

# SAFETY DATA SHEET



according to Regulation (EC) No 1907/2006 (REACH) as amended

## Urea

Creation date	01st June 2021	Version	1.2
Revision date	04th September 2023		

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

#### 1.1. Product identifier

Substance / mixture	Urea
Chemical name	substance
CAS number	Carbamid
EC (EINECS) number	57-13-6
Registration number	200-315-5
	01-2119463277-33-0000

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

##### Substance's intended use

Medicinal products. Food additive. Ingredient for cosmetics. As an ingredient for nutrient solutions in biochemistry.

##### Substance uses advised against

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

##### Distributor

Name or trade name	Macco Organiques, s.r.o.
Address	Zahradní 1938/46c, Bruntál 1, 792 01 Czech Republic
Identification number (CRN)	26819210
VAT Reg No	CZ26819210
Phone	+420 555 530 300
E-mail	macco@macco.cz

##### Competent person responsible for the safety data sheet

Name	Petr Ševčík
E-mail	petr.sevcik@macco.cz

#### 1.4. Emergency telephone number

European emergency number: 112

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification of the substance in accordance with Regulation (EC) No 1272/2008

The substance is not classified as dangerous according to Regulation (EC) No 1272/2008.

Full text of all classifications and hazard statements is given in the section 16.

##### Most serious adverse physico-chemical effects

Not specified.

##### Most serious adverse effects on human health and the environment

Not specified.

#### 2.2. Label elements

none

#### 2.3. Other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Substance does not meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

##### Chemical characterization

The substance specified below.

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 57-13-6 EC: 200-315-5 Registration number: 01-2119463277-33-0000	<b>substance main component</b> Carbamid	>99	not classified as dangerous	

Full text of all classifications and hazard statements is given in the section 16.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

##### If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

##### If on skin

Remove contaminated clothes. And wash it before reuse. Wash the affected area with plenty of water, lukewarm if possible.

##### If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Provide medical treatment, specialized if possible. No neutralization should be performed in any case!

##### If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

##### If inhaled

Not expected.

##### If on skin

Not expected.

##### If in eyes

Not expected.

##### If swallowed

Not expected.

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

Symptomatic treatment.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. Accommodate extinguishing components to the location of fire.

##### Unsuitable extinguishing media

Water - full jet.

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

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Ammonia. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

#### 5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

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### SECTION 6: Accidental release measures

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

Follow the instructions in the Sections 7 and 8. Prevent contact with skin and eyes.

#### 6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

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

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13. After removal of the product, wash the contaminated site with plenty of water.

#### 6.4. Reference to other sections

See the Section 7, 8 and 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Do not eat, drink or smoke when using this product. Prevent contact with skin and eyes.

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

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

#### 7.3. Specific end use(s)

not available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Not specified.

##### DNEL

Carbamid					
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	292 mg/m <sup>3</sup>	Chronic effects systemic		
Workers	Inhalation	292 mg/m <sup>3</sup>	Acute effects systemic		
Consumers	Inhalation	125 mg/m <sup>3</sup>	Chronic effects systemic		
Consumers	Inhalation	125 mg/m <sup>3</sup>	Acute effects systemic		
Workers	Dermal	500 mg/kg bw/day	Chronic effects systemic		
Workers	Dermal	500 mg/kg bw/day	Acute effects systemic		
Consumers	Dermal	300 mg/kg bw/day	Chronic effects systemic		
Consumers	Dermal	300 mg/kg bw/day	Acute effects systemic		
Consumers	Oral	42 mg/kg bw/day	Chronic effects systemic		
Consumers	Oral	42 mg/kg bw/day	Acute effects systemic		

##### PNEC

Carbamid			
Route of exposure	Value	Value determination	Source
Freshwater environment	47 µg/l		
Water (intermittent release)	100 mg/l		
Marine water	1.407 mg/l		
Seawater (intermittent release)	100 mg/l		

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Route of exposure	Value	Value determination	Source
Microorganisms in sewage treatment	1 g/l		
Freshwater sediment	68.66 mg/kg of dry substance of sediment		
Sea sediments	6.866 mg/kg of dry substance of sediment		
Soil (agricultural)	121 mg/kg of dry substance of soil		

### 8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

#### Eye/face protection

It is not needed.

#### Skin protection

When handling in long-term or repeatedly, use protective gloves.

#### Respiratory protection

It is not needed.

#### Thermal hazard

Not available.

#### Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

## SECTION 9: Physical and chemical properties

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

Physical state	solid
Colour	white
Odour	containing ammoniac
Melting point/freezing point	133 °C
Boiling point or initial boiling point and boiling range	cannot be determined - decomposition occurs
Flammability	non-flammable
Lower and upper explosion limit	not applicable
Flash point	not applicable
Auto-ignition temperature	not applicable
Decomposition temperature	134 °C
pH	9-10 (10% solution at 20 °C)
Kinematic viscosity	not applicable
Solubility in water	624g / L 20°C
Partition coefficient n-octanol/water (log value)	-1.73
Vapour pressure	0.002 Pa at 25 °C
Density and/or relative density	
Density	1.33 g/cm <sup>3</sup> at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available
Form	solid: crystalline

### 9.2. Other information

not available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The substance is non-flammable.

