OECD SIDS UREA

FOREWORD

INTRODUCTION

<u>UREA</u>
CAS N°: 57-13-6

Substance

End Point **IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES**

Chemical Name Urea Common Name Urea CAS Number 57-13-6 RTECS Number YR6250000

Synonyms

B-I-K **Benural 70**

Carbamide Carbamimidic acid

Carbonyl diamide Isourea Nimin **Pseudourea** UR Urea perhydrate Ureaphil Ureophil Urepearl **Urevert**

Varioform II

Properties & Definitions

CH4N2O Molecular Formula Molecular Weight 60.06 133C* Melting Point

Boiling Point 135C decomposition** State Crystal prismatic or powder

Flamable Limit Non-flammable

Density 1323 kg/m3 at 20-24C

Vapour Pressure 80 Pa (0.6 mmHg) at 20C CAL***

Octanol/Water Partition :

Coefficient

Water Solubility 1080 g/L at 20C

Solubility in other

Solvents

Colourless to white

Colour Taste Cooling, saline Odour **Almost odourless**

Additives Urea-formaldehyde binder can be used in some prilling processes. **Impurities** 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

log Pow = -1.59 at 20-25C experimental

2+ <0.0002 wt%; ash content < 0.02 wt%. Degree of purity 98-99

10 g/L in 95% alcohol, 167 g/L in methanol, 500 g/L in glycerol

wt%.

*On further heating decomposes to biuret, NH3 and cyanuric acid. On standing General Comments

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.

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 mammalians 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 (T1/2 > 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 m3/mol) indicate that urea will not evaporate from water to atmosphere.

Degradation of urea to ammonia causes NH3-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/m3 total dust and 5 mg/m3 respirable dust.

Uptake of respirable urea at 5 mg/m3 (with a 10 m3 volume of total ventilation and 100% absorption) would amount to 50 mg (inhalation dose).

The non-respirable part of urea at 10 mg/m3 and 10 m3 ventilation results in the airway deposition of 100 mg, most of which will be indested.

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 cm2 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 treshold concentration.

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

MTC: 29/100 = 0.29 mg/L

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

MTC/PEC => (a) 0.29/0.0043 = 67.4 (primary sewage plant effuent) (b) 0.29/0.0034 = 85.3 (sewage of Kemira's fertilizer factory)

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 FHF

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

Production-Trade

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

Production

<u>Quantity</u> <u>Year</u>

19062400-27963000 t/y - P 1985-1989 41440000-60789000 t/y - P 1985-1989 89800000-+134E+5 t/y - P 1989

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

Quantity Year

1470000-2350000 t/y - P 1985-1989

13 % - EX

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.

!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>

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

<u>Quantity</u> <u>Year</u>

31635000-+3617000 t/y - P

General Comments : Capacities in production or being commissioned in December 1989 in Planned

Economy Countries.

Production-Trade

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 : EUR
Area Specifications : W

Production

<u>Quantity</u> <u>Year</u>

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)

Production-Trade

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

Production

<u>Quantity</u> <u>Year</u>

3419000-+1150000 t/y - P

General Comments : Capacities in production or being commissioned in December 1989 for Central

and South America.

!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

<u>Quantity</u> <u>Year</u>

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

<u>Quantity</u> <u>Year</u>

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.

!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 : EUR

Production

Quantity Year

7144900-8321000 t/y - P 1985-1989

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)

Production-Trade

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

Production

<u>Quantity</u> <u>Year</u>

8063500-12185000 t/y - P 1985-1989

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

!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>

70000-230000 t/y - P 1987-1988

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 : CAN
Area Specifications : AMN

Production

<u>Quantity</u> <u>Year</u>

1000000-3000000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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 : CUB

Production

Quantity Year

20000-38000 t/y - P 1985-1989

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 : MEX

Production

<u>Quantity</u> <u>Year</u>

500000-640000 t/y - P 1985-1988

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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

