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**UREA**  
***CAS N°: 57-13-6***

## Substance

<i>End Point</i>	:	<b>IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>Common Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>
<i>RTECS Number</i>	:	<b>YR6250000</b>

## Synonyms

<b>Benural 70</b>	<b>B-I-K</b>
<b>Carbamide</b>	<b>Carbamimidic acid</b>
<b>Carbonyl diamide</b>	<b>Isourea</b>
<b>Nimin</b>	<b>Pseudourea</b>
<b>UR</b>	<b>Urea perhydrate</b>
<b>Ureaphil</b>	<b>Ureophil</b>
<b>Urepearl</b>	<b>Urevert</b>
<b>Varioform II</b>	

## Properties &amp; Definitions

<i>Molecular Formula</i>	:	<b>CH4N2O</b>
<i>Molecular Weight</i>	:	<b>60.06</b>
<i>Melting Point</i>	:	<b>133C*</b>
<i>Boiling Point</i>	:	<b>135C decomposition**</b>
<i>State</i>	:	<b>Crystal prismatic or powder</b>
<i>Flamable Limit</i>	:	<b>Non-flammable</b>
<i>Density</i>	:	<b>1323 kg/m3 at 20-24C</b>
<i>Vapour Pressure</i>	:	<b>80 Pa (0.6 mmHg) at 20C CAL***</b>
<i>Octanol/Water Partition Coefficient</i>	:	<b>log Pow = -1.59 at 20-25C experimental</b>
<i>Water Solubility</i>	:	<b>1080 g/L at 20C</b>
<i>Solubility in other Solvents</i>	:	<b>10 g/L in 95% alcohol, 167 g/L in methanol, 500 g/L in glycerol</b>
<i>Colour</i>	:	<b>Colourless to white</b>
<i>Taste</i>	:	<b>Cooling, saline</b>
<i>Odour</i>	:	<b>Almost odourless</b>
<i>Additives</i>	:	<b>Urea-formaldehyde binder can be used in some prilling processes.</b>
<i>Impurities</i>	:	<b>Biuret 0.3 - 2 wt%; cyanates. Analysis of technical urea gave the followings: water (as moisture) 0.4 wt%; free ammonia 0.4 wt%; Fe 2+ &lt;0.0002 wt%; ash content &lt; 0.02 wt%. Degree of purity 98-99 wt%.</b>
<i>General Comments</i>	:	<b>*On further heating decomposes to biuret, NH3 and cyanuric acid. On standing or on heating decomposes to NH3 and CO2. ** Urea decomposes before boiling. ***VP of saturated water solution=2kPa at 20C. Hypochlorites can react with urea to form the explosive compound, nitrogen trichloride. Reacts violently with gallium perchlorate.</b>

## Overall Evaluation

CURRENTLY OF LOW PRIORITY FOR FURTHER WORK

SIDS INITIAL ASSESSMENT

Urea has generally low acute ecotoxicity to organisms. The aquatic effects assessment showed that calculated PECs were lower than the MTC. Urea is very soluble in water and degrades ultimately in the inherent biodegradability test.

Although urea has generally low ecotoxicity to organisms, its well documented indirect and longterm effects to the ecosystems, e.g. eutrophication, groundwater pollution, soil acidification and ammonia emissions to air should be considered.

Urea is an important endogenous product of mammalian metabolism. This may partly explain why it has not been rigorously studied with toxicological tests. Nevertheless, urea appears to cause little or no toxicity to most mammalian species (ruminants are an exception) and humans at reasonable dose levels. The tentatively determined EHE is lower than the EDLC based on human observations.

## EXPOSURE

### TYPES OF USES AND EXPOSURE SOURCES:

#### 1) Industry

Urea is used in many industrial sectors for many functional uses e.g. as adhesives, binders, sealants, resins, fillers, analytical reagents, catalysts, intermediates, solvent, dyestuffs, fragrances, deodourisers, flavouring agents, humectants and dehydrating agents, formulation components, monomers, paint and coating additives, photosensitive agents, fertilizers, surface treatment agents. Urea is also the key synthetic ingredient in the manufacture of some medicines.

Occupational and environmental exposure during production is possible due to accidental process breakdown and disorders in reactor operations, pumping cycles, evaporation and crystallization processes, in maintenance, loading and unloading operations.

Potential occupational exposure occurs via inhalation of aerosols from urea melt and hot saturated solutions, splashed to skin or eyes or inhalation of dust.

#### 2) Agriculture

Urea is widely used as a nitrogenous fertilizer. As an animal feed supplement urea is used at approximately 3% of the grain ratio or 1% of the total ration.

The use of highly concentrated fertilizers may cause human, livestock, especially ruminant and pet hazard. Sources of exposure may be accidental inclusions of highly concentrated fertilizers in rations, application of fertilizers to fields with livestock, washing of recently applied fertilizers by rain into water supplies of livestock, spilling accidentally fertilizers on land and into ponds or watering livestock with fertilizer containers without thorough cleaning and removal of residual fertilizers.

Also various species of wild animals are exposed to urea when urea fertilizers are spread directly on the fields and in the forests. Aquatic organisms may be exposed to urea when recently applied fertilizers are washed by rain into rivers, lakes and seas.

Livestock urine can cause environmental exposure when livestock graze in the grazing season or when manure of livestock is spread to the fields (reliable estimations of the emission levels from urine of naturally living mammals can not be given).

#### 3) Deicing agent

Intensive use of urea as a deicing agent in many airports have lead to groundwater pollution. Urea is washed out from runways with the melting ice and leaches into the surface and groundwater.

#### 4) Consumer products

Urea is used in liquid soaps, detergents, household cleaning products and also in cosmetics products such as creams, shampoos, hair conditioners, hair dyes and dye removers, in ammoniated dentifrices etc. (Maximum urea concentration is commonly 1%.)

## ENVIRONMENTAL EXPOSURE

Urea is "ultimately biodegradable".

### Degradation

Urea is ultimately biodegradable in inherent biodegradability test (OECD 302 B). In semi-continuous activated sludge (SCAS) urea is biodegraded on the average of 93-98% in 24-hour cycle.

The main mode of degradation is enzymatic mineralization. In soil and water urea is expected to biodegrade fairly rapidly to ammonia and bicarbonate if temperature is not too low. Ammonia is a volatile gas in alkaline solutions. In natural waters, most ammonia appear in the form of ammonium, from which nitrogen is oxidized

as the result of bacterial action, forming nitrite and nitrate.

According to US-EPA PCGEMS-model hydrolysis of urea is expected to be extremely slow ( $T_{1/2} > 1$  years).

Bioaccumulation:

Due to low log Pow value (- 1.59 at 20-25 C) urea is not likely to undergo bioaccumulation.

#### DISTRIBUTION BETWEEN ENVIRONMENTAL COMPARTMENTS AND OCCURENCE IN THE ENVIRONMENT

The model used for estimating the partitioning of urea in the environment was the Mackay level 1 model.

According to the model there is 99.84% and 0.16% partitioning into water and air, respectively.

(i) Air

Urea is essentially non-volatile in solid form. Its high water solubility, low vapour pressure (solid pure urea 80 Pa at 20C; calculated) and consequently low Henry's law constant ( $4.4E-8$  atm m<sup>3</sup>/mol) indicate that urea will not evaporate from water to atmosphere.

Degradation of urea to ammonia causes NH<sub>3</sub>-emissions to air. Emissions are higher in alkaline soil (pH>7).

(ii) Soil

According to the worldwide use pattern of urea, when 85 - 90% of urea is used as a fertilizer, the highest environmental exposure is to soil. Urea is, however, relatively leachable from the soil into the surface and the groundwater because of its weak adsorption to the soil, high water solubility and low soil-water partition coefficient. This can happen especially if the soil surface is saturated with water, as might be the case after a rainfall.

(iii) Water

As earlier described, urea can be leached relatively easily into the surface water and the groundwater. The concentration of urea itself, however, is not generally detected, because of its high degradation rate. Therefore usually degradation products e.g. nitrate, nitrite and ammonium can be measured.

Some monitoring data are, however, available:

a) the concentration of urea in domestic sewage: 2 - 6 mg/L and in primary sewage plant effluent: 0.016 - 0.043 mg/L.

b) the concentration of urea in sewage of Kemira's fertilizer factory (Finland): 0.34 mg/L.

The monitoring data has been further used for calculation of the predicted environmental concentration (PEC).

For calculation of PEC the dilution factors of 10 for domestic waste water effluents and 100 for industrial effluents are used. Thereby (a) PEC of 0.0016 - 0.0043 mg/L is obtained for primary sewage plant effluent and (b) PEC of 0.0034 mg/L for fertilizer factory.

Environmental exposure by consumer use can be considered insignificant.

#### CONSUMER EXPOSURE

Because urea is an important endogenous product of protein catabolism in mammals and occurs in significant concentrations in blood and obviously in extracellular water, human food of animal origin contains some urea. If meat contained the same concentration of urea as human blood (about 30 mg/100 g), intake of urea from meat would amount to some tens of milligrams per day. Edible parts of plants may contain up to 4.5 per cent (oats) of their total nitrogen content as urea. The nitrogen content of grain seeds and grass is of the order 2-4%. If one per cent of the total nitrogen were urea (consequently 0.03% of the fresh weight of food of plant origin were urea), the human daily intake of urea from plants could amount up to several grams. However, due to the very limited data available concerning actual urea concentrations in e.g. root vegetables and potatoes, the uncertainties about the quantity are great. The possible food additive use of urea apparently adds little to the intake via food.

The use of urea in skin preparations (soaps, cosmetics, medicines) may lead to highly variable cutaneous doses. The highest doses would concern patients treated extensively because of dry pruritic skin. About 1 per cent of the weight of the skin preparation could be absorbed as urea (preparation contains 10% urea, 10% is absorbed) resulting mostly in the dermal uptake of some tens of milligrams per day.

Intake of urea from dental preparations cannot be estimated with any accuracy, but it probably amounts to relatively small quantities.

## OCCUPATIONAL EXPOSURE

Occupational exposure to urea can be envisaged from inhalation of aerosols and dust during production of urea, urea fertilizers and animal feed supplements, in chemical synthesis using urea as a starting material and when dispersing urea fertilizers/urea in the fields, roads and runways. In the context of airborne exposure, the non-respirable fraction will be mostly ingested. A part of the airborne dust will deposit onto the skin and, additionally, heavier contamination of the hands will result from the handling of urea. Accidental splashes to the skin are possible too.

No reports on actual measurements of urea concentration in the workplace or breathing zone air were located. The worst case scenario would assume that the exposure conforms to the permissible exposure levels of OSHA: 15 mg/m<sup>3</sup> total dust and 5 mg/m<sup>3</sup> respirable dust.

Uptake of respirable urea at 5 mg/m<sup>3</sup> (with a 10 m<sup>3</sup> volume of total ventilation and 100% absorption) would amount to 50 mg (inhalation dose).

The non-respirable part of urea at 10 mg/m<sup>3</sup> and 10 m<sup>3</sup> ventilation results in the airway deposition of 100 mg, most of which will be ingested.

The amount of urea deposited on the skin may be significant, but the fraction absorbed is likely to be less than from skin preparations (the formulation affects the penetration of urea into the skin). Consequently, although no accurate estimates can be given, percutaneous uptake probably will not be higher than the respiratory uptake and ingestion, rather it is less.

The tentative overall dose of urea resulting from the worst-case occupational exposure is thus of the order 200 mg per day.

## HUMAN TOXICITY

### a) Acute toxicity

The acute toxicity by urea is well delineated by the oral route. Toxicity is low in mammals other than ruminants, especially cattle, and sheep, in which the rumen micro-organisms contain urease activity and metabolize urea to ammonia at a high rate. In mice and rats, urea is of low toxicity even by the subcutaneous and intravenous route.

### b) Repeated dose toxicity

No well-conducted repeated dose toxicity studies on urea were located. Chronic toxicity and carcinogenicity screening studies in mice and rats fed with 4500, 9000 or 45000 ppm in diet (up to about 6750 mg/kg body weight/day for mice and about 2250 mg/kg body weight/day for rats) did not uncover any treatment-related toxic syndromes in the various organs studied.

Neither was any weight depression noted at terminal necropsy for animals of either sex or species at any dose levels. Thus the NOAELs were about 6750 mg/kg body weight/day for mice and about 2250 mg/kg body weight/day for rats.

Repeated dose toxicity studies with rats by skin application over 4 weeks and 25 weeks were conducted using urea ointment at 10%, 20% and 40% concentrations, and no consistent treatment-related toxic effects were found. The ointments were applied on a 20 cm<sup>2</sup> area of the back skin but, unfortunately, the quantities of urea applied were not given. Therefore no value for NOAEL by dermal route can be determined. It can be concluded, however, that the repeated dose toxicity of urea by dermal route was low.

### c) Reproductive/developmental toxicity

The studies cited under repeated dose toxicity did not indicate any toxic effects on the reproductive organs of mice and rats.

No adequate teratogenicity/developmental toxicity studies of urea with mammals were located. According to one rat study, 50 g/kg body weight/day administered by gavage in two doses 12 hours apart for an average of 14 days did not cause outstanding (external) teratogenicity; the mean birthweight of the newborn was lower but the litter size greater. Injection of urea into the air sack of eggs shows that urea is toxic to the development of chick embryo.

No NOAEL can be given for the reproductive/developmental toxicity of urea because appropriate studies are lacking.

