SIDS INITIAL ASSESSMENT PROFILE

CAS No.	2432-99-7
Chemical Name	11-aminoundecanoic acid
Structural Formula	$HO_2C—(CH_2)10—NH_2$

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Limited information indicated that 11-aminoundecanoic acid is rapidly and extensively absorbed by rats after an oral administration, distributed in the body and rapidly excreted mainly via urine.

The acute toxicity of 11-aminoundecanoic acid is negligible: oral LD_{50} in rats >14700 mg/kg, and dermal LD_0 in rats >2000 mg/kg.

11-aminoundecanoic acid induced no skin irritation and only a slight transient eye irritation in rabbits and did not induce positive response in a skin sensitisation assay in Guinea pigs performed according to the Magnusson and Kligman method.

A NOAEL of 5000 ppm in rats (equivalent to 472 mg/kg bw/d for males and 507 mg/kg bw/d for females) and 9000 ppm in mice was established based on a 4-week and a 13-week dietary toxicity study, respectively. At higher concentrations (up to 21000 ppm) administered for up to 13 weeks to rats and/or mice, 11-aminoundecanoic acid has produced histopathological lesions in the kidney in both species.

In vitro, 11-aminoundecanoic acid did not induce gene mutations on bacteria (Ames test), chromosomal aberrations on CHO cells and gene mutations on L5178Y cells. A slight increase of Sister Chromatid Exchanges (SCEs) has been observed in CHO cells. However, the results of *in vivo* assays override the SCEs increase: 11-aminoundecanoic acid was not genotoxic in a Drosophila recessive lethal test, an *in vivo/in vitro* DNA-repair test on rat hepatocytes and a micronucleus test in mice. In addition, in a DNA-binding study with 11-aminoundecanoic acid, using male and female F-344 rats, no indication of DNA alkylation was found in liver, kidneys or bladder. The overall interpretation of the results provided by *in vitro* and *in vivo* assays is that 11-aminoundecanoic acid is not mutagenic. 11-aminoundecanoic acid was tested for carcinogenicity in mice and rats by administration in the diet at 7500 and 15000 ppm. Increased incidence of transitional-cell carcinomas of the urinary bladder and neoplastic nodules of the liver were observed in male rats. Epithelial hyperplasia of the urinary bladder and renal pelvis were observed in male and female rats. No clear evidence for an increased incidence of treatment-related tumours was seen in mice. The carcinogenic effect observed in animals, involved only male rats treated with very high doses of 11-aminoundecanoic acid, and no clear evidence was found in female rats and in male and female mice. Consequently, the excess of malignant tumours of the urinary tract found in male rats are believed to have occurred through a non-genotoxic mechanism and to be associated with the non-neoplastic local tissue damages which were induced when the dose of 11-aminoundecanoic acid reached a sufficiently high level. IARC categorised 11-aminoundecanoic acid as "non classifiable as to its carcinogenicity to humans" (Category 3), due to the limited evidence provided by the animal data and the absence of epidemiological data (IARC, 1986).

No standard fertility studies are available. However, no effects on the reproductive organs (testes, seminal vesicles, and prostate for male or ovaries and uterus for female) were observed in good quality 90-day and 2-year studies in rats and mice where 11-aminoundecanoic acid was administered in feed at doses up to 21000 and 15000 ppm, respectively. Developmental toxicity studies have been carried out in the rat; 11-aminoundecanoic acid did not

produce embryotoxicity or fetotoxicity up to the dose-level of 18000 ppm, with the exception of a slight retardation of growth/skeletal development at dose-levels of 6000 ppm and particularly 18000 ppm (dose-level at which a slight reduction in fetal body weight was also noted). The No Adverse Effect Level for maternal toxicity and embryo-fetal development was established at 6000 ppm (i.e. 520 mg/kg/day). Based on the lack of toxicity on the reproductive organs of male and female rats and mice and the absence of embryo-toxicity and fetotoxicity in pregnant rats, 11-aminoundecanoic acid is unlikely to present reproductive toxicity.

Environment

A pKa (amine) of 11.15 and a pKa (carboxylate) of 4.55 have been determined for 11-aminoundecanoic acid. Therefore, at relevant environmental pH (6-8), the substance will be mainly in zwitterion form. The solubility of 11-aminoundecanoic is pH dependent. At 25°C and pH>=4, the solubility is at maximum 3.2 g/l, a typical value of 0.8 g/l having been measured at environmental pH. At pH <4, the solubility of 11-aminoundecanoic increases with decreasing pH (> 20 g/l below pH 3).

Due to the relatively high solubility (0.8 - 2 g/l), the low octanol-water partition coefficient (log Kow = - 0.16) and the low volatility (2.07 10^{-7} Pa at 25°C) of 11-aminoundecanoic acid, the substance will mainly be present in the aqueous phase. In water it is not expected to hydrolyse. It is readily biodegradable. It is not likely to bioaccumulate. Due to its ionised form, adsorption to soil or sediment with capacity of ion exchange may occur. In the atmosphere, 11-aminoundecanoic acid is rapidly photodegraded by reaction with hydroxyl radicals with an atmospheric average half-life of 4.3 h.

11-aminoundecanoic acid is slightly toxic to aquatic organisms, algae being the most sensitive species with a 72h EbC50 of 23 mg/l. (fish: 96 h LC50 > 833 mg/l; daphnid: 48 h EC50 > 355 mg/l). A PNEC of 45 µg/l may be derived from the NOEC of 4.5 mg/l available on algae applying a safety factor of 100.

Exposure

There is only one producer of 11-aminoundecanoic acid in the world. The production plant is located in the South of France. The annual production capacity is approximately 22,000 tonnes.

11-aminoundecanoic acid is exclusively used as a monomer for the production of polyamides 11 at three different sites; located in Europe (2 sites) and in the US (1 site). Polyamides 11 are used in a number of applications including automotive and aeronautics industries, offshore sector, sport sector, medical and food contact material sector.

The substance is produced and used in closed system. Emissions of 11-aminoundecanoic acid to the environment may occur mainly from production. Aqueous effluents are treated in a waste treatment plant where 11-aminoundecanoic acid is expected to degrade to a large extent due to its ready biodegradability. There are no aqueous streams from the processing of the substance.

There is a potential for professional exposure mainly through inhalation of particles. Personnel protection equipment (mask, gloves and safety glasses) is used during production, handling and use of the substance.

There are no direct consumer uses of 11-aminoundecanoic acid. Food contact materials made of 11-aminoundecanoic acid contain low residual levels of 11-aminoundecanoic acid (< 100 ppm) and are subject to very strict regulations (EU specific migration limit = 0.05 mg/kg food). Therefore, consumer exposure to 11-aminoundecanoic acid is not expected.

RECOMMENDATION

The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

The chemical is currently of low priority for further work because of its low hazard potential.