Quantity Year

150000-250000 t/y - P 1985-1989

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 : AFG
Area Specifications : ASIA

Production

<u>Quantity</u> <u>Year</u>

45000-60000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

380000-680000 t/y - P 1985-1989

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 : IND
Area Specifications : ASIA

Production

<u>Quantity</u> <u>Year</u>

3400000-5750000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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

<u>Quantity</u> <u>Year</u>

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

<u>Quantity</u> <u>Year</u>

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-

!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>

300000-350000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metrictons 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>

260000-400000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

835000-970000 t/y - P 1985-1989

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 : QAT
Area Specifications : ASIA

Production

<u>Quantity</u> <u>Year</u>

320000-360000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

400000-450000 t/y - P 1985-1989

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 : SYR
Area Specifications : ASIA

Production

<u>Quantity</u> <u>Year</u>

50000-90000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

70000-160000 t/y - P 1985-1988

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 : ARE
Area Specifications : ASIA

Production

<u>Quantity</u> <u>Year</u>

150000-260000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

3500-15000 t/y - P 1985-1988

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 : BGR
Area Specifications : EUR

Production

<u>Quantity</u> <u>Year</u>

330000-370000 t/y - P 1985-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

70000-80000 t/y - P 1987-1989

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 : FRG
Area Specifications : EUR

Production

<u>Quantity</u> <u>Year</u>

500000-520000 t/y - P 1987-1989

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

120000-200000 t/y - P 1985-1989

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 : IRL
Area Specifications : EUR

Production

<u>Quantity</u> <u>Year</u>

127000-147000 t/y - P 1986-1988

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

460000-600000 t/y - P 1985-1989

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 : NLD
Area Specifications : EUR

Production

<u>Quantity</u> <u>Year</u>

380000-570000 t/y - P 1985-1987

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

240000-470000 t/y - P 1985-1989

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 : PRT
Area Specifications : EUR

Production

<u>Quantity</u> <u>Year</u>

4900-9000 t/y - P 1985-1988

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

113000-165000 t/y - P 1985-1989

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 : YUG
Area Specifications : EUR

Production

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

General Comments : The given values are the production volume of urea in metric tons of N (urea N-

!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>

4800000-4950000 t/y - P 1987-1989

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 : AMN

Production

<u>Quantity</u> <u>Year</u>

3140000-6278000 t/y - P 1985-1989

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

and central America.

!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

capacites 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 forcasted 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)

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)

Uses

CAS Number : Urea 57-13-6

Use

Quantity <u>Year</u> <u>Comments</u>

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.

3 % Approximate quantity used as an animals feed

supplement of the grain ration.

1 % 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

Quantity Year Comments

Use in consumer products: Urea is used in liquid soaps, detergents and houshold 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%.

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

1 %

6.4-9.6 %

Primary References : COSDA*

wt

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)

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)

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 medecines.

Urea is used as a formulating component in cosmetics, detergents, textile dyes and numerous other products.

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)

End Point : Pathway into the Environment and Environmental Fate.

Chemical Name : Urea : 57-13-6

Test Method and Conditions

Test method : Mackay level 1 model

description

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>

to AQ 99.84 %

Partitioning into water.

to AIR 0.16 %

Partitioning into air.

to AIR

NH3 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 to Medium Quantity Time Year to Year</u>

BIOTA AGRIC to SOIL

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)

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>

2-6 mg/L

In domestic sewage

0.016-0.043 mg/L

In primary sewage plant effluent

0.0016-0.0043 mg/L

PEC for primary sewage plant effluent

20 ug/L 1980

Concentration in groundwater in airport area as of 1980

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

Concentration 39

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

<u>Matrix</u> <u>Concentrations</u> <u>Spec.</u> <u>Date</u>

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

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>

150 mg/L 1975-1990

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

Concentration 4

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

<u>Matrix</u> <u>Concentrations</u> <u>Spec.</u> <u>Date</u>

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

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

<u>Matrix</u> <u>Concentrations</u> <u>Spec.</u> <u>Date</u>

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

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 dispesrsing 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

<u>Intake</u> <u>Spec.</u> <u>Date</u>

200 mg/d

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

50 ma

Uptake of respirable urea at 5 mg/m3 (with 10 m3 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/m3 and 10 m3 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

<u>Intake</u> <u>Spec.</u> <u>Date</u>

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

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

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 : GLP: no

description

Temperature : <8 C

Test Results

Quantity <u>Time</u> <u>Comments on result</u>

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 diappearance of urea was determined by colorimetric analysis.