### d) Genetic toxicity

Urea has been negative in several appropriately conducted bacterial mutagenicity tests. Urea caused DNA single strand breaks in mammalian cells in vitro and was clastogenic for mammalian cells in vitro and in vivo but only at concentrations much beyond the physiological range (about 50-100 higher concentrations than found in human blood).

The mechanism of genotoxicity is probably non-specific (e.g. difference in osmotic pressure across the cell membrane).

e) Any other human health related information that is available

There is little data that relates urea to human health other than its use in dermatology and some more limited applications in clinical medicine. The use of urea (at 10% concentration or less) in ointments and creams to treat dry skin has been widespread, and long term follow-up studies have indicated that the substance is non-allergenic and virtually free from side effects. Among other clinical therapeutic uses, the treatment of inappropriate secretion of antidiuretic hormone (SIADH) should be noted, because its chronic form has involved long term oral administration of large amounts of urea. Most patients have tolerated urea well, although diarrhoea is sometimes reported after ingestion of 60-90 g/day. One patient who had received 30 g of urea (about 470 mg/kg body weight/day) by ingestion for 5 years did not exhibit any side effects.

The possibility exists that infection of *H. pylori* in human stomach may aggravate local effects by urea because of ammonia generation.

#### ENVIRONMENTAL ASSESSMENT

In order to calculate the maximum tolerable concentration (MTC), assessment factor 100 is used, because NOEC-values were not available and acute L(E)C50-values were available for fish and crustaceans. Toxicity Threshold-value (TT) was available for algae representing more longterm than acute toxicity. It can be assumed, however, that acute L(E)C50 for algae can not be lower than the available toxicity threshold concentration.

MTC is calculated for the most sensitive species, protozoa flagellata (*Entosiphon sulcatum*) where the lowest aquatic effect concentration, toxicity threshold (TT) (72 hours) of 29 mg/L, has been recorded:

$$\text{MTC: } 29/100 = 0.29 \text{ mg/L}$$

According to the PEC calculated, MTC/PEC > 1:

$$\begin{aligned} \text{MTC/PEC} \Rightarrow & \text{(a) } 0.29/0.0043 = 67.4 \text{ (primary sewage plant effluent)} \\ & \text{(b) } 0.29/0.0034 = 85.3 \text{ (sewage of Kemira's fertilizer factory)} \end{aligned}$$

The degradation product of urea, ammonia, is known to be toxic to all vertebrates. In neutral and acidic conditions, however, ammonia exists in the form of ammonium.

#### HUMAN HEALTH ASSESSMENT

Urea is an endogenous product of protein and aminoacid catabolism, and consequently 20-35 g of urea is excreted daily in human urine. The blood concentration of urea is also relatively high, 3.3-6.7 mmol/L. Non-physiological, 50-100 times higher urea concentrations in the cultivating medium were shown to disrupt DNA and elicit genotoxicity in mammalian cells, apparently through non-specific osmotic mechanisms. It can be expected that the human organism is well adapted to urea within the physiological range of concentrations and even beyond. This is supported by clinical evidence from high dose administration orally and intravenously for therapeutic purposes.

The bulk of human exposure to urea apparently results from urea ingestion through plant food and meat. Actual measurements concerning the urea content of food were not found, however, and therefore no certain or accurate amounts can be given. Among the consumers, patients using urea containing preparations for the treatment of dry skin may receive an additional but minor dose. Occupational exposure (via inhalation, ingestion and dermally) adds little to the amounts received from food.

The estimated human exposure (EHE) level for urea can only be given very crudely, and it can probably vary widely depending on the food consumed. As a tentative value 3 g/day (about 40 mg/kg body weight/day) is proposed.

Due to the fact that urea has not been rigorously examined with toxicity testing, meaningful NOAELs from animal studies are difficult to find. Especially it may be noted that the existing studies for reproductive and developmental toxicity are not adequate. However, chronic toxicity and carcinogenicity screening studies of urea

in diet with mice and rats suggested that the NOAELs are of the order 2000-6000 mg/kg body weight/day. In a human female patient ingestion of 470 mg/kg body weight/day of urea over 5 years did not cause adverse effects.

The estimated dose of low concern (EDLC) from animal data, using 100 as the uncertainty factor, would give 20-60 mg/kg body weight/day but, as presented above, clinical experience shows that more than ten times higher dose levels in human patients have resulted in little or no adverse effects, even over relatively long periods of time. A further perspective to the EDLC assessment is the endogenous rate of urea formation (excretion), up to about 500 mg/kg body weight/day.

Based on human observations, the EDLC appears to be about one order of magnitude higher than the proposed EHE.

## CONCLUSIONS

Based upon the available information, the initial assessment gave no indication for concern for the human health and the environment.

Based on the MTC/PEC-ratio urea is considered to possess low current concern. Urea has generally low acute ecotoxicity to organisms. The degradation product of urea, ammonia, is known to be toxic to all vertebrates. In neutral and acidic conditions, however, ammonia exists in the form of ammonium.

Instead of toxic effects, more emphasis should be put on the indirect influence of urea to the environment via eutrophication and the pollution risk of urea to groundwater, when urea is used as a fertilizer and a deicer agent in airports. Also the longterm influence of urea use e.g. soil acidification after the longterm fertilization and ammonia emissions to air can have influence to the whole ecosystem and should be considered.

Urea is an important endogenous product of mammalian metabolism. This may partly explain why it has not been rigorously studied with toxicological tests. Nevertheless, urea appears to cause little or no toxicity to most mammalian species (ruminants are more sensitive because of microbial ammonia production) and humans at reasonable dose levels. Based on the EHE/EDLC ratio, urea should be of low current concern to human health.

## RECOMMENDATIONS

No further tests are needed.

More accurate data concerning the daily intake of urea from diet are desirable.

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **WORLD**

## Production

<u>Quantity</u>	<u>Year</u>
<b>19062400-27963000 t/y - P</b>	<b>1985-1989</b>
<b>41440000-60789000 t/y - P</b>	<b>1985-1989</b>
<b>89800000-+134E+5 t/y - P</b>	<b>1989</b>

*General Comments* : 1- The total production volume of urea in metric tons of N (urea N-46%) in the world. 2- World total production volume of urea. 3- Capacities in production or being commissioned in December 1989 (reported in: Information Chimie No. 315, March, pp. 179-201, (1990).

## References

### **!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### **FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **USA**  
*Area Specifications* : **AMN**

## Production

<u>Quantity</u>	<u>Year</u>
<b>1470000-2350000 t/y - P</b>	<b>1985-1989</b>
<b>13 % - EX</b>	

*General Comments* : The given values are the production volume tonnes per annum of nitrogen (urea N-46%). The data related to the export reported in the Altman, P. L., Dittmer, D. S. Biology Data Book, Vol III, 2nd ed., Federation of American Societies for Experimental Biology, 1974, pp. 1494 & 1501.



## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **AMN**

## Production

Quantity                      Year

**11599000+630000 t/y - P**

*General Comments* : Capacities in production or being commissioned in December 1989.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**INFCAS**

Information Chimie, 315, 179-201, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Production

Quantity                      Year

**31635000+3617000 t/y - P**

*General Comments* : Capacities in production or being commissioned in December 1989 in Planned Economy Countries.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**INFCAS**

Information Chimie, 315, 179-201, (1990)

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## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **EUR**  
*Area Specifications* : **W**

## Production

Quantity                      Year

**6215000-+250000 t/y - P**

*General Comments* : Capacities in production or being commissioned in December 1989.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**INFCAS**

Information Chimie, 315, 179-201, (1990)

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## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Production

Quantity                      Year

**3419000-+1150000 t/y - P**

*General Comments* : Capacities in production or being commissioned in December 1989 for Central and South America.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**INFCAS**

Information Chimie, 315, 179-201, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **AFRI**

## Production

Quantity                      Year

**2957000-+575000 t/y - P**

*General Comments* : Capacities in production or being commissioned in December 1989.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**INFCAS**

Information Chimie, 315, 179-201, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **ASIA**

## Production

Quantity                      Year

**5295000-+2550000 t/y - P**

**28728000-+4650000 t/y - P**

*General Comments* : 1- Capacities in production or being commissioned in December 1989 in Middle East and Persian Gulf. 2- Capacities in production or being commissioned in December 1989 in Asia and Oceania.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**INFCAS**

Information Chimie, 315, 179-201, (1990)

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## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>7144900-8321000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The total production volume of urea in metric tons of N (urea N-46%) in Europe.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

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## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>8063500-12185000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The total production volume of urea in metric tons of N (urea N-46%) in Asia.

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **NGA**  
*Area Specifications* : **AFRI**

## Production

<u>Quantity</u>	<u>Year</u>
<b>70000-230000 t/y - P</b>	<b>1987-1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **CAN**  
*Area Specifications* : **AMN**

## Production

<u>Quantity</u>	<u>Year</u>
<b>1000000-3000000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

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## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **CUB**

## Production

<u>Quantity</u>	<u>Year</u>
<b>20000-38000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

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## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **MEX**

## Production

<u>Quantity</u>	<u>Year</u>
<b>500000-640000 t/y - P</b>	<b>1985-1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **TTO**

## Production

<u>Quantity</u>	<u>Year</u>
<b>150000-250000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **AFG**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>45000-60000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **BDG**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>380000-680000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **IND**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>3400000-5750000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).



## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **IDN**  
*Area Specifications* : **ASIA**

## Production

Quantity                      Year  
**1800000-2240000 t/y - P**      **1986-1989**

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **IRN**  
*Area Specifications* : **ASIA**

## Production

Quantity                      Year  
**50000-100000 t/y - P**          **1986-1988**

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **JPN**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>300000-350000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **KWT**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>260000-400000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **PAK**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>835000-970000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **QAT**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>320000-360000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **SAU**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>400000-450000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **SYR**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>50000-90000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **TUR**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>70000-160000 t/y - P</b>	<b>1985-1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **ARE**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>150000-260000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **VNM**  
*Area Specifications* : **ASIA**

## Production

<u>Quantity</u>	<u>Year</u>
<b>3500-15000 t/y - P</b>	<b>1985-1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **BGR**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>330000-370000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **CSK**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>70000-80000 t/y - P</b>	<b>1987-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FRG**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>500000-520000 t/y - P</b>	<b>1987-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **HUN**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>120000-200000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **IRL**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>127000-147000 t/y - P</b>	<b>1986-1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).



## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **ITA**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>460000-600000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **NLD**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>380000-570000 t/y - P</b>	<b>1985-1987</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **POL**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>240000-470000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **PRT**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>4900-9000 t/y - P</b>	<b>1985-1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **ESP**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>113000-165000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

**!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

**FAOSS\***

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **YUG**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>0-240000 t/y - P</b>	<b>1988</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **RUS**  
*Area Specifications* : **EUR**

## Production

<u>Quantity</u>	<u>Year</u>
<b>4800000-4950000 t/y - P</b>	<b>1987-1989</b>

*General Comments* : The given values are the production volume of urea in metric tons of N (urea N-46%).

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **AMN**

## Production

<u>Quantity</u>	<u>Year</u>
<b>3140000-6278000 t/y - P</b>	<b>1985-1989</b>

*General Comments* : The total production volume of urea in metric tons of N (urea N-46%) in north and central America.

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 40, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **WORLD**

## Production

Quantity : Year  
**41440000-60789000 t - P** : **1985-1989**

*General Comments* : The capacities of urea production have increased. By the year 1994-1995 the capacities should reach a level of the order of 60 million tonnes of nitrogen (or 130 million tonnes of urea), making the third chemical product together with ammonia and sulphuric acid, to cross the threshold of 100 million per year. The largest forecasted increase in capacity are in Saudi Arabia; Iraq and the Gulf States in general; Indonesia, India and China.

## References

### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### FAOSS\*

FAO Statistics Series. FAO Fertilizer Yearbook, 315, 179-201, (1990)

## Production-Trade

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Production

<u>Quantity</u>	<u>Year</u>
13640 t/y - P	1986
1550 t/y - P	1986
8210 t/y - P	1986
610 t/y - P	1986
34010 t/y - P	1986
40000-60000 t/y - IM	

*General Comments* : Estimated urea production of livestock in Finland. (Estimation is based on statistical figures of year 1986). Animal species and total number of animals are as follows: 1) cattle 942300; 2) Swine 1030700; 3) poultry 7035600; 4) horses 38700. Total urea produced = 34010 tonnes/year, to be compared with total urea import to Finland.

## References

### **!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

### **ENFAF\***

Keranen, S. and Niskanen, R. Effects of Nitrogen Fertilizer to Acidification in Finland : Litterature Survey, D/39, (1987)

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## Processes

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Process

*Process comments* : In modern synthetic processes, urea is made by reacting ammonia and carbon dioxide at high pressure and temperature to form ammonium carbonate and simultaneously dehydrating the ammonium carbonate to urea and water. Produced urea is purified by crystallization. Urea is also a natural end product of biochemical protein decomposition and the main solid component of mammalian urine (e.g. man produces urea in urine 20-35 g/24 hours, (200-500 mg/kg body weight-1 day-1). Urea is a natural constituent of many common foodstuffs. Up to 15 percent of the total nitrogen of young plants and about 5 percent of the nature plants is non-proteinaceous and much is in the form of urea. Urea is a normal constituent of animal tissues and fluids and is ingested in small amounts when meat is consumed. Oats may contain 4.5 percent of their total nitrogen content as urea and oil seed meals about 0.25 percent.

