinea pig, rabbit) indicate moderate-to medium toxicity (>3000-600mg/kg). Medium acute toxicity is indicated in inhalation studies (≥1.2-<5.3mg/l). Acute dermal toxicity was moderate in rat and rabbit (>2000mg/kg). Intraperitoneal administration causes high acute toxicity. (CNS was a target but long-term studies

show effects indicative of CNS toxicity were few.)

Repeat dose 90-day toxicity studies have been performed (via the oral route (rat, mouse), inhalation route (rat)). Effects on the liver, stomach, and kidney degeneration were reported. For oral exposure NOAEL is 125mg/kg/d (rat), inhalation NOAEL is ≥0.639mg/l/d. For dermal route subacute studies are available and the NOAEL is <1.66 g/kg/d.

2EH was negative in Salmonella mutagenicity tests and chromosomal aberration tests (*in vitro* and *in vivo*). Other studies indicate that 2EH does not have genotoxic activity and carcinogenic potential was not demonstrated in studies in rats and mice. NOAELrat = 50mg/kg.

Fertility studies are not available, however several oral subacute studies in rat and mice have produced alterations in testicular weight. This was not observed with rats and mice in 90-day repeat dose studies.

Developmental studies are available for rats (oral, dermal, inhalation) and mice (oral). Effects were only observed for rats treated by the oral route and included skeletal malformation and retardation. The NOAELrat,oral = 130 mg/kg, the NOAELrat,inhal = <0.85 mg/l, the NOAELrat,dermal = 840mg/kg and the NOAELmouse, oral = 191 mg/kg.

Analysis of the available data show that for an indirect, consumer or occupational setting the margin of safety for man is high.

NATURE OF FURTHER WORK RECOMMENDED

Currently considered that further Post-SIDS work is needed.

Look at with 2-Ethylhexanoic acid (149-57-5), especially regarding the reprotoxicity end-point, exposure and other data from long-term ecotoxicity tests.