Test Results

Quantity <u>Time</u> <u>Comments on result</u>

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 : Inherent Biodegradability: OECD Guideline 302 B (1981), Zahn-Wellens

description Test; GLP: no

(An)aerobic : AEROB

Exposure

Dose / Concentration : 400 mg/L

<u>Quantity</u>	<u>Time</u>	Comments on result
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

General Comments : Urea is ultimately biodegradable according to this study. (Proj. No:

1/91/0452/10/1) as cited in the reference.

References

Primary Reference : #URBSF*

BASF AG. BASF Unpublished Report, (1991)

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 SOIL

Species/strain/system : Flooded soil

Exposure

Exposure Period : 30 h

Exposure comments : 30 hours of incubation

Quantity <u>Time</u> Comments on result 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). The added urea which was hydrolysed in the floodwater after 30 hours of 3 % 30 h incubation. 64 % 30 h The added urea which was hydrolysed in the soil after 30 hours of incubation. Additional studies also showed that soil water content had little effect on urease activity, but other researchers have found hydrolysis rates to

Report number: D/39/1978

References

General Comments

Primary Reference : SOSCAK

Vlek, P. L. G. and Carter, M. C. Soil Science, 136, 56-63, (1983)

Secondary Reference : !SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High

Production Volume Chemicals Programme, (1994)

increase with increasing soil water up to field capacity.

Study

End Point : BIODEGRADATION

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

Test Subject

Organism Medium Specification

- SOIL SOIL

Test Method and Conditions

Test method : Transformation times of different nitrogen forms in soil

description

Temperature : 2-20 C

Exposure

Exposure Period : 1-4 d

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

References

Primary Reference : BUARE*

Bua. BUA Report on Chemicals of Environmental Relevance, 76

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

BACT AQ SEW

Species/strain/system : Psychrophilic bacteria

Test Method and Conditions

Temperature : 20 C Relative Humidity : 2 %

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

References

Primary Reference : HBEDC*

Verschueren, K. Handbook of Environmental Data on Organic

Chemicals, 2nd. ed., (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

BACT SOIL AQ

Exposure

Exposure comments : Main factors affecting the rates of nitrogen metabolization are the initial

concentration of the ureolytic bacteria, the physical state of the nitrifying

micro-organisms and the concentration of toxic organics.

Test Results

Quantity Time Comments on result

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) NH2CONH2 + 2H20 (Urease-enzyme) --- > NH3 + NH4 + HCO3- 2) NH4+ + 1.5 O2 Nitrosomonas ---> NO2- +

H2O + 2H+ ---> NO2- + 0.5 O2 Nitrobacter ---> NO3-

References

Primary Reference **AHCBAU**

Gunkel, K. et al. Acta Hydrochimica et Hydrobiologica, 18(1), 3-20,

Secondary Reference !SIDSP*

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

Hydrolysis 53

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

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

Medium SILT LOAM Specifications SOIL SOIL

Geographic Area FIN

Test Results

Quantity Time Comments on result

> 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 Crowly 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.

Urea adsorption by the soil was low. The following reference is also General Comments

cited: Sharply, A. N. et al. 1983. Water, Air and Soil Pollution 14(3): 425-

430 (1983); as cited in HSDB 1991.

