

FH-C20-032_V.16/ 17.02.2021

SAFETY DATA SHEET UREA

According to EC Regulation no. 1907/2006 (REACH) / EC Regulation no. 1272/2008 / *Regulation no. 2020/878*.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY

1.1. Product identification

Name: UREA
Other names: CARBAMIDE, CARBONYLDIAMIDE
IUPAC name: UREA
Chemical formula: $(\text{NH}_2)_2\text{CO}$
SMILES notation: NC(=O)N
CAS number: 57-13-6
EINECS number: 200-315-5
ECHA reference number: 01- 2119463277- 33- 0059

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

According to Article 14.4 of Annex XI, section 3 of the CE Regulation no. 1907/2006 an exposure scenario is not needed, therefore, there is no detailed information concerning the use.

Identified uses: chemical fertilizer, anti-freezing agent, food additive/foodstuff intermediate, pH regulation agent.

Uses advised against: none

1.3. Details concerning the supplier of the Safety Data Sheet

Producer:

Azomureş S.A.Tg.-Mureş, 300 Gheorghe Doja St., tel.0040-265 253 700, Romania

Fax: 0040-265 252 986, e-mail: office@azomures.com, www.azomures.com

e-mail (competent person responsible for the SDS): fds.azo@azomures.com

1.4. Emergency telephone number

The institution responsible with providing information in case of a health emergency is The National Institute for Public Health, Department for the International Sanitary Regulation and Toxicological Information.

Telephone: 0040-21.318.36.06, working hours: Monday – Friday from 8 a.m. to 3 p.m.

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SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Urea is an organic monoconstituent substance; it is not classified as hazardous, as the evidence is not sufficient for classification.

Classification according to EC Regulation no. 1272/2008 (CLP)

Conclusions are not sufficient for classification.

Human health hazard

The following aspect will be taken into consideration:

Skin contact: may cause irritation; in case of prolonged contact it may lead to dermatosis; does not cause skin irritations if immediately washed with plenty of water.

Eye contact: in case of prolonged or repeated contact with the eyes, it may cause irritation.

Ingestion: in small quantities it is unlikely to have toxic effects, but in large quantities it causes nausea, vomiting and abdominal pains.

Inhalation: this product may cause irritation of the nose and throat.

Environmental hazards

No environmental hazard assessment was conducted as urea is not a hazardous substance.

2.2. Label elements

Labeling according to CLP Regulation

According to the CLP Regulation 1272/2008/EC, the substance is not classified as dangerous.

EU label

Substance name: UREA

ECHA reference number: 01- 2119463277- 33- 0059

EINECS number: 200-315-5

Producer:

Azomureș S.A.Tg.-Mureș, 300 Gheorghe Doja St., tel. 0040-265 253 700, Romania

Fax: 0040-265 252 986, e-mail: office@azomures.com, www.azomures.com

Emergency telephone number: 0040-21.318.36.06, working hours: Monday – Friday from 8 a.m. to 3 p.m.

Content: NITROGEN (N) 46%

Biuret max. 1.2%

Net weight of the fertilizer

2.3. Other hazards

Urea is not a PBT, not a vPvB substance.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substance

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The product must be considered: Substance

UREA is a monoconstituent substance (origin: organic)

CAS number: 57-13-6

EINECS number: 200-315-5

IUPAC name: UREA

EC name: UREA

Molecular formula: CH₄N₂O

Molecular weight range: 60.0553

Purity degree: >= 95% - <=100% (w/w)

Typical concentration: 98.9% (w/w)

Concentration limit: >= 95% - <=100% (w/w)

Chemical identification of impurities

Biuret – CAS number: 108-19-0

EINECS number: 203-559-0

IUPAC name: dicarbonimidic diamide

Typical concentration: 0.8%

Concentration limit: >= 0 - <=2%

Water - CAS number: 7732-18-5

EINECS number: 231-791-2

IUPAC NAME: water

Typical concentration: 0.3% (w/w)

Concentration limit: >= 0 - <= 0.5% (w/w)

SECTION 4. FIRST AID MEASURES

4.1. Description of the first aid measures

4.1.1 First aid instructions are provided depending on the relevant exposure routes.

Skin contact: wash the affected area with plenty of water; remove contaminated clothing and wash them before reuse. If irritation persists, seek medical advice.