## References

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
3 %		Use in agriculture: Urea is widely manufactured and distributed as a nitrogenous fertilizer, particularly for fibrous-rooted crops such as rice. It is used extensively as one of the ingredients of nitrogen solutions widely used for direct field fertilizer application.
1 %		Approximate quantity used as an animals feed supplement of the grain ration. Approximate quantity used as an animal feed supplement of the total ration.

## References

*Primary References* : **GASTR\***  
 Oehme, F. W. and Barrel, D. Veterinary Gastrointestinal Toxicology, 489-490, (1986)

*Secondary References* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
1 %		Use in consumer products: Urea is used in liquid soaps, detergents and household cleaning products. It is also used in cosmetic products as creams, shampoos, hair conditioners, hair dyes and dye removers, in ammoniated dentifrices etc. Maximum urea concentration is commonly 1%.
6.4-9.6 %	wt	Urea (as 10-15% urea peroxide) in preparations for tooth bleaching yield. Following reference is also cited: management director Kaj Svenson, Suomen Teknokemian yhdistys (Cosmetics and Detergents Association in Finland).

## References

*Primary References* : **COSDA\***  
 Cosmetics and Detergent Association in Finland, (1992)

*Secondary References* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)



## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **USA**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
42 %		Fertilizer, solid
31 %		Fertilizer solutions
5 %		Urea-formaldehyde resins and adhesives
9 %		Others, including animal feed and melamine

## References

*Primary References* : **CMKRA5**  
 Karcher, AR. Chemical Profiles. Chemical Marketing Reporter, 234(13), 54, (1988)

*Secondary References* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
23 %		Fertilizer, solid
68 %		Urea-formaldehyde resins and adhesives
2 %		Deicer on airport runways
7 %		Other, including use as a nutrient in waste water treatment plant.

## References

*Primary References* : **INFFI\***  
 Information from Finnish Industry, (1990)

*Secondary References* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **WORLD**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
85-90 %		Fertilizer
2-4 %		Animal feed
8-11 %		Industrial use

## References

*Primary References* : **CHWKA9**  
Chemical Week, 112(4), 19, (1973)

*Secondary References* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)

## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
		Types of uses are divided into three: industrial use (open system and closed system), public use and export. Urea is used in all three sectors. Industrial use concerns both open and closed systems. Use categories: urea is used by the following industrial sectors : -Adhesives and sealant production -Agriculture, field crops -Agriculture, other -Electrical or electronic products -Fertilizer -Food, feed and beverage -Metallurgical -Organic chemicals, industrial -Paint and coating -Pigment, dye and printing ink -Plastic and synthetic resins -Plating and publishing -Pulp and paper -Soap and cleaning products -Textile, primary manufacture -Textile, product

## References

*Primary References* : **ECAPD\***  
Chenier,R. Environment Canada 1974. National Inventory of Sources and Emissions of Asbestos, Beryllium, Lead and Mercury. Summary of Emissions for 1970, (1991)

*Secondary References* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)

## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
		Urea is used for the following functional uses: Adhesive/binder/sealant/filter Analytical reagent Catalyst/accelerator/inhibitor/activator Chemical intermediate-organic. Chemical intermediate-inorganic, organometallic Colourant-pigment/stain/dye/ink. Paint/coating additive Fertilizer Formulation component Fragrance/perfume/deodouriser/flavouring agent Humectant/dewatering aid/dehumidifier/dehydrating agent Monomer Photosensitive agent-fluorecent agent/brightener/UV absorber .

## References

*Primary References* : **ECAPD\***  
 Chenier, R. Environment Canada 1974. National Inventory of Sources and Emissions of Asbestos, Beryllium, Lead and Mercury. Summary of Emissions for 1970, (1991)

*Secondary References* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Uses

*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
		Urea is a key synthetic ingredient in the manufacture of resins, glues, solvents and some medicines. Urea is used as a formulating component in cosmetics, detergents, textile dyes and numerous other products.

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## References

*Primary References* : **NHCUH\***  
National Health Council. Urea. Safe Use and Handling Data Sheet, I-691/Rev 90, 3

*Secondary References* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **Pathway into the Environment and Environmental Fate.**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Method and Conditions

*Test method description* : Mackay level 1 model

## Pathway and Transport

*Pathway* : **LOAD**

## Quantity Transported

<u>Medium</u>	<u>to Medium</u>	<u>Quantity</u>	<u>Time</u>	<u>Year</u>	<u>to Year</u>
	<b>to AQ</b>	<b>99.84 %</b>			
Partitioning into water.					
	<b>to AIR</b>	<b>0.16 %</b>			
Partitioning into air.					

**to AIR**

NH<sub>3</sub> emission, resulted from degradation of urea to ammonia. Emissions are higher in alkaline soil.

## References

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **Pathway into the Environment and Environmental Fate.**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Pathway and Transport

*Pathway* : **NATUR APPLI**

## Quantity Transported

<u>Medium</u>	<u>to Medium</u>	<u>Quantity</u>	<u>Time</u>	<u>Year</u>	<u>to Year</u>
<b>BIOTA</b>	<b>AGRIC to SOIL</b>				
Emission in agriculture from livestock urine when spread on the fields and in the grazing season.					

**to AIR**

Emission from urine of living animals. Reliable estimation of the emission levels cannot be given.

**to SOIL**

When 85-90% of urea is used as a fertilizer, the highest environmental exposure is to soil.

## References

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **CONCENTRATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Lifestage Sex

**AQ** **SEW**  
**AQ** **GRND**

*Species/strain/system* : Waste water

## Test Method and Conditions

*Test method description* : The monitoring data has been used for calculation of the predicted environmental concentration (PEC). For calculation of PEC the dilution factor of 10 for domestic waste water effluent is used.

## Test Results

<u>Matrix</u>	<u>Concentrations</u>	<u>Spec.</u>	<u>Date</u>
In domestic sewage	<b>2-6 mg/L</b>		
In primary sewage plant effluent	<b>0.016-0.043 mg/L</b>		
PEC for primary sewage plant effluent	<b>0.0016-0.0043 mg/L</b>		
Concentration in groundwater in airport area as of 1980	<b>20 ug/L</b>		<b>1980</b>

*General Comments* : The information concerning the groundwater is reported in the following reference: National Board of Waters and the Environment, Finland (Unpublished data).

## References

*Primary Reference* : **HBEDC\***  
 Vershueren, K. Handbook of Environmental Data on Organic Chemicals, 2nd ed., 1178, (1983)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **CONCENTRATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **FIELD**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Lifestage Sex

**AQ**      **SEW**

*Species/strain/system* : Sewage of Kemira's fertilizer factory, Finland

## Test Method and Conditions

*Test method description* : The monitoring data has been used for calculation of the predicted environment concentration (PEC). For calculation of PEC the dilution factor of 100 for industrial effluent is used.

## Test Results

Matrix      Concentrations      Spec.      Date

**0.34 mg/L**

**1993**

Concentration in fertilizer manufacturing plant waste water (highest monthly mean) as of 1993.

**0.0034 mg/L**

PEC for fertilizer factory

## References

*Primary Reference* : **TWEDO\***  
Anttalainen, M. Turku Water and Environment District Oral Communication, (1994)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)



## Study

*End Point* : **CONCENTRATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **FIELD**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Lifestage Sex

**AQ** **GRND**

*Species/strain/system* : Groundwater at the Helsinki-Vantaa Airport, Finland (1975-1990)

## Test Method and Conditions

*Test method description* : Analysis of groundwater nitrate, nitrite and ammonium concentrations

## Test Results

<u>Matrix</u>	<u>Concentrations</u>	<u>Spec.</u>	<u>Date</u>
	<b>150 mg/L</b>		<b>1975-1990</b>

Nitrate concentrations in the airport area groundwater increased up to 150 mg/L

**80 mg/L**

Due to diminished use amounts of urea in recent years, from 300 tonnes to less than 100 tonnes/year, nitrate concentrations slowly decreased to 80 mg/L.

*General Comments* : It is not likely to detect urea itself in the groundwater, but only its degradation products.

## References

*Primary Reference* : **#URNWE\***  
National Board of Waters and the Environment Unpublished Report

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **CONCENTRATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Lifestage Sex

**HUMAN** **ADULT**

*Species/strain/system* : Physiological concentrations in man

## Test Results

Matrix Concentrations Spec. Date

**URINE 20-35 g/24h**  
In urine (200-500 mg/kg body weight/day)

**120-570 mg/L**  
In sweat

**BLOOD 3.3-6.4 mmol/L**  
In blood (200-500 mg/L)

*General Comments* : The information related to concentration of urea in urine are reported in: Harper, H. A. and Rodwell, V. W. Review of Physiological Chemistry, 16th ed., Lange Medical Publications, Los Altos California, 1977, page 625.

## References

*Primary Reference* : **FASEB\***  
Altman, P. L. and Dittmer, D. S. Biology Data Book, III 2nd ed., 1494&01, (1974)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **CONCENTRATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Lifestage Sex

**HUMAN** **FOOD**  
**PLANT** **SEED**

## Test Results

Matrix Concentrations Spec. Date

**BLOOD** **30-100 mg/L**

In human blood

**4.5 %**

Edible parts of plants may contain up to 4.5 per cent (oats) of their total nitrogen content as urea.

**2-4 %**

The nitrogen content of grain seeds and grass

*General Comments* : Due to the very limited data available concerning actual urea concentrations in e.g. root vegetables and potatoes, the uncertainties about the quantity are great.

## References

*Primary Reference* : **D8REP4**  
 EPA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **HUMAN INTAKE AND EXPOSURE**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Evaluations

*Evaluation text* : Occupational and environmental exposure during production is possible due to accidental process breakdown and disorders in reactor operations, pumping cycles, evaporation and crystallization processes, in maintenance, loading and unloading operations. Potential occupational exposure occurs via inhalation of aerosols from urea melt and hot saturated solutions, or splashes to skin or eyes, or inhalation of dust. Occupational exposure can be also envisaged from inhalation of aerosols and dust during production of urea fertilizers and animal feed supplements in chemical syntheses using urea as a starting material and when dispersing urea fertilizers/urea in the fields, roads and runways. In the context of airborne exposure, the non-respirable fraction will be mostly ingested. A part of the airborne dust will deposit onto the skin and, additionally, heavier contamination of the hands will result from the handling of urea.

## References

*Secondary Reference* : **!SIDSP\***  
 Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **HUMAN INTAKE AND EXPOSURE**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex

**HUMAN** **AIR** **IHL**  
**HUMAN** **SKN**

*Species/strain/system* : Potential anthropogenic sources of exposure are manufacturing, industrial, agricultural and consumer uses.

## Test Results

Intake Spec. Date

**200 mg/d**

The tentative overall dose of urea resulting from the worst- case occupational exposure

**50 mg**

Uptake of respirable urea at 5 mg/m<sup>3</sup> (with 10 m<sup>3</sup> volume of total ventilation and 100% absorption).

**100 mg**

The airway deposition, most of which will be ingested, results from the non-respirable part of urea at 10 mg/m<sup>3</sup> and 10 m<sup>3</sup> ventilation.

## References

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
 Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **HUMAN INTAKE AND EXPOSURE**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex

**HUMAN** **FOOD** **ANI** **ORL**  
**-** **PLANT** **AGRIC** **-**  
**HUMAN** **AIR**  **IHL**

*Species/strain/system* : Potential anthropogenic sources of exposure are manufacturing, industrial, agricultural and consumer uses.

## Test Results

Intake Spec. Date

Intake of urea from meat would amount to >10 mg/L per day.

The human daily intake of urea from plants could amount up to several grams.

The possible food additive use of urea apparently adds little to the intake via food.

*General Comments* : Because urea is an important endogenous product of protein catabolism in mammals and occurs in significant concentrations in blood and obviously in extracellular water, human food of animal origin contains some urea.

## References

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
 Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **HUMAN INTAKE AND EXPOSURE**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **USA**

## Test Subject

Organism Medium Specification Route Lifestage Sex

**HUMAN**

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## Test Method and Conditions

*Test method description* : The National Occupational Hazard Survey conducted by NIOSH.

## Test Results

*General Comments* : Probable human exposure: according to the survey in the USA 855894 workers may be exposed to urea; 7% from actual observed use, 31% from observed use of a tradename product known to contain this chemical, and 62% from observed use of a product in some type of general use which leads NIOSH to suspect that chemical may be contained in the product. Exposure in farming: the use of highly concentrated fertilizers in agricultural practice and in gardens can lead to human hazards. Most toxicities from fertilizers occur in ruminants. (Reported in: Oehme, F. W. and Barrel, D. S.: Veterinary Gastrointestinal Toxicology, Chapter 17 in Rozman, K. and Hanninen, O. (eds).

## References

*Primary Reference* : **HSDBM\***  
Hazardous Substances Databank HSDB, 11, (1991)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **BIODEGRADATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

*Organism* *Medium* *Specification*  
**AQ** **FRESH**

## Test Method and Conditions

*Test method description* : GLP: no  
*Temperature* : **<8 C**

## Test Results

*Quantity* *Time* *Comments on result*

In river water at 1-15 mg/L degradation of urea is negligible below 8C for up to 14 days.

## References

*Primary Reference* : **WATRAG**  
 Evans, W. H. et al. Water Research, 7, 975-985, (1973)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **BIODEGRADATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

*Organism* *Medium* *Specification*  
**AQ** **SLUDG**

*Species/strain/system* : Semi-continuous activated sludge (SCAS)

## Test Method and Conditions

*Test method description* : The disappearance of urea was determined by colorimetric analysis.

