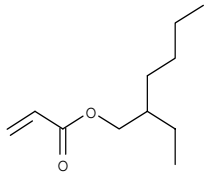
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	103-11-7
Chemical Name	2-Ethylhexylacrylate
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

2-Ethylhexyl acrylate (2-EHA) is rapidly and extensively absorbed, distributed and eliminated after oral administration. There are no specific toxicokinetic studies available using dermal administration or inhalation exposure. Studies on rats have indicated that short-chain acrylates such as 2-EHA undergo carboxylesterase-catalyzed hydrolysis to acrylic acid and 2-ethylhexanol.

Human data on the acute toxicity of 2-EHA are not available. In animal tests, single oral or dermal administration or inhalation of saturated atmospheres of 2-EHA demonstrated only low toxicity. Acute oral toxicity in rats is characterised by LD50 values of 4000 - 6000 mg/kg with slight toxic effects (scant droppings, wet yellow stained anogenital area, decreased spontaneous motoric activity and ataxia). For rabbits, a dermal LD50 value >10000 mg/kg is reported. Valid data on acute inhalation toxicity tests are not available. In a test with rats, after an 8-hours inhalation of an atmosphere saturated with EHA at 20°C no mortality and no clinical signs were observed.

Human data on the local irritant/corrosive properties of the substance are not available. 2-EHA caused severe irritation near corrosion after application to the skin of rabbits. Eye irritation was less severe in animal experiments. Considerations on the general irritation potential of 2-EHA with nasal and ocular irritations in a test on acute inhalation toxicity with rats warrants classification and labelling for respiratory irritation. Based on the observation on eye and skin irritation 2-EHA is considered to be a respiratory irritant.

Positive patch-tests are reported for humans. In various test models involving guinea pigs, 2-EHA proved sensitizing, with and without adjuvants. 2-EHA has a moderate sensitizing potential in experimental animals.

The relevant toxic effect after 90-day inhalation exposure of rats to 2-EHA was dose-related increased degeneration of the olfactory epithelium at concentrations from 30 ppm and higher (0.225 mg/l). The NOAEC for local effects on the respiratory tract was 10 ppm (0.075 mg/l). Animals exposed to 2-EHA concentrations of 30 ppm or higher showed poor health condition (lethargy, ptosis) during exposure period and reduced body weight gain, but no toxic effect on internal organs was identified (NOAEC for systemic effects). Minimal liver damage was indicated by elevated liver enzyme activities at a concentration of 100 ppm (0.75 mg/l). Valid studies with dermal or oral application routes are not available. Cancer studies and less documented subchronic studies with dermal application revealed that 2-EHA causes skin irritation at concentrations > 2.5% (LOAEL).

2-EHA is negative in bacterial mutation tests. Data from mammalian cells give no relevant evidence for clastogenicity; however, a fully reliable *in vitro* study is lacking. 2-EHA seems to have a low potential for induction of gene mutations in mammalian cells. Since this effect is limited to doses with strong cytotoxicity, it is highly unlikely that this potential will be expressed *in vivo*. The data from *in vitro* mammalian cell indicator tests do not add

relevant information. An *in vivo* UDS assay in rats performed according to OECD Guideline 486 was negative. Cleavage products of 2-EHA - acrylic acid (SIAR, cf. finalised EU Risk Assessment) and 2-ethylhexanol - were negative in *in vivo* chromosomal aberration mutagenicity tests. From all these data there is no relevant evidence that 2-EHA might be an *in vivo* mutagen.

There are no data available to the carcinogenic effects with respect to oral or inhalation exposure routes. Findings from the dermal mouse carcinogenicity study showed that 2-EHA induces skin tumors at concentrations which were highly irritative. However, other studies on different mouse strains did not confirm this finding. Acrylic acid, the hydrolysis product, did not induce tumors in mice treated dermally and in rats administered orally. Also, there is no concern from cancer data on 2-ethylhexanol. It is concluded that equivocal results from mice painting studies give no significant evidence of carcinogenic properties of 2-EHA.

From animal testing screening information on reproductive toxicity is available from a developmental toxicity study supplemented with data from a 3 month inhalation study indicating no effects on male and female reproductive organs investigated histologically. In both tests exposure up to and including 100 ppm (appr. 0.75 mg/l) was investigated. Evaluation of the available screening information so far does not provide evidence for significant reproductive toxicity of 2-EHA.

Environment

The environmental behaviour of 2-ethylhexyl acrylate is determined by the following characteristics:

The liquid substance (melting point = -90 °C; boiling point = 216 °C) has a water solubility of 9.6 mg/l and a vapour pressure of 12 Pa. With a Henry´s law constant of H = 230 $Pa \cdot m^3/mol$ evaporation from surface water is rapid and therefore an important fate process.