References

Primary Reference SSSJD4

Hongprayoon, C. et al. Soil Science Society of America Journal, 55,

1130-34, (1991)

Secondary Reference !SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High

Evaporation 55

Study

End Point : EVAPORATION

Chemical Name : Urea
CAS Number : 57-13-6
Study type : LAB
Medium : AQ
Specifications : FRESH
Geographic Area : FIN

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

m3/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

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/m3;

optimum water content for compaction 0.196-0.219 kg/kg; Clod density 1.46-1.68 mg/m3; water content at -1.5 MPa potential 0.125-0.192 kg/kg. Particle size distribution 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 NH4+ 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, NH4NO3

and urea-NH4NO3 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

Absorption

Study

End Point : ABSORPTION

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

Test Subject

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

HUMAN SKN

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

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)

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

End Point : BIOCONCENTRATION

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

Test Results

General Comments : Due to the low log Pow value urea is not likely to undergo

bioaccumulation.

References

Secondary Reference : !SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High

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

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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

RAT ORL M LD50 Oral LD50 for male rats was established

F as 14300 mg/kg and for female rats as

15000 mg/kg body weight.

General Comments : 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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

RAT SCU M LD50 Subcutaneous LD50 for male and

F

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)

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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

MOUSE ORL M LD50 Oral LD50 for male and female mice

was established as 11500 mg/kg and 13000 mg/kg, respectively.

13000 Hig/kg, respectively

General Comments : The general symptoms consisted mainly of sedation, loss of righting reflex and

F

staggening 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 : 9200-10700 mg/kg BW

Test Method and Conditions

Test method description

GLP: no

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

MOUSE SCU M LD50 Subcutaneous LD50 for male and

F

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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

CATTL ORL LD50 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

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 : GLP: no

description

Test Results

<u>Organism Medium Spec. Route Lifestage Sex Effect Comments</u>

SHEEP ORL LD50 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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Comments

CATTL ORL LD50 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)

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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

RAT IVN M LD50 Intravenous LD50 for male and female

F

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)

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

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

MOUSE IVN M LD50 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 : GLP: no

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

DOG IVN LD50 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

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

Ruminants Species/strain/system

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 synthetize 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)

!SIDSP* Secondary Reference

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High

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

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

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

DOG SCU

Test Method and Conditions

Test method description

GLP: no

Exposure

Dose / Concentration : 3000-9000 mg/kg BW

IRPTC Data Profile

Affected in
Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

DOG SCU 12

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.

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

PLSMA BIOCH

Plasma urea levels were 200 to 700 mg/100 mL

BEHAV

Mild drowsiness

URINE INCR Increased diuresis

NEF

Treatment did not affect hematocrit, platelet counts nor EEg.

References

Primary Reference : D8REP4

FDA (US-Food and Drug Admin.). Health Hazard Evaluation Determination

Report, PB288673, (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 IVN

Test Method and Conditions

Test method : GLP: no description

Exposure

Dose / Concentration : 3000 mg/kg BW

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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)

Study

End Point : MAMMALIAN TOXICITY

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

Test Subject

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

GPIG IVN

Species/strain/system : Guinea pig

Test Method and Conditions

Test method : GLP: no

description

Exposure

Dose / Concentration : 4800 mg/kg BW

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

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 : GLP: no description

Exposure

Dose / Concentration : 3310-3610 mg/kg BW

Test Results

Affected in
Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

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

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

SKIN NEF

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

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

PIG ORL JUV

Species/strain/system : Young pigs

Test Method and Conditions

Test method

GLP: no

description

Exposure

Dose / Concentration : 16000 mg/kg BW

Test Results

Affected in
Organ Effect Roy OpSet Say Exposed - Contr

Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

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 cm2

area) for 4 weeks.

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls
----NEF

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

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

GLP: unknown

description

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

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 cm2 area for 24 weeks.

