

# Safety Data Sheet

According to Regulation (EC) No 2015/830



## Urea 46% N Prills LBU

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name **Van Iperen Urea 46% N Prills LBU**  
Synonyms Carbamide, carbonyl diamide, diamide of carbonic acid  
Molecular formula (NH<sub>2</sub>)<sub>2</sub>CO  
CAS Number 57-13-6  
EC Number 200-315-5  
Registration number 01-2119463277-33-0044

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

According to Regulation (EC) No 1272/2008 and Council Directive 67/548/EWG urea is not classified as a dangerous substance  
The most common use of urea as: as a fertilizer, additive to feeds, antifreeze and de-icing products, intermediate, pH regulator.

#### 1.3. Details of the supplier of the safety data sheet

Van Iperen International BV  
Smidsweg 24  
3273 LK Westmaas - Nederland  
T +31 (0) 186 578 888 - F +31 (0) 186 573 452  
[info@iperen.com](mailto:info@iperen.com) - [www.vaniperen.com](http://www.vaniperen.com)

#### 1.4. Emergency telephone number

In case of emergency contact the national emergency telephone number: UK and Ireland: 112 or 999

Country	Official advisory body	Address	Emergency number
Ireland (Republic of)	National Poisons Information Centre Beaumont Hospital	Beaumont Hospital Beaumont Road 9 Dublin	: +353 1 8379964
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance

According to Regulation (EC) No 1272/2008 and Council Directive 67/548/EWG the substance is not classified as a dangerous.

Human Health effects

Skin effect Longer contact may cause skin irritation

Eyes effect Longer contact may cause serious eye irritation. Remove contact lenses.

Swallowing Ingestion of a larger amount (above 50 g) leads to gastrointestinal discomforts.

Inhalation High concentration of airborne dust may cause nose irritation and irritation of the upper respiratory tract.

Long - term effects No negative effects are known. In a natural state it is present in a human's body. Urea is used as an ingredient of cosmetics, medical preparations, is a product of metabolism in a human's body and is present in urine.

Fire and products of thermal decomposition

Inhalation of gases coming from thermal decomposition may cause irritation and caustic action for the respiratory system. Influence on lungs may occur over some time.

Fire and warming Urea decomposes when heating producing ammonia. In case of fire toxic gases containing ammonia, carbon dioxide and nitric oxides - NO<sub>x</sub> may be released.

#### 2.2. Label elements

According to Regulation (EC) No 1272/2008 the substance is not classified as a dangerous.

#### 2.3. Other hazards

Urea is neither a PBT nor a vPvB substance.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Product containing urea as a main ingredient. (total content of urea min. 99 %).

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Inhalation Remove injured from exposure area. In severe cases, or if recovery is not rapid or complete seek medical attention.

Skin contact: Rinse contaminated area with plenty of water. Remove contaminated clothing and wash before reuse. If irritation persists seek medical attention.

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Eye contact: Wash thoroughly with water for at least 10 minutes. Obtain medical attention.

Swallowing Wash out mouth with water. Do not induce vomiting. If patient is conscious, give water to drink. If patient feels unwell seek medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

Acute and delayed symptoms and effects do not occur in normal conditions of use (see section 11).

### 4.3. Indication of any immediate medical attention and special treatment needed

Medical assistance is needed in case of inhalation of large amounts of dust.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media Apply the best known means to extinguish fire.

Unsuitable extinguishing media No data

### 5.2. Special hazards arising from the substance or mixture

Contact with skin

- Skin having contact with a melted material to be washed with a large amount of water.
- Provide medical attention.

Inhalation

- Remove the injured from area endangered with toxic gases.
- Provide the injured warmth and calmness.
- Persons exposed to inhalation of gases being products of decomposition should be provided with immediate medical attention.

### 5.3. Advice for firefighters

Irritating substances may be emitted upon thermal combustion so self-contained breathing apparatus will be required.

- Call fire brigade.
- Avoid inhaling of vapours (they are toxic). Stand with a face towards fire, always back to a wind.
- When extinguishing a fire, use proper masks. If vapours are released, use breathing apparatus.
- Use large amount of water.
- Prevent release of a melted product to sewage ducts.