#### 10.2. Chemical stability

The product is stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

Unknown.

#### 10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

#### 10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents. Violently react with nitrites.

#### 10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire. Ammonia.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the substance.

#### Acute toxicity

Based on available data the classification criteria are not met.

Carbamid					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD <sub>50</sub>	14300 mg/kg		Rat	

#### Skin corrosion/irritation

Based on available data the classification criteria are not met.

Carbamid				
Route of exposure	Result	Method	Exposure time	Species
Dermal	Not irritating	OECD 404	4 hours	Rabbit

#### Serious eye damage/irritation

Based on available data the classification criteria are not met.

Carbamid				
Route of exposure	Result	Method	Exposure time	Species
Eye	Irritating	OECD 405		Rabbit

#### Respiratory or skin sensitisation

No data available for the substance. Based on available data the classification criteria are not met.

#### Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carbamid					
Result	Method	Exposure time	Specific target organ	Species	Sex
Negative	OECD 471			Bacteria (Salmonella typhimurium)	

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### Carcinogenicity

No data available for the substance. Based on available data the classification criteria are not met.

### Reproductive toxicity

Based on available data the classification criteria are not met.

Carbamid							
Effect	Parameter	Method	Value	Exposure time	Result	Species	Sex
Developmental toxicity	NOAEL	OECD 414	>1000 mg/kg bw/day	15 days	No effect, No effect	Rat	F/M

### Toxicity for specific target organ - single exposure

No data available for the substance. Based on available data the classification criteria are not met.

### Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Carbamid						
Route of exposure	Parameter	Value	Exposure time	Result	Species	Sex
Oral	NOAEL	45000 mg/kg	12 months	No effect, No effect	Mouse	F/M

### Aspiration hazard

No data available for the substance. Based on available data the classification criteria are not met.

## 11.2. Information on other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## SECTION 12: Ecological information

### 12.1. Toxicity

Based on available data the classification criteria are not met.

#### Acute toxicity

Carbamid						
Parameter	Method	Value	Exposure time	Species	Environment	Value determination
LC <sub>50</sub>	OECD 236	21060 mg/l	96 hours	Fish (Danio rerio)	Fresh water	
EC <sub>50</sub>		>10000 mg/l	24 hours	Daphnia (Daphnia magna)	Fresh water	Static system
EC <sub>10</sub>	OECD 201	6895.8 mg/l	72 hours	Algae (Raphidocelis subcapitata)	Fresh water	Static system
EC <sub>50</sub>		10000 mg/l	16 hours	Bacteria (Pseudomonas putida)	Fresh water	Static system

#### Chronic toxicity

Carbamid						
Parameter	Method	Value	Exposure time	Species	Environment	Value determination
EC <sub>10</sub>	OECD 215	7247 mg/l	28 days	Fish (Oreochromis mossambicus)	Fresh water	Semi static system

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Carbamid						
Parameter	Method	Value	Exposure time	Species	Environment	Value determination
EC <sub>10</sub>	OECD 211	140.7 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Semi static system

### 12.2. Persistence and degradability

The following data are available.

#### Biodegradability

Carbamid				
Parameter	Value	Exposure time	Environment	Result
	100 %	21 days	Activated sludge	Easily biodegradable

### 12.3. Bioaccumulative potential

No data available for the substance.

### 12.4. Mobility in soil

No data available for the substance.

### 12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

### 12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

### 12.7. Other adverse effects

Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

#### Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

#### Waste type code

06 10 00 wastes from the MFSU of nitrogen chemicals, nitrogen chemical processes and fertiliser manufacture

#### Packaging waste type code

06 10 00 wastes from the MFSU of nitrogen chemicals, nitrogen chemical processes and fertiliser manufacture

## SECTION 14: Transport information

### 14.1. UN number or ID number

not subject to transport regulations

### 14.2. UN proper shipping name

not relevant

### 14.3. Transport hazard class(es)

not relevant

### 14.4. Packing group

not relevant

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### 14.5. Environmental hazards

not relevant

### 14.6. Special precautions for user

Reference in the Sections 4 to 8.

### 14.7. Maritime transport in bulk according to IMO instruments

not relevant

## SECTION 15: Regulatory information

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the 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/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

### 15.2. Chemical safety assessment

Not available.

## SECTION 16: Other information

### Other important information about human health protection

The user is responsible for adherence to all related health protection regulations.

### Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EC <sub>10</sub>	Concentration of a substance when it is affected 10% of the population
EC <sub>50</sub>	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
log K <sub>ow</sub>	Octanol-water partition coefficient
NOAEL	No observed adverse effect level
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million

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REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative

### Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

### Recommended restrictions of use

not available

### Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

### The changes (which information has been added, deleted or modified)

The version 1.2 replaces the SDS version from 14.07.2022. Changes were made in sections 8, 11, 12 and 15.

### More information

Classification procedure - calculation method.

### Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.