## Test Results

Quantity                      Time                      Comments on result

**93-98 %**                      **24 h**                      Mean disappearance of urea in 24-hour cycle

*General Comments* : Urea is biodegradable in semi-continuous activated sludge (SCAS). (Job No. 1449006, as cited in the reference).

## References

*Primary Reference* : **ANCHAM**  
EPA. Analytical Chemistry, 71-8, (1983)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **BIODEGRADATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism   Medium   Specification

**AQ**                      **SLUDG**

*Species/strain/system* : Activated sludge from a laboratory sewage treatment facility fed with domestic and synthetic sewage; adapted.

## Test Method and Conditions

*Test method description* : Inherent Biodegradability: OECD Guideline 302 B (1981), Zahn-Wellens Test; GLP: no

*(An)aerobic* : **AEROB**

## Exposure

*Dose / Concentration* : **400 mg/L**



## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
3 %	3 h	Decomposed urea
52 %	7 h	Decomposed urea
60 %	10 d	Decomposed urea
85 %	14 d	Decomposed urea
96 %	16 d	Decomposed urea
<i>General Comments</i>	:	Urea is ultimately biodegradable according to this study. (Proj. No: 1/91/0452/10/1) as cited in the reference.

## References

<i>Primary Reference</i>	:	<b>#URBSF*</b> BASF AG. BASF Unpublished Report, (1991)
<i>Secondary Reference</i>	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

<i>End Point</i>	:	<b>BIODEGRADATION</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>
<i>Study type</i>	:	<b>LAB</b>
<i>Geographic Area</i>	:	<b>FIN</b>

## Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>
<b>AQ</b>		
<b>SOIL</b>		
<i>Species/strain/system</i>	:	Flooded soil

## Exposure

<i>Exposure Period</i>	:	<b>30 h</b>
<i>Exposure comments</i>	:	30 hours of incubation

## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
		A laboratory study demonstrated that the main site of urea hydrolysis in flooded soil columns was in the soil and not the floodwater (ureolytic bacterial action).
3 %	30 h	The added urea which was hydrolysed in the floodwater after 30 hours of incubation.
64 %	30 h	The added urea which was hydrolysed in the soil after 30 hours of incubation.
<i>General Comments</i> :		Report number: D/39/1978

## References

<i>Primary Reference</i> :	<b>SOSCAK</b> Vlek, P. L. G. and Carter, M. C. Soil Science, 136, 56-63, (1983)
<i>Secondary Reference</i> :	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

<i>End Point</i> :	<b>BIODEGRADATION</b>
<i>Chemical Name</i> :	<b>Urea</b>
<i>CAS Number</i> :	<b>57-13-6</b>
<i>Study type</i> :	<b>LAB</b>
<i>Geographic Area</i> :	<b>FIN</b>

## Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>
-	<b>SOIL</b>	
<b>BACT</b>	<b>SOIL</b>	

## Test Method and Conditions

<i>Test method description</i> :	Transformation times of different nitrogen forms in soil
<i>Temperature</i> :	<b>2-20 C</b>

## Exposure

<i>Exposure Period</i> :	<b>1-4 d</b>
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## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
	<b>4 d</b>	Transformation of urea-N to ammonium-N by urease at 2C
	<b>2 d</b>	Transformation of urea-N to ammonium-N by urease at 10C
	<b>1 d</b>	Transformation of urea-N to ammonium-N by urease at 20C
<b>50 %</b>	<b>6 wk</b>	Conversion (transformation of ammonium-N to nitrate-N by bacteria) at 5C
<b>50 %</b>	<b>4 wk</b>	Conversion (transformation of ammonium-N to nitrate-N by bacteria) at 8C
<b>50 %</b>	<b>2 wk</b>	Conversion (transformation of ammonium-N to nitrate-N by bacteria) at 10C
<b>50 %</b>	<b>1 wk</b>	Conversion (transformation of ammonium-N to nitrate-N by bacteria) at 20C

## References

<i>Primary Reference</i>	:	<b>BUARE*</b> Bua. BUA Report on Chemicals of Environmental Relevance, 76
<i>Secondary Reference</i>	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

<i>End Point</i>	:	<b>BIODEGRADATION</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>
<i>Study type</i>	:	<b>LAB</b>
<i>Geographic Area</i>	:	<b>FIN</b>

## Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>
<b>BACT</b>	<b>AQ</b>	<b>SEW</b>
<i>Species/strain/system</i>	:	Psychrophilic bacteria

## Test Method and Conditions

<i>Temperature</i>	:	<b>20 C</b>
<i>Relative Humidity</i>	:	<b>2 %</b>

## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
<b>11.6 mg/L</b>	<b>1 h</b>	Maximum degradation rate per hour at 20C
<b>10.9 mg/L</b>	<b>1 h</b>	Average degradation rate per hour at 20C
<b>4.0 mg/L</b>	<b>1 h</b>	Maximum degradation rate per hour at 2C
<b>3.2 mg/L</b>	<b>1 h</b>	Average degradation rate per hour at 2C

## References

<i>Primary Reference</i>	:	<b>HBEDC*</b> Verschueren, K. Handbook of Environmental Data on Organic Chemicals, 2nd. ed., (1983)
<i>Secondary Reference</i>	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

<i>End Point</i>	:	<b>BIODEGRADATION</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>
<i>Study type</i>	:	<b>LAB</b>
<i>Geographic Area</i>	:	<b>FIN</b>

## Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>
<b>BACT</b>	<b>SOIL</b>	
	<b>AQ</b>	

## Exposure

<i>Exposure comments</i>	:	Main factors affecting the rates of nitrogen metabolism are the initial concentration of the ureolytic bacteria, the physical state of the nitrifying micro-organisms and the concentration of toxic organics.
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## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
		Main mode of degradation is enzymatic mineralization. In soil and water urea is expected to biodegrade fairly rapidly to ammonia and bicarbonate if temperature is not too low.
		Main mode of degradation : 1) $\text{NH}_2\text{CONH}_2 + 2\text{H}_2\text{O}$ (Urease-enzyme) --- > $\text{NH}_3 + \text{NH}_4 + \text{HCO}_3^-$ 2) $\text{NH}_4^+ + 1.5 \text{O}_2$ Nitrosomonas ---> $\text{NO}_2^- + \text{H}_2\text{O} + 2\text{H}^+$ ---> $\text{NO}_2^- + 0.5 \text{O}_2$ Nitrobacter ---> $\text{NO}_3^-$

## References

- Primary Reference* : **AHCBAU**  
Gunkel, K. et al. Acta Hydrochimica et Hydrobiologica, 18(1), 3-20,  
(1990)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **HYDROLYSIS**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Test Method and Conditions

*Test method description* : Calculation by PCHYDRO-model. PCHYDRO, a hydrolysis rate estimation model, is a part of the US-EPA PCGEMS-modelling system (Personal Computer Version of the Graphical Exposure Modelling System); GLP: no

## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
50 %	>1 y	Estimated half-life. PCHYDRO-model estimated the urea hydrolysis to be extremely slow.

## References

*Primary Reference* : **#URNWE\***  
National Board of Waters and the Environment Unpublished Report, (1994)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

<i>End Point</i>	:	<b>SORPTION</b>		
<i>Chemical Name</i>	:	<b>Urea</b>		
<i>CAS Number</i>	:	<b>57-13-6</b>		
<i>Study type</i>	:	<b>LAB</b>		
<i>Medium</i>	:	-	<b>SILT</b>	<b>LOAM</b>
<i>Specifications</i>	:	-	<b>SOIL</b>	<b>SOIL</b>
<i>Geographic Area</i>	:	<b>FIN</b>		

## Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
		Urea is relatively leachable from the soil into the surface and the groundwater because of its weak adsorption to the soil, high water solubility and soil-water partition coefficient. This can happen especially if the soil surface is saturated with water, as might be the case after a rainfall.
		Urea adsorption coefficient in Crowley silt loam flooded soil column ranged from 0.037 (50 mg N/L) to 0.064 (1000 mg N/L) depending on the concentration of urea water.
<i>General Comments</i>	:	Urea adsorption by the soil was low. The following reference is also cited: Sharply, A. N. et al. 1983. Water, Air and Soil Pollution 14(3): 425-430 (1983); as cited in HSDB 1991.

## References

<i>Primary Reference</i>	:	<b>SSSJD4</b> Hongprayoon, C. et al. Soil Science Society of America Journal, 55, 1130-34, (1991)
<i>Secondary Reference</i>	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

<i>End Point</i>	:	<b>EVAPORATION</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>
<i>Study type</i>	:	<b>LAB</b>
<i>Medium</i>	:	<b>AQ</b>
<i>Specifications</i>	:	<b>FRESH</b>
<i>Geographic Area</i>	:	<b>FIN</b>

## Test Results

*General Comments* : Urea is essentially non-volatile in solid form. Its high solubility and low vapour pressure and consequently low Henry's law constant (4.4E-8 atm m<sup>3</sup>/mol) indicate that urea itself will not evaporate from water to atmosphere.

## References

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **ECOSYSTEMS**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Test Subject

*Species/strain/system* : Soil properties after long-term fertilization with urea  
*Ecosystems* : TERR

## Test Substance

*Description of the test substance* : Nitrogenous fertilizers

## Test Method and Conditions

*Test method description* : Effects monitored: soil pH and micronutrients availabilities.

## Exposure

*Exposure comments* Physical properties of soil: maximum bulk density 1.49-1.60 mg/m<sup>3</sup>; optimum water content for compaction 0.196-0.219 kg/kg; Clod density 1.46-1.68 mg/m<sup>3</sup>; water content at -1.5 MPa potential 0.125-0.192 kg/kg. Particle size distributiion at 0.06 to 0.14 m soil layer: sand (0.05-2 mm), coarse silt (0.02-0.05 mm), fine silt (0.002-0.02 mm), clay (<0.002 mm).

## Test Results

*General Comments* : 20 years of urea fertilization reduced soil pH significantly, compared with the control area. The soil acidification occurs due to nitrification of NH<sub>4</sub><sup>+</sup> which is decomposition product of urea. Urea fertilization caused also an increase in micronutrients (Fe, Cu, Mn) and a decrease in available P (phosphor) and exchangeable bases (Ca, Mg, Na). Soil acidification occurred also on areas treated with ammonia, NH<sub>4</sub>NO<sub>3</sub> and urea-NH<sub>4</sub>NO<sub>3</sub> mixture.

## References

*Primary Reference* : **SSSJD4**  
Darusman, L. R. et al. Soil Science Society of America Journal, 55, 1097-00, (1991)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **ABSORPTION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
<b>HUMAN</b>			<b>SKN</b>				

## Test Results

*General Comments* : Urea penetrates rapidly into the human stratum corneum; penetration is enhanced at higher urea concentrations and with time. However, transport to systemic circulation is slow and limited. About 5.9% of urea applied to human skin was recovered in the urine.

## References

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **DISTRIBUTION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*  
**HUMAN** **ORL**

## Test Results

*General Comments* : Urea is extremely soluble in water and is adsorbed and distributed rapidly after oral doses. In man the peak concentration in blood is attained in 30 to 90 minutes after oral dose. The dose of 30 g urea (about 0.5 g/kg) doubles serum urea levels in 20 minutes and a maximum level of 94.6 mg/100 mL is achieved in 90 minutes (mean control 36 mg/ 100 mL).

## References

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **DISTRIBUTION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*  
**RAT** **SKN**

## Test Results

*General Comments* : Subcutaneous injection of urea to pregnant rats showed that the substance readily penetrated the placenta and raised fetal urea concentrations.

## References

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

<i>End Point</i>	:	<b>BIOCONCENTRATION</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>
<i>Study type</i>	:	<b>LAB</b>
<i>Geographic Area</i>	:	<b>FIN</b>

## Test Results

<i>General Comments</i>	:	Due to the low log Pow value urea is not likely to undergo bioaccumulation.
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## References

<i>Secondary Reference</i>	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **EXCRETION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Geographic Area* : **FIN**

## Test Results

*General Comments* : Ammonia is toxic to all vertebrates. It can be converted to the less toxic urea, but this is a metabolically expensive process found only in terrestrial vertebrates that cannot readily excrete ammonia, and marine fish that use urea as osmotic filter. Freshwater fish mostly excrete ammonia with only a small quantity of urea. Urea is the end product of biochemical protein decomposition and the main component of mammalian urine.

## References

*Primary Reference* : **NATUAS**  
Randall, D. J. et al. Nature

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Species/strain/system* : Strain not mentioned  
*Frequency* : **1 x**  
*Dose / Concentration* : **14300-15000 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			ORL		M F	LD50	Oral LD50 for male rats was established as 14300 mg/kg and for female rats as 15000 mg/kg body weight.
<i>General Comments</i>		: The general symptoms consisted mainly of sedation, loss of righting reflex and staggering gait.					

## References

*Primary Reference* : **OYYAA2**  
 Sato, N. et al. Oyo Yakuri  
 (Pharmacometrics), 13, 749-772, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
 Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Frequency* : **1 x**  
*Dose / Concentration* : **8200-9400 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			SCU		M F	LD50	Subcutaneous LD50 for male and female rats was established as 9400 mg/kg and 8200 mg/kg body weight, respectively.

## References

- Primary Reference* : **OYYAA2**  
Sato, N. et al. Oyo Yakuri  
(Pharmacometrics), 13, 749-772, (1978)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Species/strain/system* : Strain not mentioned  
*Frequency* : **1 x**  
*Dose / Concentration* : **11500-13000 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>MOUSE</b>			<b>ORL</b>		<b>M</b> <b>F</b>	<b>LD50</b>	Oral LD50 for male and female mice was established as 11500 mg/kg and 13000 mg/kg, respectively.
<i>General Comments</i>	: The general symptoms consisted mainly of sedation, loss of righting reflex and staggering gait.						