If water containing a dissolved product is released to sewage or waters, inform local authorities immediately.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective clothing.

### 6.2. Environmental precautions

Prevent large amounts from getting through to environment or waterways. Keep animals away from large spills.

Pay attention to avoid pollution of waters or sewage ducts and inform proper authorities in case of their accidental pollution.

### 6.3. Methods and material for containment and cleaning up

Any spillage of urea should be immediately cleaned and placed in a clean, labelled container.

Depending on a degree and type of pollution, a collected product may be used as a fertilizer for agricultural purposes scattering it with a thin layer over a field or product may be transferred to a specialized company for neutralization purposes.

### 6.4. Reference to other sections

See section 1 for emergency contact information and section 13 for waste disposal.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Avoid contact with eyes. Avoid repeated or prolonged contact with skin or clothing. Avoid dust inhalation. Wear suitable protective clothing.

Avoid excessive accumulation of dusts. Avoid unnecessary exposure to atmospheric air to prevent moisture retention. When handling the product for a longer time, wear proper protective clothes and gloves.

### 7.2. Conditions for safe storage, including any incompatibilities

Store in cool and dry conditions. Keep away product from ignition sources. Keep storage rooms clean. Storage buildings should be dry and well vented.

### 7.3. Specific end use(s)

Urea is not classified as a dangerous substance. Exposure scenarios have not been made.

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

DNELs for workers

Acute - systemic effects Dermal DNEL: 580 mg/kg bw/d

Acute - systemic effects Inhalation DNEL: 292 mg/m<sup>3</sup>

Long-term - systemic effects Dermal DNEL: 580 mg/kg bw/d

Long-term - systemic effects Inhalation DNEL: 292 mg/m<sup>3</sup>

DNELs for general population

Acute - systemic effects Dermal DNEL: 580 mg/kg bw/d

Acute - systemic effects Inhalation DNEL: 125 mg/m<sup>3</sup>

Acute - systemic effects Oral DNEL: 42 mg/kg bw/d

Long-term - systemic effects Dermal DNEL: 580 mg/kg bw/d

Long-term - systemic effects Inhalation DNEL: 125 mg/m<sup>3</sup>

Long-term - systemic effect Oral DNEL: 42 mg/kg bw/d

PNEC<sub>2</sub>

PNEC aqua (freshwater) 0.047 g/L

#### 8.2. Exposure controls

When handling the product for a longer time, wear proper protective gloves. At high concentration of dusts, wear proper dust-masks.

Avoid excessive accumulation of dusts and install a local exhaust ventilation system where it is necessary.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state at 20°C and 1013 hPa	Solid
	Odorless
Melting / freezing point	407 K at 1013 hPa
Boiling point (at 1013 hPa)	Urea decomposes before reaching the boiling point.
Relative density	1330 at 20°C
Vapour pressure	0.002 Pa at 298 K
Water solubility	624000 mg/L at 20 °C
Partition coefficient n-octanol/water (log value)	Log Kow (Pow): -1.73 at 20 °C
Surface tension	Not applicable due to the chemical structure.
Flammability	Non flammable
Flash point	The substance decomposes at the melting point.
Self-ignition temperature	No evidence of self-ignition property of urea.
Explosive properties	No explosive properties.
Oxidising properties	No oxidising properties.
Stability in organic solvents and identity of relevant degradation products	The stability of the substance in organic solvents is not a critical property.
Granulometry	Fraction 1 – 3 mm min. 90%
Dissociation constant	Above 0.6 (pKb)
Viscosity	The substance is a solid at room temperature.

#### 9.2. Other information

No data.

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Non reactive during storage, handling and application in normal conditions.

#### 10.2. Chemical stability

Stable during storage, handling and application in normal conditions.

#### 10.3. Possibility of hazardous reactions

Unknown.

#### 10.4. Conditions to avoid

Heating above the melting point.

Welding or heat treatment of equipment on installation, where urea may be present without earlier thorough washing to remove all residue of a fertilizer.

#### 10.5. Incompatible materials

Strong oxidants, acids, alkalis, nitrates, calcium hypochlorite or sodium hypochlorite.

#### 10.6. Hazardous decomposition products

Urea reacts with calcium hypochlorite or sodium hypochlorite forming explosive nitrogen trichloride.

