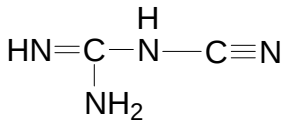
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	461-58-5
Chemical Name	Cyanoguanidine
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

No metabolism data specific to cyanoguanidine is available.

The oral LD_{50} is greater than 30,000 mg/kg bw in female rats. Data on inhalative and dermal acute toxicity are not available.
This substance is considered to be irritating to the skin in guinea pigs. Data on eye irritation are not available. No sensitising potential has been demonstrated in guinea pigs in three maximization studies. The potential was not clearly demonstrated in human. Most workers did not become sensitive to this substance, however, there might be some workers who became sensitive for specific reasons (cross sensitisation or adjuvant effect of co-factors).

A combined repeated dose toxicity study with the reproduction/developmental toxicity screening test [OECD TG 422] was conducted using SD rats at doses of 0, (vehicle; 3% gum arabic solution), 40, 200, and 1,000 mg/kg/day. The dosing period for males was 44 days, and females were dosed from 14 days before mating to day 3 of lactation. This substance had no effect on clinical signs, body weights, food consumption or necropsy findings. The organ weights were similar among all groups. No histopathological changes ascribable to this substance in these organs were found in either sex. The NOAEL for the repeat dose toxicity is considered to be 1,000 mg/kg/day for both sexes.

The reverse mutation studies in bacteria [OECD TG 471 and 472] gave negative results. The *in vitro* chromosomal aberration test with Chinese hamster lung cells (CHL/IU) [OECD TG 473] with and without metabolic activation was also negative. Therefore, this substance is not genotoxic.

A combined repeated dose toxicity study with the reproduction/developmental toxicity screening test [OECD TG 422] (0, 40, 200, 1,000 mg/kg/day) was conducted using SD rats. This substance had no effects on reproductive parameters such as the mating index, fertility index, numbers of corpora lutea or implantations, implantation index, delivery index, gestation index, gestation length, parturition or maternal behavior. On examination of neonates there were no significant differences between the control and treated groups in the number of offspring or live offspring, sex ratio, live birth index, viability index or body weight. No abnormal findings ascribable to this substance were found for external examination or clinical signs or on necropsy of the offspring. The NOAEL for reproductive and developmental toxicity is considered to be 1,000 mg/kg/day.

A carcinogenicity study was conducted in male and female Fischer 344 rats fed diets containing this substance at 0, 2.5 and 5% (male: 837.2 and 1958.6, female: 1001.3 and 2169.2 mg/kg bw/day) for up to 2 years. The study did not suggest an association of the substance with an increased tumor incidence.

Environment

Cyanoguanidine is a white crystalline powder, which is soluble in water (40 g/L at 25 °C). Melting point, boiling point, and vapour pressure are 209.5 °C, solidified at 252 °C , and equal or less than 0.0045 Pa (100 °C), respectively. This substance does not hydrolyse under environmental conditions. Indirect photo-oxidation by hydroxy radicals in the atmosphere is predicted to occur with a half-life of 3.1 hours. This substance is not readily biodegradable under aerobic condition within 28 days (BOD = 0 %). However, a prolonged study showed that this substance is completely biodegraded within 34 weeks under aerobic conditions, while two-thirds of the total is biodegraded within 60 weeks under anaerobic conditions. This substance has a low bioaccumulative potential (BCF (*Cyprinus carpio*, 48days): equal or less than 3.1). Fugacity modeling (Mackay level III) predicts that if the substance is released to water, it will not migrate into other compartments. When this substance is released to air or soil, it is mainly distributed to water and soil.

This substance has been tested in aquatic species (algae, invertebrates and fish). An acute growth inhibition test was performed using green algae (OECD TG 201, *Selenastrum capricornutum*). The EC_{50} (biomass; 0-72 h) was 935 mg/L and the EC_{50} (growth rate; 24-72 h) was > 1,000 mg/L. An acute toxicity test for invertebrates was performed using water fleas (OECD TG 202, *Daphnia magna*). The 48-h EC_{50} was > 1,000 mg/L. An acute toxicity test [OECD TG 203] and a prolonged toxicity test [OECD TG 204] for fish were performed using Medaka (*Oryzias latipes*). The 96-h LC_{50} and the 14-d LC_{50} were both >100 mg/L. A chronic reproduction toxicity test for invertebrates was performed using water fleas (OECD TG 211, *Daphnia magna*). The 21-d EC_{50} and the 21-d NOEC were 69.6 mg/L and 25.0 mg/L, respectively. In microorganisms, this substance is known to have an inhibition activity of the nitrification of ammonium in various systems.

Exposure

The production volume of cyanoguanidine was estimated to be approximately 40,000 t/year worldwide in 2002, and not manufactured at present in Japan. This substance is a basic chemical, and used in industry for electrical/electronic engineering, metal extraction, refining and processing of metals, paper, pulp and board, textile processing, pharmaceuticals and intermediates. This substance is also used as absorbent, adhesive, binding, coloring, electroplating, surface-active agents, and agricultural chemicals (fertilizer).

During production and use of this substance, occupational exposure is possible by inhalation and dermal route. The workplace exposures during manufacturing processes are controlled by personal protective equipment. Consumer exposure is also possible by inhalation and dermal route.

RECOMMENDATION

The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

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