## References

- Primary Reference* : **OYYAA2**  
Sato, N. et al. Oyo Yakuri  
(Pharmacometrics), 13, 749-772, (1978)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Frequency* : **1 x**  
*Dose / Concentration* : **9200-10700 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>MOUSE</b>			<b>SCU</b>		<b>M</b> <b>F</b>	<b>LD50</b>	Subcutaneous LD50 for male and female mice was established as 9200 mg/kg and 10700 mg/kg body weight, respectively.

## References

*Primary Reference* : **OYYAA2**  
Sato, N. et al. Oyo Yakuri (Pharmacometrics), 13, 749-772, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Species/strain/system* : Cow  
*Dose / Concentration* : **510 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>CATTL</b>			<b>ORL</b>			<b>LD50</b>	Oral LD50 for cow was established as 510 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)



## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Dose / Concentration* : **510 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>SHEEP</b>			<b>ORL</b>			<b>LD50</b>	Oral LD50 for sheep was established as 510 mg/kg body weight .

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Species/strain/system* : Cow  
*Dose / Concentration* : **600-1080 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>CATTL</b>			<b>ORL</b>			<b>LD50</b>	Oral LD50 for cows was established as 600 - 1080 mg/kg body weight.

## References

- Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

- End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**
- Frequency* : **1 x**  
*Dose / Concentration* : **5300-5400 mg/kg BW**

## Test Method and Conditions

- Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			IVN		M F	LD50	Intravenous LD50 for male and female rats was established as 5400 mg/kg and 5300 mg/kg body weight, respectively.

## References

- Primary Reference* : **OYYAA2**  
 Sato, N. et al. Oyo Yakuri (Pharmacometrics), 13, 749-772, (1978)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

- End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**
- Frequency* : **1 x**  
*Dose / Concentration* : **4600-5200 mg/kg BW**

## Test Method and Conditions

- Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>MOUSE</b>			<b>IVN</b>		<b>M</b> <b>F</b>	<b>LD50</b>	Intravenous LD50 for male and female mice was established as 4600 mg/kg and 5200 mg/kg body weight, respectively.

## References

*Primary Reference* : **OYYAA2**  
Sato, N. et al. Oyo Yakuri (Pharmacometrics), 13, 749-772, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*Dose / Concentration* : **10000 mg/kg BW**

## Test Method and Conditions

*Test method description* : GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>DOG</b>			<b>IVN</b>			<b>LD50</b>	Intravenous LD50 for dogs was established as > 10000 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**MAMM**

*Species/strain/system* : Ruminants

## Test Method and Conditions

*Test method description* : GLP: no

*General Comments* : Urea is generally regarded a safe and efficient feed additive (substitute for natural proteins) for ruminants. The toxicity of urea depends on the formation of ammonia. Problems occur when ingested urea releases more ammonia than in the rumen microorganisms can fully utilize to synthesize amino acids and protein. Urea can cause clinical signs of toxicosis in ruminants at 300 - 500 mg/kg body weight and death at 1000 - 1500 mg/kg body weight. Horses are less susceptible, urea being lethal at approximately 4000 mg/kg body weight. Monogastric animals, such as swine and baby calves, are not affected by urea on biuret except for a mild diuretic action.

## References

*Primary Reference* : **GASTR\***  
Veterinary Gastrointestinal Toxicology, 489-490, (1986)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**CATTL** **ORL**

*Species/strain/system* : Cow

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **116 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>LDLO</b>				

Oral LDLO for cows was established as 116 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**DOG** **SCU**

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **3000-9000 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
	<b>LDLO</b>				

Subcutaneous LDLO for dogs was established at a dose level of 3000-9000 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
<b>DOG</b>			<b>SCU</b>			<b>12</b>	

*Species/strain/system* : Strain not specified

## Test Method and Conditions

*Test method description* : GLP: unknown

## Exposure

*Exposure Type* : **SHORT**  
*Exposure Period* : **45 d**  
*Dose / Concentration* : **3000-4000 mg/kg**  
*Exposure comments* : Urea was injected subcutaneously every 8 hours to 12 unilaterally nephrectomized dogs for 45 days.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>PLSMA</b>	<b>BIOCH</b>				
Plasma urea levels were 200 to 700 mg/100 mL					
	<b>BEHAV</b>				
Mild drowsiness					
	<b>URINE</b>	<b>INCR</b>			
Increased diuresis					
	<b>NEF</b>				
Treatment did not affect hematocrit, platelet counts nor Eeg .					

## References

<i>Primary Reference</i>	:	<b>D8REP4</b> FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB288673, (1978)
<i>Secondary Reference</i>	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

<i>End Point</i>	:	<b>MAMMALIAN TOXICITY</b>
<i>Chemical Name</i>	:	<b>Urea</b>
<i>CAS Number</i>	:	<b>57-13-6</b>

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
<b>DOG</b>			<b>IVN</b>				

## Test Method and Conditions

<i>Test method description</i>	:	GLP: no
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## Exposure

<i>Dose / Concentration</i>	:	<b>3000 mg/kg BW</b>
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## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
	<b>LDLO</b>				
Intravenous LDLO for dogs was 3000 mg/kg body weight.					

## References

- Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

- End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

- | <u>Organism</u>                           | <u>Medium</u> | <u>Specification</u> | <u>Route</u> | <u>Lifestage</u> | <u>Sex</u> | <u>Number exposed</u> | <u>Number controls</u> |
|---|---------------|----------------------|--------------|------------------|------------|-----------------------|------------------------|
| <b>GPIG</b>                               |               |                      |              |                  |            |                       | <b>IVN</b>             |
| <i>Species/strain/system</i> : Guinea pig |               |                      |              |                  |            |                       |                        |

## Test Method and Conditions

- Test method description* : GLP: no

## Exposure

- Dose / Concentration* : **4800 mg/kg BW**

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
	<b>LDLO</b>				

Intravenous LDLO for guinea pigs was established as 4800 mg/kg body weight.

## References

- Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HORSE** **ORL**

*Species/strain/system* : Pony

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **3310-3610 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>LDLO</b>				

Oral LDLO for pony was established at dose level of 3310- 3610 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HUMAN** **SKN**

## Exposure

*Exposure comments* : Urea has been extensively used during the last two decades in the treatment of dry skin, both clinically and in cosmetic products.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>SKIN</b>	<b>NEF</b>				

No long-term side effects have been found. No reports of contact allergy were located and, in spite of common use for many years, no epidermal or dermal atrophy has been reported.

## References

*Primary Reference* : **HAUTAW**  
Stuttgen, G. Hautarzt, Suppl. 11, 9-12, (1992)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1995)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
<b>PIG</b>			<b>ORL</b>	<b>JUV</b>			

*Species/strain/system* : Young pigs

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **16000 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
	<b>LDLO</b>				

Oral LDLO for pigs was established as >16000 mg/kg body weight.

*General Comments* : Ten % (m/m) urea in pig food over a period of 5 days was without apparent deleterious effects.

## References

*Primary Reference* : **JAVTAP**  
Button, J. P. et al. Journal of the South African Veterinary Association, 53(1), 67-68, (1982)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**RAT** **SKN**

*Species/strain/system* : Wistar rats

## Test Method and Conditions

*Test method description* : GLP: unknown

## Exposure

*Exposure Type* : **SHORT**  
*Exposure Period* : **4 wk**  
*Exposure comments* : Urea in 10%, 20% or 40% ointment was applied to the back skin (20 cm<sup>2</sup> area) for 4 weeks.

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
	<b>NEF</b>				

No dose-dependent toxicity was observed. There were no consistent treatment-related effects on standard haematological parameters, clinical chemistry, organ weights or organ histopathology, including testicles, prostate, seminal vesicles, ovaries and uterus.

## References

*Primary Reference* : **OYYAA2**  
 Sato, N. et al. Oyo Yakuri  
 (Pharmacometrics), 13, 749-772, (1977)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
 Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT

ORL

*Species/strain/system* : Strain not specified

## Test Substance

*Description of the test substance* : Purity not known

## Test Method and Conditions

*Test method description* : GLP: unknown

## Exposure

*Exposure Type* : **LONG**  
*Exposure Period* : **190 d**  
*Dose / Concentration* : **20000-250000 mg/kg DIET**  
*Exposure comments* : Rats were fed a diet containing 20000-250000 ppm urea for 190 days (about 2000-25000 mg/kg/day).

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**DEATH**

250000 ppm and 20000 ppm were lethal in 12 days and 20-76 days, respectively.

**BW****DECR  
BEHAV**

There was weight loss and suppression of sexual function at lower doses.

*General Comments* : Author's comment: "the validity of the study is limited by the small number of animals used (often 1 to 3 per group) and failure to report actual food intake. Extreme weight loss of the rats suggested that inanition was likely".

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**RAT** **SKN**

*Species/strain/system* : Wistar rats

## Test Method and Conditions

*Test method description* : GLP: unknown

## Exposure

*Exposure Type* : **LONG**  
*Exposure Period* : **24 wk**  
*Exposure comments* : Urea ointments of 10%, 20% or 40% concentrations were applied to the back skin on a 20 cm<sup>2</sup> area for 24 weeks.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>NEF</b>				

There were no consistent treatment-related effects on standard hematological parameters, clinical chemistry or different organs.

## References

*Primary Reference* : **OYYAA2**  
 Sato, N. et al. Oyo Yakuri  
 (Pharmacometrics), 13, 749-772, (1977)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
 Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**RBT** **ORL**

*Species/strain/system* : Rabbit

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **5000 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>LDLO</b>					

Oral LDLO for rabbits was established as 5000 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
<b>RBT</b>							<b>SCU</b>

**RBT** **SCU**

*Species/strain/system* : Rabbit

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **3000-9000 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>LDLO</b>					

Subcutaneous LDLO for rabbits was established at dose level of 3000-9000 mg/kg body weight.

## References

- Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

- End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

- | <u>Organism</u>                       | <u>Medium</u> | <u>Specification</u> | <u>Route</u> | <u>Lifestage</u> | <u>Sex</u> | <u>Number exposed</u> | <u>Number controls</u> |
|---------------------------------------|---------------|----------------------|--------------|------------------|------------|-----------------------|------------------------|
| <b>RBT</b>                            |               |                      | <b>IVN</b>   |                  |            |                       |                        |
| <i>Species/strain/system</i> : Rabbit |               |                      |              |                  |            |                       |                        |

## Test Method and Conditions

- Test method description* : GLP: no

## Exposure

- Dose / Concentration* : **7320 mg/kg BW**

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
	<b>LDLO</b>				

Intravenous LDLO for rabbits was established as 7320 mg/kg body weight.

## References

- Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**RBT** **IVN**

*Species/strain/system* : Rabbit

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **6310 mg/kg BW**

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>LDLO</b>				

Intravenous LDLO for rabbits was established as 6310 mg/kg body weight.

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MAMMALIAN TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**SHEEP** **ORL**

## Test Method and Conditions

*Test method description* : GLP: no

## Exposure

*Dose / Concentration* : **160 mg/kg BW**



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## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**LDLO**

Oral LDLO for sheep was established as 160 mg/kg body weight .

## References

*Primary Reference* : **D8REP4**  
FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **CARCINOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**MOUSE** **ORL** **M**  
**F**

*Species/strain/system* : CB7B1/6 mice

## Test Method and Conditions

*Test method description* : Chronic toxicity and carcinogenicity screening study over 12 months; GLP: no data

## Exposure

*Exposure Type* : **LONG**  
*Dose / Concentration* : **0.45-4.5 g/kg DIET**  
*Exposure comments* : Mice were fed a diet containing 0.45%, 0.9% or 4.5% of urea over 12 months.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>NEF</b>				

No carcinogenic effects were found.

*General Comments* : OECD/SIDS Comment: 5 animals per sex from all dose groups were necropsied at the end of the treatment period, and the gonads were histologically examined. No pathology was reported. After further 4 months of follow up all survivors were killed, necropsied and the tissues were fixed. However, concerning the reproductive organs, histological tumor data on the ovary and the uterus only were given. Other sex organs may not have been histologically studied.

## References

*Primary Reference* : **JEPTDQ**  
 Fleischman, R. W. et al. Journal of Environmental Pathology and Toxicology, 3(5/6), 149-170, (1980)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **CARCINOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
<b>RAT</b>			<b>ORL</b>		<b>M</b> <b>F</b>		

*Species/strain/system* : Fischer 344 rats

## Test Method and Conditions

*Test method description* : Chronic toxicity and carcinogenicity screening study over 12 months; GLP: no data

## Exposure

*Exposure Type* : **LONG**  
*Exposure Period* : **12 mo**  
*Dose / Concentration* : **4.5-45 g/kg DIET**  
*Exposure comments* : Rats were fed a diet containing 0.45%, 0.9% or 4.5% of urea over 12 months.

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
	<b>NEF</b>				

Not carcinogenic

*General Comments* : OECD/SIDS Comment: 5 animals per sex from all dose groups were necropsied at the end of the treatment period, and the gonads were histologically examined. No pathology was reported. After further 4 months of follow up all survivors were killed, necropsied and the tissues were fixed. The testes, prostate and uterus were histologically examined for the occurrence of tumours. Although there was a statistically increased incidence of interstitial cell adenomas of the testis in the high dose group, its biological significance was deemed questionable, since the lesions may occur in 100% of controls.