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### a) Toxicokinetics (absorption, metabolism, distribution and elimination)

Dermal absorption

Dermal absorption values of 7.2-9.5% is reported for urea.

Absorption rate (%): 9.5

Basic toxicokinetics

The handling of urea by the human body is well characterised as it is a normal product of protein catabolism and is normally produced in large quantities.

##### b) Acute toxicity

Urea is of very low acute toxicity by all routes investigated. The acute oral LD50 of urea is reported to be 14.3-15.0 g/kg bw in the rat and 11.5-13.0 g/kg bw in the mouse. The acute subcutaneous LD50 is reported to be 8.2-9.4 g/kg bw in the rat and 9.2-10.7 g/kg bw in the mouse. The acute intravenous LD50 of urea is reported to be 5.3-5.4 g/kg bw in the rat and 4.6-5.2 g/kg bw in the mouse.

LD50 (oral): 14300 mg/kg bw

##### c) Irritation

Data from various species (including human volunteers) indicate that urea is not irritating to intact skin. The results of a guideline-compliant eye irritation study do not trigger classification as an eye irritant.

Skin irritation / corrosion: not irritating

Eye irritation: not irritating

##### d) Corrosivity

Human and animal data show that urea is not corrosive.

##### e) Sensitisation

Skin sensitisation

Urea is naturally present at relatively high concentrations in human skin (up to 1% by weight) and is widely used in skin creams for the treatment of dry and irritant skin conditions without any reports of sensitisation reactions. It is therefore considered to be very unlikely to be a skin sensitizer.

not sensitising

Respiratory sensitisation

There are no animal or human data which indicate that urea is a respiratory sensitizer.

not sensitising

##### f) Repeated dose toxicity

12-month carcinogenicity screening studies in the rat and mouse demonstrate that urea is of very low chronic toxicity by the oral route. Similarly, no evidence of local or systemic toxicity was seen in 4-week and 25-week dermal toxicity studies in the rat. No clear toxicity was seen in dogs administered high doses of urea by subcutaneous injection over a period 45 days.

(route: oral): NOAEL: 2250 mg/kg bw/day

##### g) Mutagenicity

Negative results are reported in three Ames tests. Positive results are reported in assays for mutagenicity and clastogenicity in mammalian cells, however the value of these studies are limited by the extremely high test concentrations. A positive result is reported in a mouse bone marrow assay of unconventional design, however this study is not considered to be reliable. Based on its physiological role and presence in the body at high concentrations, urea is not considered to be genotoxic.

Genetic toxicity: negative

##### h) Carcinogenicity

No evidence of carcinogenicity was seen in NCI screening studies in the rat and mouse.

(route: oral): NOAEL4 : 2250 mg/kg bw/day

##### i) Toxicity for reproduction

Effects on fertility

No standard studies are available. It is considered extremely unlikely that occupational, primary or secondary exposure to urea will result in any effects on fertility as the levels of exposure will be insignificant compared to those present in the body as a result of protein catabolism.

Developmental toxicity

No standard studies are available. It is considered extremely unlikely that occupational, primary or secondary exposure to urea will result in developmental toxicity as the levels of exposure will be insignificant compared to those present in the maternal and foetal circulation as a result of protein catabolism.

(route: oral): LOAEL5: 500 mg/kg bw/day

Toxicity to reproduction: other studies

No additional information is available.

##### j) Neurotoxicity

No data are available and none are required. There is no evidence of neurotoxicity from the standard toxicity studies, including the chronic toxicity studies of Fleischmann et al. (1980) in the rat and mouse (Section 5.6.1.1), which did not detect any behavioural changes or brain pathology at dose levels of up to 45000 ppm in the diet.

##### k) Immunotoxicity

No data are available and none are required. There is no evidence of immunotoxicity from the standard toxicity studies including the chronic toxicity studies of Fleischmann et al. (1980) in the rat and mouse (Section 5.6.1.1), which did not detect any pathological changes in the lymph nodes, spleen, thymus and bone marrow at dose levels of up to 45000 ppm in the diet.

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Urea does not fulfill the T criteria.

