# SIDS INITIAL ASSESSMENT PROFILE

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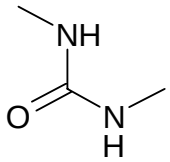
| **CAS No.** | **96-31-1** |
| **Chemical Name** | **1,3-Dimethylurea** |
| **Structural Formula** |  |

## SUMMARY CONCLUSIONS OF THE SIAR

### Human Health

1,3-Dimethylurea was not tested in experimental studies for its toxicokinetics.
The approximate oral LD50 of 1,3-dimethylurea in rats was determined to be 4,000 mg/kg bw. Clinical signs of toxicity were nonspecific and included apathy and narcotic-like state at dose levels near to or exceeding the LD50. No valid test is available on the acute inhalation toxicity. 1,3-Dimethylurea has not been tested for its acute dermal toxicity.
1,3-Dimethylurea (tested as 80 % aqueous solution) was only slightly irritating to the skin of rabbits after 24 hours of occlusive exposure. The undiluted test material induced lacrimation, corneal opacities and redness in the eyes of rabbits with some effects (redness, corneal opacity). The effects were still present in one of the two studies at study termination on day 8 in one animal.

After repeated oral administration for 28 days by gavage to rats in a study following OECD TG 407 (1981), 1,3-dimethylurea caused alterations in the kidneys (tubular necroses, desquamation of tubular epithelial cells and protein casts in the tubuli) in males at 150 and 450 mg/kg bw/day, and nonspecific tubular hyperplasia in females at 450 mg/kg bw/day. The NOAEL was 50 mg/kg bw/day.

1,3-Dimethylurea was not mutagenic in bacterial and mammalian cell culture systems and did not induce chromosomal aberrations in Mouse Lymphoma cells, both in the presence and in the absence of metabolic activation systems. There is no available information from *in vivo* genotoxicity studies in mammals. It is noted that mutagenic nitrosoureas may be produced from 1,3-dimethylurea with nitrite; therefore, a mutagenic potential cannot be totally excluded.

1,3-Dimethylurea had no adverse effects on reproductive performance and fertility of rats in a combined reproduction/developmental toxicity, screening test according to OECD TG 421 (NOAEL, reproductive performance/fertility: 200 mg/kg bw/day (highest tested dose level)). No teratogenic effects, but embryo-/fetotoxicity (reduced placental and fetal body weights) and an increase in the incidence of fetuses with a soft tissue variation (hydroureter) and with delayed ossifications in sternebrae were found at maternally toxic dose levels in a developmental toxicity study in rats in accordance with OECD TG 414 (NOAEL for developmental toxicity and maternal toxicity: 30 mg/kg bw/day).

It is noted that carcinogenic nitrosoureas may be formed with nitrite.

### Environment

1,3-Dimethylurea is an organic solid with a melting point of 102 – 107 °C and a density of 1.142 g/cm$^3$. It has a

water solubility of 765 g/l at 21.5 °C, (pH = 9 – 9.5 at 100 g/l), a vapor pressure of 0.00042 hPa (at 20 °C) and a measured log $K_{OW}$ of –0.783 (at 25 °C).

The substance is readily biodegradable as shown in a DOC Die-Away-Test according to OECD TG 301A with non-adapted inoculum. At a test substance concentration of 50 mg/l, a biodegradation of > 93 % within 10-days was found. In unsterilized soil 1,3-dimethylurea is fairly rapidly mineralized.
The log Kow and a calculated BCF of 3 do not indicate a significant potential for bioaccumulation.
Using a fugacity model (Mackay level I), the substance is predicted to appear mainly in the aqueous compartment (> 99.9 %), with 0.0013 % in soil and 0.0013 % in sediment, and negligible amounts in air. The hydrosphere is therefore the target compartment for this substance. 1,3-Dimethylurea is potentially susceptible to hydrolysis because of the amide structure. The calculated half-life for hydrolysis, however, is over one year. The half-life for photo-oxidation in water (reaction with OH radicals) is estimated at 111 days. The calculated half-life for the photo-oxidation (reaction with hydroxyl radicals) of 1,3-dimethylurea in air is 5.2 days. Adsorption to solid phase is not expected based on a calculated log Koc of 0.946.

Short-term tests with fish, invertebrates and algae are available for 1,3-dimethylurea. The lowest effects values from the short-term tests are: *Leuciscus idus*: 96h-$LC_{50}$ ca. 10,000 mg/l, *Daphnia magna*: 48h-$EC_{50}$ > 500 mg/l, *Scenedesmus subspicatus* 72h-$E_rC_{50}$ > 500 mg/l (72h-$E_bC_{50}$ = 560 mg/l). Applying an assessment factor of 1000 according to the EU Technical Guidance Document, a $PNEC_{aqua}$ of 0.5 mg/l is derived from the 48h $EC_{50}$ for *Daphnia magna*.

**Exposure**

For 2001, estimated production quantities are less than 10,000 metric tonnes in Europe (Germany), less than 5,000 metric tonnes in the US and less than 15,000 metric tonnes in Asia (the worldwide production volume being less than 25,000 metric tonnes).
The substance is mainly used as an industrial intermediate in the synthesis of caffeine, pharmachemicals, textile aids, herbicides and others. According to Swiss, Danish and Swedish Product Registers 1,3-dimethylurea is contained in a large number of products. Some of them may be available to consumers and contain the substance in concentrations up to 10 %.
Releases into the environment may occur from production of 1,3-dimethylurea and from its use as intermediate as well as from use of products containing the substance.
Occupational exposure may occur during production and processing of 1,3-dimethylurea. No workplace exposure information is available with regard to the manufacturing and processing sites.

## RECOMMENDATION

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

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