## References

*Primary Reference* : **JEPTDQ**  
 Fleischman, R. W. et al. Journal of Environmental Pathology and Toxicology, 3(5/6), 149-170, (1980)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

### BACT

### VTR

*Species/strain/system* : Salmonella typhimurium TA98, TA100, TA1537

## Test Substance

*Description of the test substance* : Purity unknown

## Test Method and Conditions

*Test method description* : Bacterial test, Ames test; GLP: no data

## Exposure

*Exposure comments* : Test performed with and without metabolic activation.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**NEF**

Negative results with and without metabolic activation

## References

*Primary Reference* : **GMCRCDC**  
Ishidate, M. et al. GANN Monograph on Cancer Research, 27, 95-108, (1981)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BACT****VTR**

*Species/strain/system* : Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538  
Escherichia coli WP2uvrA

## Test Substance

*Purity Grade* : **99%**  
*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : Bacterial test (Ames test); GLP: not known

## Exposure

*Dose / Concentration* : **5-5000 ug/ PLATE**  
*Exposure comments* : Tests were performed with and without metabolic activation.

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
	<b>NEF</b>				

Negative results with and without metabolic activation at a dose range of 5-5000 ug/plate.

## References

*Primary Reference* : **SAIGBL**  
 Shimizu, H. et al. Japanese Journal of Industrial Health, 27, 400-419, (1985)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BACT****VTR**

*Species/strain/system* : Salmonella typhimurium TA98, TA100, TA1535, TA1537

## Test Substance

*Purity Grade* : **99%**  
*Vehicle - Solvent* : **DMSO**

## Test Method and Conditions

*Test method description* : Bacterial test (Ames test); GLP: not known

## Exposure

*Dose / Concentration* : **100-10000 ug/ PLATE**  
*Exposure comments* : Tests were performed with and without metabolic activation with rat liver and hamster liver S9 mix.

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
	<b>NEF</b>				

Negative results at a dose range of 100-10000 ug/plate with and without metabolic activation.

**CELL**

Minimum concentration at which toxicity to bacteria was observed: 100-10000 ug/plate depending on strain.

## References

*Primary Reference* : **ENMUDM**  
 Mortelmans, K. et al. Environmental Mutagenesis, 8 Suppl. 7, 1-119, (1986)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HAMST****VTR**

*Species/strain/system* : Chinese hamster fibroblast (CHL)

## Test Substance

*Description of the test substance* : Purity unknown  
*Vehicle - Solvent* : Physiological saline

## Test Method and Conditions

*Test method description* : Chromosomal aberration test; GLP: not known

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
<b>CHROM</b>	<b>STRUC</b>				

Positive results without metabolic activation at 266 mmolar. Aberrations in 37% of metaphases at 24 hours (chromosomal gaps, chromatid or chromosomal breaks, translocations, fragmentation).

**NEF**

Negative result with metabolic activation

*General Comments* : OECD/SIDS Comment: The maximally effective concentration was 266 mmolar, a very high concentration suggesting a low clastogenic potential.

## References

*Primary Reference* : **MUREAV**  
Ishidate, M. and Odashima, S. Mutation Research, 48, 337-354, (1977)

*Secondary Reference* : **!SIDS\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HAMST** **VTR**

*Species/strain/system* : Chinese hamster fibroblast (CHL)

## Test Method and Conditions

*Test method description* : Chromosomal aberration test; GLP: not known

## Exposure

*Dose / Concentration* : **13 g/L**  
*Exposure comments* : Urea concentration 216 mmolar

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
<b>CHROM</b>	<b>STRUC</b>				

Positive results without metabolic activation. Chromosomal aberrations were detected in 20% of metaphases at 216 mmolar concentration.

*General Comments* : OECD/SIDS Comment: chromosomal aberrations detected in 20% of metaphases at urea concentration of 13 g/L (216 mmolar) indicate a low clastogenic potential.

## References

*Primary Reference* : **GMCRDC**  
Ishidate, M. et al. GANN Monograph on Cancer Research, 27, 95-108, (1981)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**MOUSE** **VTR**

*Species/strain/system* : Mouse lymphoma heterozygous L5178Y TK+/-



## Test Substance

*Purity Grade* : **AG**

## Test Method and Conditions

*Test method description* : Mouse Lymphoma TK Locus Assay; GLP: no data

## Exposure

*Dose / Concentration* : **7.9-38 g/L**

*Exposure comments* : Concentrations of 132 - 662 mmolar of urea were used with and without metabolic activation.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
	<b>NEF</b>				
Negative result with metabolic activation					
<b>GENE</b>	<b>MUT</b>				
	<b>NEF</b>				
	<b>INC</b>				
Weakly positive at very high urea concentrations 530 - 662 mmolar negative at 132 mmolar, equivalent at 265 - 397 mmolar.					
	<b>CELL</b>				
Lowest concentration producing cell toxicity: 265 mmolar					
<i>General Comments</i>	: OECD/SIDS Comment: Authors discuss the possibility that the positive genotoxic findings may depend on secondary cellular effects (e.g. difference in osmotic pressure across the cell membrane) at high concentration which might not take place under in vivo conditions.				

## References

*Primary Reference* : **MUTAEX**  
Wangenhaim, J. and Bolcsfoldi, G. Mutagenesis, 3, 193-205, (1988)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

**MOUSE** **VTR**

*Species/strain/system* : Mouse lymphoma L5178Y TK+/-

## Test Substance

*Purity Grade* : **AG**

## Test Method and Conditions

*Test method description* : Analysis for DNA singlestrand breaks by alkaline unwinding and hydroxyapatite elution; GLP: no data

## Exposure

*Dose / Concentration* : **20.5-43.0 g/L**  
*Exposure comments* : Concentrations of 339 - 718 mmolar of urea were used.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>DNA</b>	<b>STRUC</b>				

Positive result at very high concentrations (628 and 718 mmolar) with relative fractions of ssDNA of 9.2 and 17.3%, respectively, without metabolic activation.

### **NEF**

Although a dose response was found, lower urea concentrations (359 - 339 mmolar) did not yield responses classified as positive.

## References

*Primary Reference* : **MUREAV**  
 Garberg, P. et al. Mutation Research, 203, 155-176, (1988)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

**MOUSE** **ORL**

*Species/strain/system* : Swiss albino mice

## Test Substance

*Description of the test substance* : Purity unknown

## Test Method and Conditions

*Test method description* : Bone marrow cytogenetic assay; GLP: no data

## Exposure

*Exposure Type* : **SHORT**  
*Exposure Period* : **5 d**  
*Dose / Concentration* : **500 mg/ ANIMAL**  
*Exposure comments* : Mice were fed with urea 500 mg per animal per day in food for 5 days (dosage approaching an acute lethal dose).

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>CHROM</b>	<b>STRUC</b>				
Bone marrow cell, metaphases exhibited chromosome breaks, acentric fragments, translocations, gaps and constrictions at a 7-fold rate compared to controls.					
<i>General Comments</i>	: OECD/SIDS Comment: the interpretation of this clastogenic effect is limited by the usage of a single extremely high dose level.				

## References

*Primary Reference* : **CYTOAN**  
 Chaurasia, O. P. and Sinha, S. P. Cytologia, 52, 877-882, (1987)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **MUTAGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
<b>RAT</b>							
<i>Species/strain/system</i>	: Rat hepatocytes						

## Test Substance

*Purity Grade* : **AG**  
*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : Analysis for DNA singlestrand breaks by alkaline elution; GLP: no data

## Exposure

*Dose / Concentration* : **18-180 mg/L**  
*Exposure comments* : Concentrations of 0.3 - 3 mmolar were used.

---

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>NEF</b>				
Negative result					

## References

- Primary Reference* : **MUREAV**  
Sina, J. F. et al. Mutation Research, 113, 357-391, (1984)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)
-

## Study

*End Point* : **SENSITIZATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HUMAN**

**SKN**

## Test Substance

*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : GLP: unknown

## Exposure

*Exposure comments* : 10% water solution

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>SKN</b>	<b>NEF</b>				
No skin sensitization					

## References

*Primary Reference* : **VDVEAV**  
Alchangian, L. V. et al. Vestnik Dermatologii Venerologii, 9, 26-29, (1986)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **IRRITATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HUMAN**

**SKN**

## Test Substance

*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : Chamber-Scarification Test; GLP: unknown

## Exposure

*Exposure Type* : **ACUTE**  
*Dose / Concentration* : **75-300 g/L**  
*Exposure comments* : 7.5% and 30% urea solutions in water were applied.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>SKN</b>	<b>IRRIT</b>				
Slight irritation with 7.5% urea					
<b>SKN</b>	<b>IRRIT</b>				
Marked irritation with 30% urea					
<b>SKN</b>	<b>IRRIT</b>				
Comparison between hypo- and hyperactive individuals with 30% urea in water after 48 hours: hyporeactors score 0.8 (slight); hyperreactors score 2.4 (moderate) on the scale 0-4.					

## References

*Primary Reference* : **38FTAB**  
 Frosch, P. J. et al. Cutaneous Toxicity: Proceedings of the Conference on Cutaneous Toxicity, 127-153, (1977)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **IRRITATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**HUMAN**

**SKN**

## Test Substance

*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : Not specified; GLP: unknown

## Exposure

*Exposure Type* : **ACUTE**  
*Dose / Concentration* : **100 g/L**  
*Exposure comments* : 10% water solution of urea

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>SKIN</b>	<b>NEF</b>				
No irritation after 24 hours					

## References

*Primary Reference* : **VDVEAV**  
Alchangian, L. V. et al. Vestnik Dermatologii Venerologii, 9, 26-29, (1986)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **IRRITATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**MOUSE**

**SKN**

**M**

*Species/strain/system* : Nude MF1h mice

## Test Substance

*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : GLP: unknown

## Exposure

*Exposure Type* : **ACUTE**  
*Dose / Concentration* : **100-109 g/L**  
*Exposure comments* : 10% solution

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>SKIN</b>	<b>NEF</b> <b>NEF</b>				

The skin of nude mice showed no irritation. 10% urea induced no discernible change in the histological appearance of the skin.

## References

*Primary Reference* : **JPPMAB**  
 Lashmar, U. T. et al. Journal of Pharmacy & Pharmacology, 41, 118-121, (1981)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **IRRITATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

**RBT** **SKN**

*Species/strain/system* : Rabbit

## Test Substance

*Vehicle - Solvent* : Water

## Test Method and Conditions

*Test method description* : GLP: unknown



## Exposure

*Exposure Period* : **20 h**  
*Dose / Concentration* : **500 g/L**  
*Exposure comments* : 20 hours semioclusive application of 50% urea water solution on the back and ear skin of rabbit.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>SKN</b>	<b>NEF</b>				
No irritation of the skin after 24 hours					

## References

*Primary Reference* : **#URBSF\***  
 BASF AG. BASF Unpublished Report

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **IRRITATION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
<b>RBT</b>							<b>OCU</b>
<i>Species/strain/system</i> : Rabbit							

## Test Method and Conditions

*Test method description* : OECD 405; GLP: yes

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
<b>EYE</b>	<b>NEF</b>				
Not irritating (no irritancy after 24 hours)					

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## References

*Primary Reference* : **#URBSF\***  
BASF AG. BASF Unpublished Report

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **REPRODUCTION**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**

*General Comments* : OECD/SIDS Conclusion: Based on the carcinogenicity screening studies with mice and rats and repeated dose toxicity studies by dermal route with rats, where no toxic effects were observed in the gonads, even at the histopathological examination, and the lack of evidence for developmental toxicity in limited mouse and rat studies, urea would not be expected to display significant potential for reproductive toxicity.

## References

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

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## Study

*End Point* : **TERATOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BIRD** **INJ**

*Species/strain/system* : Chick embryo

## Test Method and Conditions

*Test method description* : GLP: no data

## Exposure

*Exposure comments* : 50 to 900 mg of urea dissolved in egg albumin was injected into eggs between 7th and 20th hours of incubation.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>EMBRY</b>	<b>STRUC</b>				

Among 132 embryos 78 showed neural, vascular or cardiac abnormalities.

*General Comments* : "The results indicate that urea was teratogenic in chick embryo".

## References

*Primary Reference* : **D8REP4**  
 FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **TERATOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BIRD** **INJ**

*Species/strain/system* : Chick embryo

## Test Substance

*Purity Grade* : **AG**  
*Vehicle - Solvent* : Distilled water

## Test Method and Conditions

*Test method description* : GLP: no data

## Exposure

*Dose / Concentration* : **200-1200 mg/kg**  
*Exposure comments* : 200, 400, 800 and 1200 mg/kg eggs was injected in a volume of 0.05 mL distilled water into the air sack of the eggs on day 16, 17 and 18 of incubation.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**EMBRY**      **DEATH**

Mortality of the embryos varied 8.8-38.9%, dose-dependently. The mortality in the control group was 6.1%.

**EMBRY**      **BIOCH**

In the treated embryos, the plasma T3 level increased and T4 level decreased.

**EMBRY**      **STRUC**

Electron microscopy revealed cytoplasmic oedema, mitochondrial swelling and membrane damage in thyroid cells.

*General Comments* : The results indicate that urea was foetotoxic to the chicken.