Based on the physical chemical properties of 2-ethylhexyl acrylate, the atmosphere is the main target compartment for distribution and only small amounts remain in the hydrosphere. Using the fugacity model of Mackay (level 1) about 97% are expected to be distributed to the atmosphere, about 1% remain in the surface water and less than 1% are expected to end up in each soil and sediment.

The estimated atmospheric half-life is approximately 19 hours. Hydrolysis and photolysis in water are not relevant degradation processes in the environment, but 2-ethylhexyl acrylate can be classified as readily biodegradable.

From the log Pow of 3.9 BCF- and Koc-values can be calculated indicating a moderate potential for bioaccumulation and geoaccumulation.

The valid ecotoxicological studies in fish, invertebrates and plants where the effect concentrations are based on analytical monitoring are compiled below:

Rainbow trout, *Oncorhynchus mykiss* , 96 h-LC50 = 1.8 mg/l
Crustacean, *Daphnia magna*, 48 h- EC50 = 1.3 mg/l (swimming ability)
Green algae, *Desmodesmus subspicatus*, 72 h-E_RC50 = 1.71 mg/l (growth)
Protozoa, *Chilomonas paramaecium* , 48 h-TGK (EC5) = 2.3 mg/l (growth, nominal concentration)

For aquatic organisms a Predicted No Effect Concentration (PNEC) of 1.3 µg/l can be calculated from the lowest reported acute test result for *Daphnia magna* (48 h- EC50 = 1.3 mg/l) applying an assessment factor of 1000.

For microorganisms in waste water treatment plants a PNEC of 2.3 mg/l can be derived based on the 48 h-TGK (EC5) reported for protozoan using an assessment factor of 1.

Data on biotic or abiotic effects in the air compartment are not available. Because of the short half-life of 2-ethylhexyl acrylate in the atmosphere (about 19 hours) adverse effects are not expected.

Exposure

Six companies are known to produce or import 2-ethylhexyl acrylate within the European Union. In 1999 the total EU production volume was 70,000 t/a, the import volume was approximately 30,000 t/a and 10,000 t/a were exported.

From the actual figures available for 1999, a total amount of 90,000 t/a is estimated to be available on the European market, 32,000 tonnes of that are used as an internal intermediate and 58,000 tonnes are sold to external processing sites. Recent information obtained from industry confirmed that no significant changes of the tonnages have to be expected for 2000 and 2001.

2-Ethylhexyl acrylate is used as a monomer in the chemical industry for the production of polymers and copolymers, which are mainly processed further to aqueous polymer dispersions. The polymers and polymer dispersions are used in adhesives and as binders for paints. Other applications include coatings raw materials and uses in the plastics and textiles industries.

In addition, 2-ethylhexyl acrylate is used as a monomer in construction-industry chemicals (e.g. floor coatings, road-marking substances) in concentrations between 0.1 - 21 %.

Releases of 2-ethylhexyl acrylate into the environment are expected to occur mainly during production and processing with waste water and exhaust gases.

Further releases are expected through residual monomeric acrylate-contents in the polymeric products. According to the producer, the aqueous polymer dispersions, as the main products, contain less than 200 mg monomeric 2-ethylhexyl acrylate per kg. Through storage of the polymeric products the residual monomers may partly polymerise and quantification of the releases into the environment from polymeric products can be performed only roughly.

RECOMMENDATION

Human Health: The chemical is a candidate for further work.
Environment: The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human Health: The chemical is a candidate for further work. Hazardous properties have been identified for this substance (local effects after repeated inhalation, irritation, sensitisation). In an assessment performed in the European Union in the context of the EU Existing Substances Regulation, exposure leading to concern has been identified during formulation of preparations, production and polymerisation and the use of formulations containing monomeric 2-EHA in the building trade. Other member countries may wish to perform an exposure assessment for humans and if necessary a risk assessment.

Environment:
2-Ethylhexyl acrylate possesses properties indicating a hazard for the environment. Based on data present by the Sponsor Country, exposure to the environment is anticipated to be low, and therefore this chemical is currently of low priority for further work. Countries may desire to investigate any exposure scenarios that were not presented by the Sponsor Country.

A comprehensive risk assessment has been performed in the European Union in the context of the EU Existing Substances Regulation. From the comparison between estimated exposure levels from all life cycle steps with the

Predicted No Effect Concentrations it is deduced, that 2-ethylhexyl acrylate represents, based on the present data configuration, no risk to the environment. There is therefore at present no need for further testing or gathering of exposure information.