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

References

Primary Reference : OYYAA2

NEF

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

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

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

Jrgan Επεcτ Rev. UnSet Sex Exposed - Controls -------

LDLO

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)

Study

End Point : MAMMALIAN TOXICITY

CAS Number : Urea : 57-13-6

Test Subject

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

RBT IVN

Species/strain/system : Rabbit

Test Method and Conditions

Test method : GLP: no

description

Exposure

Dose / Concentration : 7320 mg/kg BW

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

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

Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO

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

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

Carcinogenicity 81

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

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

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

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

RAT ORL M

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

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

Mutagenicity 83

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 : Bacterial test, Ames test; GLP: no data

description

Exposure

Exposure comments : Test performed with and without metabolic activation.

Test Results

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

Negative results with and without metabolic activation

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

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 : Bacterial test (Ames test); GLP: not known

description

Exposure

Dose / Concentration : 5-5000 ug/ PLATE

Exposure comments : Tests were performed with and without metabolic activation.

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

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

Mutagenicity 85

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 : Bacterial test (Ames test); GLP: not known

description

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

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

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

Purity unknown

substance

Vehicle - Solvent : Physiological saline

Test Method and Conditions

Test method description

Chromosomal aberration test; GLP: not known

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

CHROM STRUC

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 : !SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High

Mutagenicity 87

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

Chromosomal aberration test; GLP: not known

description

Exposure

Dose / Concentration : 13 g/L

Exposure comments : Urea concentration 216 mmolar

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

CHROM STRUC

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

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

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

Negative result with metabolic activation

GENE MUT

NEF INC

Weakly positive at very high urea concentrations 530 - 662 mmolar negative at 132 mmolar, equivalent at 265 - 397 mmolar.

CELL

Lowest concentration producing cell toxicity: 265 mmolar

General Comments : 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+/-

Mutagenicity 89

Test Substance

Purity Grade : AG

Test Method and Conditions

Test method : Analysis for DNA singlestrand breaks by alkaline unwinding and

description 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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

DNA STRUC

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

Purity unknown

substance

Test Method and Conditions

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

description

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

CHROM STRUC

Bone marrow cell, metaphases exhibited chromosome breaks, acentric fragments, translocations, gaps and constrictions at a 7-fold rate compared to controls.

General Comments : 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

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

RAT VTR

Species/strain/system : Rat hepatocytes

Test Substance

Purity Grade : AG
Vehicle - Solvent : Water

Test Method and Conditions

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

Exposure

Dose / Concentration : 18-180 mg/L

Exposure comments : Concentrations of 0.3 - 3 mmolar were used.

Test Results

Organ Effect Rev. OnSet Sex Exposed - Controls

NEF

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

End Point : SENSITIZATION

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

Test Subject

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

HUMAN SKN

Test Substance

Vehicle - Solvent : Water

Test Method and Conditions

Test method description

GLP: unknown

Exposure

Exposure comments : 10% water solution

Test Results

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

SKN NEF 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

Irritation 93

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 : Chamber-Scarification Test; GLP: unknown

description

Exposure

Exposure Type : ACUTE

Dose / Concentration : 75-300 g/L

Exposure comments : 7.5% and 30% urea solutions in water were applied.

Test Results

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

SKN IRRITSlight irritation with 7.5% urea

SKN IRRIT

Marked irritation with 30% urea

SKN IRRIT

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

End Point : IRRITATION

Chemical Name : Urea
CAS Number : 57-13-6
Study type : LAB

Test Subject

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

HUMAN SKN

Test Substance

Vehicle - Solvent : Water

Test Method and Conditions

Test method : Not specified; GLP: unknown

description

Exposure

Exposure Type : ACUTE
Dose / Concentration : 100 g/L

Exposure comments : 10% water solution of urea

Test Results

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

SKIN NEFNo 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

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

MOUSE SKN M

Species/strain/system : Nude MF1h mice

Irritation 95

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

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 : GLP: unknown

description

Exposure

Exposure Period : 20 h

Dose / Concentration : 500 g/L

Exposure comments : 20 hours semiocclusive application of 50% urea water solution on the back

and ear skin of rabbit.