## References

*Primary Reference* : **AVSCA7**  
 Mora, S. et al. Acta Veterinaria Scandinavica, Suppl. 87, 197-198, (1991)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **TERATOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
-----------------	---------------	----------------------	--------------	------------------	------------	-----------------------	------------------------

<b>MOUSE</b>			<b>ORL</b>		<b>F</b>	<b>10</b>	
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*Species/strain/system* : ICR mice

## Test Method and Conditions

*Test method description* : A single oral dose study; GLP: no

## Exposure

*Exposure Type* : **ACUTE**  
*Exposure Period* : **10 TDP**  
*Frequency* : **1 x**  
*Dose / Concentration* : **2000 mg/kg BW**  
*Exposure comments* : A single dose of 2000 mg/kg was administered orally to 10 pregnant mice on day 10 of pregnancy.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>NEF</b>				

No effects on foetal data (live/dead, sex, external defects, soft tissue and skeletal defects).

### NEF

No maternal toxicity

*General Comments* : Not teratogenic. OECD/SIDS comment: "not an adequate teratogenicity study".

## References

*Primary Reference* : **TJADAB**  
 Teramoto et al. Teratology, Journal of Abnormal Development, 23, 335-342, (1981)

*Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **TERATOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
-----	-----	-----	-----	-----	-----	-----	-----
<b>RAT</b>			<b>ORL</b>		<b>F</b>	<b>4</b>	

*Species/strain/system* : Wistar rats

## Test Method and Conditions

*Test method description* : A single oral dose study; GLP: no

## Exposure

*Exposure Type* : **ACUTE**  
*Exposure Period* : **12 TDP**  
*Frequency* : **1 x**  
*Dose / Concentration* : **2000 mg/kg BW**  
*Exposure comments* : A single dose of 2000 mg/kg was administered to 4 pregnant rats on day 12 of pregnancy.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**NEF**

No effects on foetal data (live/dead, sex, external defects, soft tissue and skeletal defects)

**NEF**

No maternal toxicity

*General Comments* : Not teratogenic. OECD/SIDS comment: "not an adequate teratogenicity study".

## References

*Primary Reference* : **TJADAB**  
Teramoto et al. Teratology, Journal of Abnormal Development, 23, 335-342, (1981)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **TERATOGENICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**

## Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
RAT			ORL		F	6	

*Species/strain/system* : Wistar rats

## Test Method and Conditions

*Test method description* : Within 48 hours after delivery the pups were killed and the kidneys examined; GLP: no data

## Exposure

*Exposure Type* : **SHORT**  
*Exposure Period* : **14 d**  
*Dose / Concentration* : **50 g/kg BW/d**  
*Exposure comments* : Urea was administered by gavage in 2 doses 12 hours apart to 6 rats during pregnancy for an average of 14 days and the dams were allowed to delivery.

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**NEF**

No hypertrophy or other kidney changes were detected nor were any teratogenic effects noted.

*General Comments* : OECD/SIDS Comment: "not a full-range teratogenicity study".

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## References

- Primary Reference* : **ZEIUR\***  
Seipelt, H. et al. Zeitschrift Urologie, 62, 623-627, (1969)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High  
Production Volume Chemicals Programme, (1994)
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## Study

*End Point* : **AQUATIC ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

*Species/strain/system* : Snail (*Helisoma trivolvis*)

## Test Method and Conditions

*Test method description* : Static; GLP: not known

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>MOLL</b>	<b>AQ</b>	<b>FRESH</b>		<b>EGG</b>		<b>LC50</b>	LC50 for 24 hours for egg = 14241 mg/L; LC50 for 24 hours for juveniles = 18255 mg/L; LC50 for 24 hours for adults = 30060 mg/L.
				<b>JUV</b>			
				<b>ADULT</b>			

## References

*Primary Reference* : **AECTCV**  
Tchounwou, P. B. et al. Archives of Environmental Contamination and Toxicology, 21, 359-364, (1991)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **AQUATIC ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

*Species/strain/system* : Mosquito (*Aedes aegypti*) larvae

## Test Method and Conditions

*Test method description* : Static; GLP: no

## Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
<b>INSEC</b>	<b>AQ</b>	<b>FRESH</b>		<b>LARVA</b>		<b>LC50</b>	LC50 for 4 hours = 60000 mg/L.

## References

- Primary Reference* : **JIVPAZ**  
Kramer, V. C. et al. Journal of Invertebrate Pathology, 42, 285-287, (1983)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

- End Point* : **AQUATIC ACUTE TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**
- Species/strain/system* : Barilius barna

## Test Method and Conditions

- Test method description* : Static

## Test Results

- | <u>Organism</u>         | <u>Medium</u> | <u>Spec.</u>                         | <u>Route</u> | <u>Lifestage</u> | <u>Sex</u> | <u>Effect</u> | <u>Effect Comments</u>         |
|-------------------------|---------------|--------------------------------------|--------------|------------------|------------|---------------|--------------------------------|
| <b>FISH</b>             | <b>AQ</b>     |                                      |              |                  |            | <b>LC50</b>   | LC50 for 96 hours > 9100 mg/L. |
| <i>General Comments</i> |               | : Urea is not acutely toxic to fish. |              |                  |            |               |                                |

## References

- Primary Reference* : **HCPBE5**  
Dodriyal, A. K. and Bahuguna, A. K. Himalayan Chemical Pharma. Bulletin, 5, 15-16, (1988)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
-

## Study

*End Point* : **AQUATIC TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**ALGAE AQ FRESH**

*Species/strain/system* : Green algae (Scenedesmus quadricauda)

## Test Method and Conditions

*Test method description* : Cell multiplication inhibition test

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**BIOMA**

Toxicity threshold for 192 hours > 10000 mg/L

*General Comments* : Urea is not toxic to algae.

## References

*Primary Reference* : **VJWWAU**  
Bringmann, G. and Kuhn, R. Vom Wasser, 50, 45-60, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **AQUATIC TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**PROTO AQ FRESH**

*Species/strain/system* : Flagellate (Entosiphon sulcatum)

## Test Method and Conditions

*Test method description* : Cell multiplication inhibition test; static; GLP: no

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

### BIOMA

Toxicity threshold for 72 hours = 29 mg/L

### BIOMA      UNS

To some extent urea exhibited selective toxic action on Entosiphon sulcatum. For example toxicity threshold for chloroform was > 6560 mg/L.

*General Comments* : Urea exhibits to some extent toxic action to Entosiphon sulcatum.

## References

*Primary Reference* : **WATRAG**  
Bringmann, G. and Kuhn, R. Water Research, 14, 231-241, (1980)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **AQUATIC TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**ALGAE** **AQ** **FRESH**

*Species/strain/system* : Blue-green algae (Microcystis aeruginosa)

## Test Method and Conditions

*Test method description* : Cell multiplication inhibition test. Single species tests such as "Microtox Photobacterium Luminescence Test" and tests on overall processes such as nitrification or soil respiration are included in this item. GLP: not known

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>BIOMA</b>	<b>INHIB</b>				

Toxicity threshold for 192 hours = 47 mg/L

*General Comments* : Urea exhibits to some extent toxic action to Microcystis aeruginosa.

## References

*Primary Reference* : **VJWWAU**  
Bringmann, G. and Kuhn, R. Vom Wasser, 50, 45-60, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **AQUATIC TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BACT** **AQ** **MARIN**

*Species/strain/system* : Bioluminescent bacteria (Photobacterium luminescence)

## Test Method and Conditions

*Test method description* : Microtox Photobacterium Luminescence Test. Single species tests such as "Microtox Photobacterium Luminescence Test: and tests on overall processes such as nitrification or soil respiration are included in this item. GLP: no known

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
	<b>EC50</b>				
EC50 for 5 minutes = 24000 mg/L					

## References

*Primary Reference* : **ASTTAB**  
Bulich, A. A. et al. ASTM Special Technical Publication Aquatic Toxicology and Hazard Assessment, ASTM STP 737, 338-347

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **AQUATIC TOXICITY**

*Chemical Name* : **Urea**

*CAS Number* : **57-13-6**

*Study type* : **LAB**

*Geographic Area* : **FIN**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

**CRUS** **AQ** **FRESH**

*Species/strain/system* : Water flea (Daphnia magna)

## Test Method and Conditions

*Test method description* : DIN 38412 Teil 11 (modified)

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
	<b>EC50</b>				
EC50 for 24 hours > 10000 mg/L.					
<i>General Comments</i> : Urea is not acutely toxic to daphnids.					

## References

- Primary Reference* : **ZWABAQ**  
Bringmann, G. and Kuhn, R. Zeitschrift fuer Wasser und Abwasser Forschung, 15(1), 1-6, (1982)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
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## Study

- End Point* : **AQUATIC TOXICITY**
- Chemical Name* : **Urea**
- CAS Number* : **57-13-6**
- Study type* : **LAB**
- Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**FISH**      **AQ**      **FRESH**

*Species/strain/system* : Golden orfe (*Leuciscus idus melanotous*)

## Test Method and Conditions

*Test method description* : Static; GLP: no

## Exposure

*Exposure Type* : **ACUTE**

## Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
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**LC0**

LC0 for 48 hours > 10000 mg/L

*General Comments* : Urea is not acutely toxic to fish.

## References

- Primary Reference* : **ZWABAQ**  
Juhnke, I. and Ludemann, D. Zeitschrift fuer Wasser und Abwasser Forschung, 11, 5, (1978)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
-

## Study

*End Point* : **AQUATIC TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

**FISH** **AQ** **ESTUA**  
**FRESH**

*Species/strain/system* : Tilapia (Tilapia mossambica)

## Test Method and Conditions

*Test method description* : Test method not specified

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

**LC0**

LC0 for 96 hours = 20000 mg/L.;

**LC50**

LC50 for 96 hours = 22500 mg/L.;

**LC100**

LC100 for 96 hours = 25000 mg/L

**BW** **DECR**  
**BW** **SIZE**  
**BEHAV**

When the fish was reared in different sublethal concentrations (5, 10, 15 and 20 g/L, test period 25 days) of urea, there was a decrease in feeding and growth rates. In addition to the realized energy from food consumption, the fish lost reserve energy at the highest concentration of

urea. Conversion efficiency fell rapidly as the concentration increased.

*General Comments* : Urea is not acutely toxic to fish. Tilapia mossambica lives under wide variety of environmental circumstances tolerating different osmotic conditions. This chemical fertilizer appeared to be metabolic stressor at high concentrations.

## References

*Primary Reference* : **ENECEV**  
Palanichamy, S. et al. Environment and Ecology, 3(2), 157-161, (1985)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)



## Study

*End Point* : **TERRESTRIAL TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**WORM TERR**

*Species/strain/system* : Grassland earthworms (Oligochaeta, Lumbricidae)

## Test Method and Conditions

*Test method description* : Effects monitored: earthworm numbers and biomass. Fertilizer was organic coated urea, the organic coating being based on soybean oil at annual rate of 60, 120 & 180 kg N/ha. Soil was treated annually for 20 years.  
*Organic Matter Content* : **6.2-6.7 %**

## Exposure

*Exposure comments* : Sandy loam soil. The organisms relation to soil acidification was studied.

## Test Results

Application of nitrogenous fertilizers to grassland for long period may have a deleterious effect on earthworms in the absence of liming.

## References

- Primary Reference* : **AEENDO**  
 Wei-Chum Ma, L. et al. Agriculture, Ecosystems and Environment, 30, 71-80, (1990)
- Secondary Reference* : **!SIDSP\***  
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
-

## Study

*End Point* : **TERRESTRIAL TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BACT** **TERR**

*Species/strain/system* : Soil bacteria (Pseudomonas putida)

## Test Method and Conditions

*Test method description* : Cell multiplication inhibition test. Single species tests such as "Microtox Photobacterium Luminescence Test" and tests on overall processes such as nitrification or soil respiration, are included in this item. GLP: not known

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
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**BIOMA** **INHIB**

Toxicity threshold for 16 hours > 10000 mg/L

## References

*Primary Reference* : **WATRAG**  
Bringmann, G. and Kuhn, R. Water Research, 14, 231-241, (1980)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **TERRESTRIAL TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

**BIRD** **TERR**

*Species/strain/system* : Pigeon

## Test Method and Conditions

*Test method description* : Test method not specified; GLP: no

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	<b>LDLO SCU</b>				

Lowest lethal dose found = 16000 mg/kg

*General Comments* : Urea is not acutely toxic to pigeon.

## References

*Primary Reference* : **D8REP4**  
FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination Report, PB-288673, (1978)

*Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

## Study

*End Point* : **TERRESTRIAL TOXICITY**  
*Chemical Name* : **Urea**  
*CAS Number* : **57-13-6**  
*Study type* : **LAB**  
*Geographic Area* : **FIN**

## Test Subject

*Organism* *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

**PLANT TERR**

*Species/strain/system* : Soybean (Glycine max. L.) Merr

## Test Method and Conditions

*Test method description* : Test method not specified; GLP: no

## Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
<b>LEAF</b>	<b>STRUC</b>				

Leaf-tip necrosis observed after foliar fertilization of soybean with urea.

### NOEL

Maximum concentration at which no effect was observed within the period of the test < 0.01 wt -% urea of dry weight of leaves (= 9 mg/leaf, a 7-day study).

*General Comments* : It was concluded in this study that necrosis resulted from accumulation of toxic amounts of urea rather than from formation of toxic amounts of ammonia.

