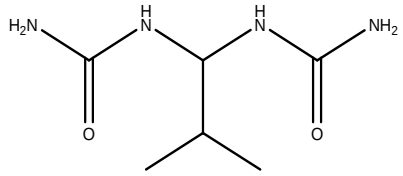
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	6104-30-9
Chemical Name	Urea, N,N''-(2-methylpropylidene)bis- (IBDU)
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Urea, N,N''-(2-methylpropylidene)bis- (IBDU) had a low acute toxicity by the oral route. The only clinical signs noted after oral exposure to rats were tachypnoea and piloerection (LD50, rat, oral: > 10 000 mg/kg bw, IBDU purity. 90 - 96 %). There are no valid acute studies available using the inhalation or dermal routes of exposure.

No eye or skin irritation studies of IBDU according to the current standard are available. Nevertheless the available studies with rabbits are considered of sufficient and good quality to allow the evaluation of these endpoints. IBDU (0.5 g) as a 50 % aqueous suspension was not irritating to the skin of rabbits under semi-occlusive conditions for 20 hours and 0.05 ml IBDU was slightly irritating to the eyes of rabbits.

After repeated oral administration over 4 weeks by gavage to rats in a screening study following OECD TG 422 (1996), the “No Observed Effect Levels” (NOAELs) were 300 mg/kg bw/day for females (reduced body weight gain during pregnancy and lactation at 1000 mg/kg bw/day), and 1000 mg/kg bw/day for males (highest tested dose level).

IBDU was tested negative in a standard and pre-incubation Ames test performed with *Salmonella typhimurium* TA1535, TA1537, TA98 and TA100 according OECD TG 471 (1983) both with and without metabolic activation (rat liver S-9 mix) up to 5000 µg/plate. In vivo, IBDU did not induce micronuclei in male mice treated up to the highest guideline recommended dose (2000 mg/kg bw) in a study performed in accordance with OECD TG 474. Although the ratio between polychromatic and normochromatic erythrocytes was not changed thus lacking to show that the test substance has reached the bone marrow, there is evidence for systemic availability from the above mentioned repeated dose toxicity study in rats where kidney effects were observed in males at 300 mg/kg bw/day.

In a reproductive/developmental toxicity screening test (OECD TG 422), and in a modern one-generation study, IBDU had no effects on the reproductive function of rats (NOAEL: 1200 mg/kg bw/day; highest dose tested). The NOAEL for general toxicity was 300 mg/kg bw/day (reduced body weight gain in females during pregnancy and lactation at 1000 mg/kg bw/day). No developmental effects were seen in a study performed in accordance with OECD TG 414 on Wistar rats (NOAEL developmental toxicity: 1000 mg/kg bw/day; NOAEL maternal toxicity: 300 mg/kg bw/day), and in the above mentioned screening test in rats according to OECD TG 422 (NOAEL developmental toxicity: 1000 mg/kg bw/day and NOAEL maternal toxicity: 300 mg/kg bw/day).

Environment

IBDU is a solid substance which melts at 205 °C under decomposition. The water solubility is in the range between 0.3 and 3.0 g/l at 20 °C. Henry's law constant was calculated as $4.11*10^{-13}$ Pa*m^3/mol from which a vapour pressure of $4.7*10^{-12}$ can be derived. According to a fugacity model (Mackay level I), the main target compartment for IBDU is water (almost 100 %), with negligible amounts in the other compartments. The Henry Constant indicates a negligible volatility from water. In air the substance is indirectly photodegraded by hydroxyl radicals (0.5×10^6 OH/cm^3 as a 24 h average) with a calculated half-life for photo-oxidation of 8.2 hours.

IBDU is potentially susceptible to hydrolysis because of its structure. The calculated half-life for hydrolysis, however, is more than one year. Adsorption to solid phase is not expected based on a calculated log K_{oc} of 1.4.

The substance is readily biodegradable as shown in a test according to OECD TG 301C with non-adapted inoculum. At a test substance concentration of 100 mg/l, a biodegradation of 78 % was found within 28 days (72 % within 7 days, and 78 % within 14 days). In soil, IBDU is hydrolyzed to urea and isobutyraldehyde. These two substances are at least inherently biodegradable and have a low acute toxicity (urea: > 100 and isobutyraldehyde: > 10 mg/l). Urea is decomposed by urease into NH_3 and CO_2 (ammonification) and NH_3 then protonated into the ammonium ion. The latter volatilizes or is oxidized via nitrite into nitrate (nitrification). The measured log K_{ow} of - 0.903 for IBDU (at room temperature) does not indicate a significant potential for bioaccumulation.

Short-term tests with fish, invertebrates and algae were available for IBDU. The effect values from the short term tests are: *Salmo gairdneri*: 96h-LC_{50} > 1000 mg/l, *Daphnia magna*: 48h-EC_{50} = 500 mg/l, *Scenedesmus subspicatus*: 72h-E_rC_{50} > 500 mg/l. Applying an assessment factor of 1000 according to the EU Technical Guidance Document, a $PNEC_{aqua}$ of 500 µg/l is derived from the 48h-EC_{50} for *Daphnia magna*.
The 14d-LC_{50} for *Eisenia fetida* was 648 mg/kg soil.

Exposure

In 2003, the worldwide production volume for IBDU was between 30 000 and 50 000 metric tons. Since there is only one producer in each region (Germany, Canada, Japan), no production volumes can be provided for the regions for confidentiality reasons.

The main use of IBDU is as a slow nitrogen release fertilizer for horticulture and turfgrasses. It is marketed worldwide, mainly in the form of granules for professional and consumer use (wide dispersive use). The main route for occupational and consumer exposure is skin contact.

Emissions of IBDU to the environment may occur during manufacture, processing and use of products containing the substance. In the sponsor country, emissions from a production plant amount to about 2 tons/year (as TOC) and 8 tons/year (as NH_4-N). Approximately 488 kg/year are emitted into the air. From the use as fertilizer, an exposure of the terrestrial compartment takes place.

Occupational exposure may occur during production, processing and use of IBDU containing products. No workplace exposure information is available with regard to the manufacturing and processing sites. Exposure of the general public through the environment is not considered as significant as the substance is biodegradable and has no bioaccumulation potential.

RECOMMENDATION AND 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 profile.