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

SKN NEF

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

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RBT OCU

Species/strain/system : Rabbit

Test Method and Conditions

Test method description

: OECD 405; GLP: yes

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

EYE NEF

Not irritating (no irritancy after 24 hours)

Irritation 97

References

Primary Reference : #URBSF*

BASF AG. BASF Unpublished Report

Secondary Reference : !SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High

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

Teratogenicity 99

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

EMBRY STRUC

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

MOUSE ORL F 10

Species/strain/system : ICR mice

Test Method and Conditions

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

description

IRPTC Data Profile

Teratogenicity 101

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT ORL F 4

Species/strain/system : Wistar rats

Test Method and Conditions

Test method : As 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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT ORL F 6

Species/strain/system : Wistar rats

Test Method and Conditions

Test method : Within 48 hours after delivery the pups were killed and the kidneys examined; description 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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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".

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

End Point **AQUATIC ACUTE TOXICITY**

Chemical Name Urea CAS Number 57-13-6 Study type LAB Geographic Area FIN

Snail (Helisoma trivolvis) Species/strain/system

Test Method and Conditions

Test method Static; GLP: not known

description

Test Results

Route Lifestage Sex Effect Effect Comments Organism Medium Spec.

MOLL **FRESH EGG LC50** LC50 for 24 hours for egg = 14241 AQ JUV

mg/L; LC50 for 24 hours for juveniles =

18255 mg/L; LC50 for 24 hours for

adults = 30060 mg/L.

ADULT

References

Primary Reference **AECTCV**

Tchounwou, P. B. et al. Archives of Environmental Contamination and

Toxicology, 21, 359-364, (1991)

!SIDSP* Secondary Reference

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 Static; GLP: no description

Test Results

Route Lifestage Sex Effect Effect Comments Organism Medium Spec.

INSEC AQ **FRESH LARVA LC50** 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)

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 : Static

description

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Comments

FISH AQ LC50 LC50 for 96 hours > 9100 mg/L.

General Comments: 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

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls
-----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)

Aquatic Toxicity 107

Test Method and Conditions

Test method description

Cell multiplication inhibition test; static; GLP: no

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

BIOMA INHIB

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 : Bioluminiscent bacteria (Photobacterium luminescence)

Aquatic Toxicity 109

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

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

EC50

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 : DIN 38412 Teil 11 (modified) description

Test Results

EC50 for 24 hours > 10000 mg/L.

General Comments : 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)

Study

End Point : AQUATIC TOXICITY

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

Test Subject

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

FISH AQ FRESH

Species/strain/system : Golden orfe (Leuciscus idus melanotous)

Test Method and Conditions

Test method

Static; GLP: no

description

Exposure

Exposure Type : ACUTE

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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

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 : Test method not specified

description

Test Results

Affected in

Organ Effect Rev. OnSet Sex Exposed - Controls

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 varity 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

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

End Point : TERRESTRIAL TOXICITY

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

Test Subject

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

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 knwon

Test Results

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

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

BIRD TERR

Species/strain/system : Pigeon

Test Method and Conditions

Test method description

Test method not specified; GLP: no

Test Results

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

LDLO SCU

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 : Test method not specified; GLP: no

description

Test Results

Affected in Organ Effect Rev. OnSet Sex Exposed - Controls

LEAF STRUC

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.

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

Chemical Name :

Reported Name : Urea
CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information :

GBR REG USE PESTI RSTR Permitted for use only as a home garden fu

USE CONSM RSTR pear tre

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 COMPONENT OF RUBBER PRODUCTS PERMITTED FOR CO NTACT WITH FOOD AND

GOODS MXL THE HUMAN RODY MAXIMUM LIMIT FOR THE FINAL PRODUCTS: 30MG/G

THE HUMAN BODY. MAXIMUM L IMIT FOR THE FINAL PRODUCTS: 30MG/G.