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## References

- Primary Reference* : **PNASA6**  
Krogmeier, J. M. et al. Proceedings of the National Academy of Sciences of the United States of America, 86, 8189-91, (1989)
- Secondary Reference* : **!SIDSP\***  
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)
-

## Substance

Chemical Name :  
 Reported Name : Urea  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

GBR REG USE PESTI RSTR  
 USE CONSM RSTR Permitted for use only as a home garden fungicide on cut stumps of trees and on apple and pear trees.  
Title : Pesticides 1992: Pesticides approved under the Control of Pesticides Regulations 1986  
Reference : PACPR\*, 500, xlv, 1992 Effective Date : 01MCH1991  
Last Amendment : Entry / Update : NOV1992

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

CSK REG FOOD - PRMT  
 GOODS MXL COMPONENT OF RUBBER PRODUCTS PERMITTED FOR CONTACT WITH FOOD AND THE HUMAN BODY. MAXIMUM LIMIT FOR THE FINAL PRODUCTS: 30MG/G.  
Title : DIRECTIVE NO. 62 ON HYGIENIC REQUIREMENTS ON RUBBERS AND RUBBER GOODS COMING IN CONTACT WITH FOODSTUFFS AND HUMAN ORGANISM  
Reference : HPMZC\*, 54, 1982 Effective Date : 1JAN1983  
 HYGIENICKE PREDPISY MINISTERSTVA ZDRAVOTNICTVI CSR (HYGIENIC REGULATIONS OF MINISTRY OF HEALTH OF CSR)  
Last Amendment : Entry / Update : DEC1991

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

CSK REG GOODS - RSTR  
 MXL MAXIMUM LIMITS IN COSMETICS: 50MG/G  
Title : DIRECTIVE NO. 34 ON HYGIENIC REQUIREMENTS ON COSMETICS, DETERGENTS, AND GOODS OF PERSONAL USE  
Reference : HPMZC\*, 32, 1970 Effective Date : 1JAN1971  
 HYGIENICKE PREDPISY MINISTERSTVA ZDRAVOTNICTVI CSR (HYGIENIC REGULATIONS OF MINISTRY OF HEALTH OF CSR)  
Last Amendment : Entry / Update : DEC1991

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

*Area Type Subject Spec. Description Level / Summary Information :*

CSK REG USE AGRIC PRMT SUBSTANCE IS APPROVED AS PESTICIDE. SPECIFIC USES, LIMITATIONS AND SAFETY PRECAUTIONS ARE GIVEN.  
Title : LIST OF PERMITTED CHEMICALS FOR PLANT PROTECT ION  
Reference : SPPOR\*, 290, 1990 Effective Date : JAN1991  
 SEZNAM POVOLENYCH PRIPRAVKU NA OCHRANU ROSTLIN (LIST OF PERMITTED CHEMICALS FOR PLANT PROTECTION)  
Last Amendment : Entry / Update : DEC1991

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

*Area Type Subject Spec. Description Level / Summary Information :*

DEU REC AQ - CLASS THIS SUBSTANCE IS CLASSIFIED AS SLIGHTLY HAZARDOUS TO WATER (WATER-  
 USE INDST RQR HAZARD CLASS: WGK 1). ( THE DIFFERENT CLASSES ARE: WGK 3 = VERY HAZAR DOUS; WGK 2 = HAZARDOUS; WGK 1 = SLIGHTLY HAZ ARDOUS; WGK 0 = IN GENERAL NOT HAZARDOUS.) TH E CLASSIFICATION FORMS THE BASIS FOR WATER-PR OTECTION REQUIREMENTS FOR INDUSTRIAL PLANTS I N WHICH WATER- HAZARDOUS SUBSTANCES ARE HANDLE D.  
Title : ADMINISTRATIVE RULES CONCERNING WATER-HAZARDO US SUBSTANCES (VERWALTUNGSVORSCHRIFT WASSERGE FAEHRDENDE STOFFE)  
Reference : GMSMA6, 8, 114, 1990 Effective Date :  
 Gemeinsames Ministerialblatt. Joint Ministerial Papers  
Last Amendment : Entry / Update : DEC1991

## Substance

Chemical Name : UREA  
 Reported Name : urea  
 CAS Number : 57-13-6

*Area Type Subject Spec. Description Level / Summary Information :*

GBR REG TRNSP MARIN RQR CATEGORY C SUBSTANCE: DISCHARGE INTO THE SEA IS PROHIBITED; DISCHARGE  
 AQ MARIN RSTR OF TANK WASHINGS AND RESIDUAL MIXTURES IS SUBJECT TO RESTRICTIONS .  
 AQ EMI RSTR (APPLIES TO SOLUTION WITH AMMONIUM NITRATE CONTAINING AQUA AMMONIA).  
Title : THE MERCHANT SHIPPING (CONTROL OF POLLUTION B Y NOXIOUS LIQUID SUBSTANCES IN BULK) REGULATI ONS 1987, SCHEDULE 1  
Reference : GBRSI\*, 551, 15, 1987 Effective Date : 06APR1987  
 Statutory Instruments  
Last Amendment : GBRSI\*, 2604, 2, 1990 Entry / Update : 1992  
 Statutory Instruments

## Substance

Chemical Name : UREA  
 Reported Name : urea  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

GBR	REG	TRNSP AQ AQ	MARIN MARIN EMI	RQR RSTR RSTR	CATEGORY D SUBSTANCE: DISCHARGE INTO THE SEA IS PROHIBITED; DISCHARGE OF RESIDUAL MIXTURES IS SUBJECT TO RESTRICTIONS. (APPLIES TO UREA SOLUTION WITH AMMONIUM MONO-HYDROGEN PHOSPHATE, AMMONIUM DI-HYDROGEN PHOSPHATE AND POTASSIUM CHLORIDE, APPLIES ALSO TO UREA SOLUTION WITH AMMONIUM NITRATE, AND ALSO TO UREA SOLUTION WITH AMMONIUM PHOSPHATE).
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**Title** : THE MERCHANT SHIPPING (CONTROL OF POLLUTION BY NOXIOUS LIQUID SUBSTANCES IN BULK) REGULATIONS 1987, SCHEDULE 1

**Reference** : GBRSI\*, 551, 15, 1987 **Effective Date** : 06APR1987  
 Statutory Instruments

**Last Amendment** : GBRSI\*, 2604, 2, 1990 **Entry / Update** : 1992  
 Statutory Instruments

## Substance

Chemical Name : UREA  
 Reported Name : urea  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

GBR	REG	TRNSP AQ AQ	MARIN MARIN EMI	RQR RQR RQR	CLASSIFIED AS A NON-POLLUTING LIQUID SUBSTANCE. DOCUMENTARY EVIDENCE OF ASSESSMENT AND APPROVAL REQUIRED BY A CARRIER. DISCHARGE INTO THE SEA IS NOT PROHIBITED. (APPLIES TO SOLUTION).
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**Title** : THE MERCHANT SHIPPING (CONTROL OF POLLUTION BY NOXIOUS LIQUID SUBSTANCES IN BULK) REGULATIONS 1987, SCHEDULE 2

**Reference** : GBRSI\*, 551, 15, 1987 **Effective Date** : 06APR1987  
 Statutory Instruments

**Last Amendment** : GBRSI\*, 2604, 2, 1990 **Entry / Update** : 1992  
 Statutory Instruments

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

KEN	REG	FOOD	ADDIT	PRMT	FOOD ADDITIVE PERMITTED AS YEAST FOOD. FOOD PRODUCTS IN OR UPON WHICH IT IS PERMITTED AND MAXIMUM LEVELS OF USE ARE LISTED.
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**Title** : THE FOOD, DRUGS AND CHEMICAL SUBSTANCES (FOOD LABELLING, ADDITIVES AND STANDARDS) REGULATIONS, 1978

**Reference** : GSKEN\*, 40, 406, 1978 **Effective Date** :  
 KENYA GAZETTE SUPPLEMENT NO. 40, SPECIAL ISSUE  
 (LEGISLATIVE SUPPLEMENT NO. 27)

**Last Amendment** : **Entry / Update** : SEP1982

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

RUS REG AIR AMBI MAC 0.2 MG/M3 AV/D.  
Title :  
Reference : Effective Date : AUG1984  
Last Amendment : PDKAV\*, 3086-84, 1984 Entry / Update : SEP1985  
 PREDELNO DOPUSTIMYE KONTSENTRATSII (PDK)  
 ZAGRYAZNYAYUSHCHIKH VESHCHESTV V ATMOSFERNOM  
 VOZDUKHE NASELENNYKH MEST  
 (MAXIMUM ALLOWABLE CONCENTRATIONS (MAC) OF  
 CONTAMINANTS IN THE AMBIENT AIR OF RESIDENTIAL AREAS)

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

RUS REG AQ SURF MAC SURFACE WATER FOR FISHING : 80.0 MG/L  
Title :  
Reference : Effective Date :  
Last Amendment : PDKTV\*, 1978 Entry / Update : SEP1985  
 PREDELNO-DOPUSTIMYE KONTSENTRATSII I  
 ORIENTIROVOCHNYE BEZOPASNYEUROVNI VOZDEISTVIA  
 VREDNYKH VESHCHESTV V OBJEKTAKH VNESHNEI SREDY.  
 NORMATIVNYE MATERIALY.  
 (MAXIMUM ALLOWABLE CONCENTRATIONS AND PRELIMINARY  
 SAFETY LEVELS OF TOXIC SUBSTANCES IN ENVIRONMENT.  
 STANDARDS.)

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

RUS REG AIR OCC MAC CLASS CLV: 10MG/M3 (AEROSOL) HAZARD CLASS: II  
Title :  
Reference : Effective Date : 01JAN1989  
Last Amendment : GOSTS\*, 12.1.005, 1988 Entry / Update : MAY1990  
 GOSUDARSTVENNYI STANDART SSSR  
 (STATE STANDARD OF USSR)



## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

RUS REG AIR OCC MAC CLASS CLV: 25MG/M3 (VAPOUR, AEROSOL- APPLIES TO FER TILIZER MIXT. WITH AMMONIA); HAZ. CLASS: IV  
Title :  
Reference : Effective Date : 1JAN1989  
Last Amendment : GOSTS\*, 12.1.005, 1988 Entry / Update : MAY1990  
 GOSUDARSTVENNYI STANDART SSSR  
 (STATE STANDARD OF USSR)

## Substance

Chemical Name :  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

USA REG CLASS MANUF FOOD PESTI PESTI ADDIT RQR PRMT RQR CASE NAME UREA; Summary - THIS SUBSTANCE IS I NCLUDED ON A LIST OF ACTIVE INGREDIENTS CONTA INED IN A PRODUCT FIRST REGISTERED BEFORE NOV EMBER 1, 1984, FOR WHICH A REGISTRATION STAND ARD HAS NOT BEEN ISSUED. PUBLICATION OF THIS LIST INITIATES AN ACCELERATED REREGISTRATION AND DATA C ALL-IN FOR PRODUCTS CONTAINING THE LISTED ACTIVE INGREDIENTS.  
Title : FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICI DE ACT PESTICIDES REQUIRED TO BE REREGISTERED ; LIST D  
Reference : FEREAC, 54, 204, 43388, 1989 Effective Date : 1989  
 Federal Register  
Last Amendment : FEREAC, 54, 204, 43388, 1989 Entry / Update : JAN1992  
 Federal Register

## Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

EEC REG FEED - PRMT TECHNICALLY PURE UREA MAY BE MARKETED AS FEED INGSTUFF UNDER THE CONDITIONS LAID DOWN.  
Title : COUNCIL DIRECTIVE OF 30 JUNE 1982 CONCERNING CERTAIN PRODUCTS USED IN ANIMAL NUTRITION (82 /471/EEC).  
Reference : OJEC\*\*, L213, 8, 1982 Effective Date : 01JUL1988  
 Official Journal of the European (Communities)Union  
Last Amendment : OJEC\*\*, L239, 36, 1988 Entry / Update : SEP1987  
 Official Journal of the European (Communities)Union

Substance

Chemical Name : UREA  
 Reported Name : UREA  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

EEC	REG	FOOD FOOD FOOD	-	RQR MXL RSTR	THE SUBSTANCE MAY BE USED FOR THE MANUFACTURE OF REGENERATED CELLULOSE FILM WHICH IS INTENDED TO OR DOES COME INTO CONTACT WITH FOODSTUFFS. IT MAY BE USED AS SOFTENER; MAXIMUM CONTENT OF SOFTENERS IN TOTAL: 27%.
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Title : COUNCIL DIRECTIVE OF 25 APRIL 1983 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO MATERIALS AND ARTICLES MADE OF REGENERATED CELLULOSE FILM INTENDED TO COME INTO CONTACT WITH FOODSTUFFS. (83/229/EEC).

Reference : OJEC\*\*, L123, 31, 1983 Effective Date : 01APR1987  
 Official Journal of the European (Communities)Union

Last Amendment : OJEC\*\*, L228, 32, 1986 Entry / Update : OCT1987  
 Official Journal of the European (Communities)Union

Substance

Chemical Name :  
 Reported Name : Urea  
 CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

IMO	REC	AQ AQ	EMI MARIN	RSTR RSTR	Category C substance (substance which is slightly toxic to aquatic life): discharge into the sea of this substance, of ballast water, tank washings or other residues or mixtures containing such a substance shall be prohibited except where specified conditions are satisfied. Technological requirements prescribe equipments and designs that must be present on the tankers as well as port facilities for receiving residues or mixtures containing the regulated substance. Technical assistance for training of scientific and technical personnel shall be promoted where requested by the Parties of the Convention. (Applies to urea/ammonium nitrate solution containing aqua ammonia)
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Title : International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78).

Reference : Effective Date :

Last Amendment : IMODC\*, Entry / Update : SEP1994