Aquatic compartment (including sediment)

Fish

Urea is of very low acute toxicity to fish: reported LC50 values range from >6810 to 28000 mg/L

LC50/6 for freshwater fish: 6810 mg/L

Long-term toxicity to fish

Urea is of inherently low toxicity to fish species: it is a normal product of protein catabolism and therefore fish have evolved effective excretion mechanisms. Additionally, exposure will be limited by the action of microorganisms and incorporation of urea into the urea cycle.

Short-term toxicity to aquatic invertebrates

Low toxicity was demonstrated in Daphnia, freshwater snails and Aedes aegypti larvae.

EC50/7/LC50 for freshwater invertebrates: 10000 mg/L

Long-term toxicity to aquatic invertebrates

A waiver is proposed on exposure grounds. Urea is of inherently low toxicity to species of aquatic invertebrates and exposure will be limited by the action of microorganisms and incorporation of urea into the urea cycle.

Algae and aquatic plants

The 192 hour toxicity threshold of blue-green algae urea was 47 mg/l. To some extent urea exhibits toxic action to Microcystis aeruginosa. The 7 day toxicity threshold of urea to Scenedesmus quadricauda was >10000 mg/l.

EC10/LC10 or NOEC for freshwater algae: 47 mg/L

Sediment organisms

Urea is rapidly broken down by soil and sediment bacteria and assimilated into the nitrogen cycle. The very high water solubility of urea and low adsorption additionally indicates very low exposure to sediment organisms.

Other aquatic organisms

No data are available

Toxicity to aquatic micro-organisms

The 72 hour toxicity threshold of Entosiphon sulcatum to urea was 29 mg/l, and the 16 hour toxicity threshold of urea to Pseudomonas putida was > 10000 mg/l.

Terrestrial compartment

Toxicity to soil macro-organisms

Application of urea (in common with other nitrogen fertilizers) releases ammoniacal-N which is nitrified to nitrate: an acidic species that causes gradual lowering of soil pH unless the effect is counteracted by lime application. This is not a direct effect of exposure to urea.

Toxicity to terrestrial plants

Low toxicity to plants is predicted: the substance is widely used as a fertilizer and therefore has a beneficial effect on plant growth.

Toxicity to soil micro-organisms

Urea is of inherently low toxicity to microorganisms as it is utilized as a nutrient and nitrogen source.

Toxicity to other terrestrial organisms

No data are available.

Atmospheric compartment

No data are available.

Non compartment specific effects relevant for the food chain (secondary poisoning)

Toxicity to birds

A waiver is proposed on exposure grounds.

Toxicity to mammals

No additional data are available; low toxicity is predicted on a base of the physiological production of urea by mammalian species.

#### 12.2. Persistence and degradability

Urea does not fulfill the P or vP criteria.

#### 12.3. Bioaccumulative potential

Urea does not fulfill the B or vB criteria.

#### 12.4. Mobility in soil

Highly biodegradable in soil and in water.

#### 12.5. Results of PBT and vPvB assessment

Urea is neither a PBT nor a vPvB substance.

#### 12.6. Other adverse effects

No data.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

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Remains of the product, including packaging waste, should be transferred to the specialized companies with an appropriate waste management permit.

Depending on a degree and type of contamination, the product is either used as a fertilizer for agricultural purposes or transferred to the specialized company for neutralization.

In case of spill of fertilizer - see Section 6 of the safety data sheet.

### SECTION 14: Transport information

Urea is not classified, that means they are not considered as dangerous materials according to Orange Book of UN and international transport codes, eg. RID (railway), ADR (roads transport) and IMDG (see transport).

#### 14.1. UN number

Not applicable.

#### 14.2. UN proper shipping name

Not applicable.

#### 14.3. Transport hazard class(es)

Not applicable.

#### 14.4. Packing group

Not applicable.

#### 14.5. Environmental hazards

Not applicable.

#### 14.6. Special precautions for user

Not applicable.

#### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance.

· Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC. (Official Journal of the European Union of 30.12.2006, L 396. with later changes)

· Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Official Journal of the European Union of 31.12.2008, L 353. with later changes)

#### 15.2. Chemical safety assessment

The chemical safety assessment has been made.

### SECTION 16: Other information

#### Company disclaimer

*The information provided in this safety data sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any proceed, unless specified in the text.*