Title: DIRECTIVE NO. 62 ON HYGIENIC REQUIREMENTS ON RUBBERS AND

RUBBER GOODS COMING IN CONTACT WI TH FOODSTUFFS AND HUMAN

ORGANISM

<u>Reference</u>: HPMZC*, 54, 1982 <u>Effective Date</u>: 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 MAXIMUM LIMITS IN COSMETICS: 50MG/G

MXL <u>Title</u>: 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

117

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.

<u>Title</u>: LIST OF PERMITTED CHEMICALS FOR PLANT PROTECT ION

Reference: SPPOR*, 290, 1990 Effective Date: JAN199

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
USE INDST ROR

THIS SUBSTANCE IS CLASSIFIED AS SLIGHTLY HAZA RDOUS TO WATER (WATER-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.) THE 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)

<u>Reference</u>: GMSMA6, 8, 114, 1990 <u>Effective Date:</u>

Gemeinsames Ministerialblatt. Joint Ministerial Papers

<u>Last Amendment :</u> <u>Entry / Update :</u> 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

AQ MARIN RSTR AQ EMI RSTR CATEGORY C SUBSTANCE: DISCHARGE INTO THE SEA IS PROHIBITED; DISCHARGE OF TANK WASHINGS AND RESIDUAL MIXTURES IS SUBJECT TO RESTRICTIONS . (APPLIES TO SOLUTION WITH AMMONIUM NITRATE CONTAINING AQUA AMMONIA).

<u>Title</u>: 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

<u>Last Amendment :</u> GBRSI*, 2604, 2, 1990 <u>Entry / Update :</u> 1992

Statutory Instruments

Chemical Name : UREA
Reported Name : urea
CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information:

GBR REG TRNSP MARIN RQR

AQ MARIN RSTR AQ EMI 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 PHOSPHA TE, AMMONIUM DIHYDROGEN PHOSPHATE AND POTASS IUM CHLORIDE, APPLIES ALSO TO UREA SOLUTION WITH AMMONIUM NITRATE, AND ALSO TO UREA SOLUTI ON WITH AMMONIUM PHOSPHATE).

Title: THE MERCHANT SHIPPING (CONTROL OF POLLUTION B Y NOXIOUS LIQUID

SUBSTANCES IN BULK) REGULATI ONS 1987, SCHEDULE 1

<u>Reference</u> : GBRSI*, 551, 15, 1987 <u>Effective Date</u> : 06APR1987

Statutory Instruments

<u>Last Amendment :</u> GBRSI*, 2604, 2, 1990 <u>Entry / Update :</u> 1992

Statutory Instruments

Substance

Chemical Name : UREA
Reported Name : urea
CAS Number : 57-13-6

<u>Area Type Subject Spec. Description Level / Summary Information :</u>

GBR REG TRNSP MARIN RQR
AQ MARIN RQR

AQ MARIN RQR AQ EMI RQR CLASSIFIED AS A NON-POLLUTING LIQUID SUBSTANC E. DOCUMENTARY EVIDENCE OF ASSESSMENT AND APP ROVAL REQUIRED BY A CARRIER. DISCHARGE INTO THE SEA IS NOT PROHIBITED. (APPLIES TO SOLUTIO N).

Title: THE MERCHANT SHIPPING (CONTROL OF POLLUTION BY NOXIOUS LIQUID

SUBSTANCES IN BULK) REGULATI ONS 1987, SCHEDULE 2

<u>Reference</u> : GBRSI*, 551, 15, 1987 <u>Effective Date</u> : 06APR1987

Statutory Instruments

<u>Last Amendment :</u> GBRSI*, 2604, 2, 1990 <u>Entry / Update :</u> 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 P RODUCTS IN OR UPON WHICH

IT IS PERMITTED ANDM AXIMUM LEVELS OF USE ARE LISTED.

