

Urea

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 24/01/2012 Revision date: 03/04/2017

264954

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Urea
EC-No. : 200-315-5
CAS-No. : 57-13-6
Product code : 264954
Formula : CH₄N₂O
Synonyms : Carbamid
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients**3.1. Substances**

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Urea	(CAS-No.) 57-13-6 (EC-No.) 200-315-5	98.5 - 101.5	Not classified

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**

First-aid measures after inhalation	: Assure fresh air breathing. Get medical advice and attention if you feel unwell.
First-aid measures after skin contact	: Wash skin with mild soap and water. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Give water to drink. Seek medical advice. If you feel unwell, seek medical advice.

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

Symptoms/effects : Nausea. Vomiting.

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

No additional information available

SECTION 5: Fire-fighting measures**5.1. Extinguishing media**

Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides.
Explosion hazard	: Large amounts: Risk of dust explosion.

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5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.
Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Wear proper protective equipment.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

- Emergency procedures : Avoid raising dust. Ensure adequate air ventilation.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment.

6.2. Environmental precautions

- Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water.

6.4. Reference to other sections

- No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

- Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed.
Maximum storage period : 5 year

7.3. Specific end use(s)

- Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

- No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

- Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

- Wear suitable protective clothing

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Respiratory protection:

Dust production: dust mask with filter type P1

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 60.1 g/mol
Colour	: White.
Odour	: Ammonia.
Odour threshold	: No data available
pH	: ca. 9
pH solution	: 10 %
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 133 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: > 132 °C
Flammability (solid, gas)	: No data available
Vapour pressure	: < 0.1 hPa 20°C
Relative vapour density at 20 °C	: No data available
Relative density	: 1.34
Density	: 720 - 760 kg/m ³
Solubility	: Insoluble in water. Water: ca. 1000 g/l
Log Pow	: -1.59
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Potential dust explosion hazard.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

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10.4. Conditions to avoid

heat.

10.5. Incompatible materials

Strong oxidizers. Bases. Chlorine. Halogens. Nitrites.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Not classified

Urea (57-13-6)	
LD50 oral rat	8471 mg/kg
LD50 dermal rat	8200 mg/kg

Skin corrosion/irritation : Not classified
pH: ca. 9Serious eye damage/irritation : Not classified
pH: ca. 9

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Urea (57-13-6)	
LC50 fish 1	> 6810 mg/l Oncorhynchus mykiss, 96 h
EC50 Daphnia 1	> 10000 mg/l

12.2. Persistence and degradability

Urea (57-13-6)	
Biodegradation	96 % 16 d

12.3. Bioaccumulative potential

Urea (57-13-6)	
Log Pow	-1.59

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**- Overland transport**

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Urea is not on the REACH Candidate List

Urea is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

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1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Respiratory protection	Modified	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier.

SDS EU (REACH Annex II) Version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product