

SIDS INITIAL ASSESSMENT PROFILE

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| CAS No. | 123-42-2 |
| Chemical Name | Diacetone Alcohol |
| Structural Formula | $ \begin{array}{c} \text{O} \qquad \text{CH}_3 \\ \parallel \qquad \quad \\ \text{CH}_3-\text{C}-\text{CH}_2-\text{C}-\text{OH} \\ \quad \quad \quad \\ \quad \quad \quad \text{CH}_3 \end{array} $ |

RECOMMENDATIONS

The chemical is currently of low priority for further work.

SUMMARY CONCLUSIONS OF THE SIAR**Human Health**

Oral LD₅₀ of diacetone alcohol is more than 4,000 mg/kg. This chemical is moderately irritating to skin and irritating to eyes but there is no available data for sensitisation. In oral rat study by an OECD combined repeated dose and reproductive/developmental toxicity screening test [TG 422] at doses of 0, 30, 100, 300 and 1,000 mg/kg/day for at least 44 days, decreased locomotor activity and less response to stimulation by knocking sounds or palpation were observed in males and females of the 300 and 1,000 mg/kg groups. Histopathological examination revealed increases of deposition of hyaline droplets in the proximal tubular epithelium at doses of 100 mg/kg or more, basophilic tubules at doses of 300 and 1,000 mg/kg and dilatation of the distal tubules at dose of 1,000 mg/kg in male kidneys. Slight but no significant increases of dilated distal tubules and fatty degeneration of the proximal tubular epithelium were observed in female kidneys at doses of 300 and 1,000 mg/kg. Furthermore, hepatocellular hypertrophy was evident in both sexes of the 1,000 mg/kg group, and vacuolization of the cells of the zona fasciculata in the adrenals of males receiving 1,000 mg/kg. Based on renal toxicity in male, NOAEL by oral administration was considered 30 mg/kg/day. An inhalation rat study conducted for 6 hr/day, 6 day/week, 6 weeks at doses of 0.232, 1.035 and 4.494 g/m³ demonstrated the histologic changes in the proximal tubules of the kidneys toxicity in males at the highest dose. As only liver weight was increased at mid dose, NOAEL was considered at 1.035 g/m³ for 6 hr/day, 6 day/week. The daily intake is roughly calculated as 156 mg/kg/day. In a reproductive/developmental toxicity study [OECD TG22] there were no statistically significant adverse effects noted at any doses. However the composite data at the 1000 mg/kg dose group suggests that there may be chemically related adverse effects such as decreased tendency in the fertility index, number of implantations, and implantation index. Two mothers were not able to normally carry the litter. Therefore a NOAEL for reproductive/developmental toxicity was considered to be 300 mg/kg/day. Evidence of malformations was not observed at any dose. This chemical was not genotoxic in bacterial test and chromosomal aberration test *in vitro* [OECD TG 471 & 473]. The lowest reported concentration to cause adverse symptoms in humans is 0.475 g/m³, although the reliability of the study is not clear because of insufficient information.

Environment

Diacetone alcohol is readily biodegradable (OECD TG 301C: 100% after 14-day). The lowest acute and chronic toxicity data were 96h LC₅₀ (420 mg/l) of fish (Bluegill; *Lepomis macrochirus*) and 21d NOEC (>100 mg/l) of *Daphnia magna*, respectively. Assessment factor of 100 was used to chronic toxicity data to determine PNEC, which is >1.0 mg/l. Toxicity of this chemical to aquatic organisms is low, because all toxicity data are higher than 100 mg/l.

Exposure

The production volume is 3,236 tonnes/year in 1995 in Japan. All of this chemical produced in Japan is used as solvent. A generic fugacity model (Mackey level III) shows this chemical would be distributed mainly to water. As this chemical is contained as a solvent for specific paint products and used in industrial sites, user exposure may take place at using sites in the industry.

NATURE OF FURTHER WORK RECOMMENDED

No recommendation.