Title: THE FOOD, DRUGS AND CHEMICAL SUBSTANCES (FOOD LABELLING,

ADDITIVES AND STANDARDS) REGULATI ONS, 1978

Reference : GSKEN*, 40, 406, 1978 Effective Date :

KENYA GAZETTE SUPPLEMENT NO. 40, SPECIAL ISSUE (LEGISLATIVE SUPPLEMENT NO. 27)

Last Amendment: Entry / Update: SEP1982

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 :

Effective Date: AUG1984 Reference

PDKAV*, 3086-84, 1984 SEP1985 Last Amendment: Entry / Update :

> PREDELNO DOPUSTIMYE KONTSENTRATSII (PDK) ZAGRYAZNYAYUSHCHIKH VESHCHESTV V ATMOŚFERNOM

VOZDUKHE NASELENNYKH MEST

(MAXIMUM ALLOWABLE CONCENTRATIONS (MAC) OF CONTAMINANTS IN THEAMBIENT 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 :

Effective Date : Reference

PDKTV*, 1978 SEP1985 Last Amendment: Entry / Update :

PREDELNO-DOPUSTIMYE KONTSENTRATSII I

ORIENTIROVOCHNYE BEZOPASNYEUROVNI VOZDEISTVIA VREDNYKH VESHCHESTV V OBIEKTAKH VNESHNEI SREDY.

NORMATIVNYE MATERIALY.

(MAXIMUM ALLOWABLE CONCENTRATIONS AND PRELIMINARY SAFETY LEVELSOF TOXIC SUBSTANCES IN ENVIRONMENT.

STANDARDS.)

Substance

Chemical Name **UREA UREA** Reported Name CAS Number 57-13-6

Area Type Subject Spec. <u>Description</u> <u>Level / Summary Information :</u>

RUS REG AIR occ MAC CLV: 10MG/M3 (AEROSOL) HAZARD CLASS: II

CLASS Title :

> Reference Effective Date: 01JAN1989

GOSTS*, 12.1.005, 1988 Last Amendment: Entry / Update : MAY1990

GOSUDARSTVENNYI STANDART SSSR

(STATE STANDARD OF USSR)

Chemical Name : UREA
Reported Name : UREA
CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information:

RUS REG AIR OCC MAC CLV: 25MG/M3 (VAPOUR, AEROSOL- APPLIES TO FER TILIZER MIXT. WITH AMMONIA);

CLASS HAZ. CLASS: IV

Title :

Reference : 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

<u>Area Type Subject Spec. Description Level / Summary Information :</u>

USA REG CLASS PESTI RQR
MANUF PESTI PRMT
FOOD ADDIT 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

<u>Reference</u>: FEREAC, 54, 204, 43388, 1989 <u>Effective Date</u>: 1989

Federal Register

<u>Last Amendment</u>: FEREAC, 54, 204, 43388, 1989 <u>Entry / Update</u>: 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.

<u>Title</u>: 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

Chemical Name : UREA
Reported Name : UREA
CAS Number : 57-13-6

Area Type Subject Spec. Description Level / Summary Information:

EEC REG FOOD - RQR

FOOD MXL FOOD RSTR THE SUBSTANCE MAY BE USED FOR THE MANUFACTURE OF REGENERATED CELLULOSE FILM WHICH IS INTEN DED TO OR DOES COME INTO CONTACT WITH FOODSTU FFS. IT MAY BE USED AS SOFTENER; MAXIMUM CONT ENT OF SOFTENERS IN TOTAL: 27%.

<u>Title</u>: COUNCIL DIRECTIVE OF 25 APRIL 1983 ON THE APP ROXIMATION OF THE LAWS OF THE MEMBER STATES R ELATING TO MATERIALS AND ARTICLES MADE OF REG ENERATED CELLULOSE FILM INTENDED TO COME INTO

CONTACT WITH FOODSTUFFS. (83/229/EEC).

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

<u>Area Type Subject Spec. Description Level / Summary Information :</u>

IMO REC AQ EMI RSTR AQ MARIN 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)

<u>Title</u>: 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 :

<u>Last Amendment</u>: IMODC*, <u>Entry / Update</u>: SEP1994