Eye contact: rinse/irrigate eyes with plenty of water for at least 10 minutes; if irritation persists, seek medical advice.

Ingestion: rinse mouth with water, do not induce vomiting; if the patient is conscious, give water to drink. If the patient feels unwell, seek medical advice.

Inhalation: remove the contaminated person from the exposure area; in severe cases, or if recovery is not fast or complete, seek specialized medical advice.

4.1.2 Recommendations:

Wash the exposed areas with plenty of water, and if necessary, seek medical advice.

4.2. The most important symptoms and effects, acute as well as delayed

No available data.

4.3. Indications concerning any emergency medical assistance and necessary special treatments

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Not available.

SECTION 5. FIREFIGHTING MEASURES

5.1. Fire extinguishing means

Adequate extinguishing means

Use the most efficient available means to extinguish the fire.

In case of fire, use plenty of water, foam or mechanical powder.

Inadequate extinguishing means

There are no data available for the products that must not be used for fire extinguishing.

5.2. Special hazards arising from the substance or mixture

Upon thermal combustion, irritating substances may be released, therefore, a gas mask is necessary.

5.3. Advice for firefighters

The protection of the firefighters is ensured with insulating devices and protection equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non - emergency personnel

(a) Protective equipment

Hand protection:

Wear impervious protection gloves (nitrilic rubber, cross nitrile with cotton inner lining), permeability resistance 6;

Eye protection:

Tight eye protection (plastic frame, polycarbonate lens)

Protective face mask (polycarbonate)

Skin protection

Protective clothing:

Dust resistant overalls (breastplate duck overalls, coat).

Winter or summer shirt (natural fibers – duck)

Protective footwear:

Protective boots resistant to corrosive chemical agents (rubber, PVC).

Chemical and mechanical aggression resistant boots, with anti-static properties that allow usage in explosive environments (leather with rubber soles).

(b) Use a self-contained breathing apparatus and adequate equipment for firefighting.

Open doors and windows to produce maximum ventilation of the room.

6.2. Precautions for the environment

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Avoid contact of large quantities with vegetation or water courses. Keep animals away from the area where a large quantity of the product was discharged.

Avoid contamination of water courses and drains, and in case of accidental discharge, inform local authorities.

6.3. Methods and material for containing fires and for cleaning

Cleaning method for a spilled quantity: vacuum or sweep up and store in containers suitable for subsequent recycling.

6.4. Reference to other sections

Note: see chapter Exposure control / individual protection, for information concerning personal protection equipment and the section Disposal considerations.

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

7.1.1 Recommendations for safe handling

Avoid contact with the eyes.

Avoid repeated or prolonged contact with skin or clothing.

Avoid dust inhalation.

When handling the product for longer periods of time, wear adequate protective equipment – gloves and goggles.

Use adequate ventilation system (natural ventilation).

Avoid contamination, especially with incompatible materials: strong oxidizers, acids, bases, nitrates, sodium or calcium hypochlorite.

7.1.2 Recommendations concerning good general hygiene practices at the work place

(a) Do not eat, drink or smoke in the working area. “NO SMOKING” signs are to be placed in the working area.

(b) Wash hands thoroughly after each use.

(c) Remove contaminated clothing and protection equipment before entering lunch areas.

7.2. Safe storage conditions, including possible incompatibilities

The product should be stored temporarily only in packaged, protected and well-ventilated areas.

The product should be stored away from sources of heat and fire.

Protection measures for the storage areas will be ensured.

Do not store together with combustible materials and pesticides.

Stacking of bags should be made in such a way that any danger is avoided.

7.3 Specific end use (s)

Specific end uses of urea: not applicable.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

No official limits are specified.

ACGIH (1995-1996) recommended values for inhalable particles:

TLV/TWA: 10 mg/m³

Relevant DNEL / DMEL values and NOAEL values are provided in the CSA, depending on the type of exposure for workers in an industrial setting and for the general public.

No local effects were observed following dermal and inhalation exposure, therefore no DNEL values were derived for local effects.

Systemic effects

The starting point for DNEL derivation is an oral LOAEL value of 500 mg/kg bw/day.

DNEL values for workers are calculated using assessment factors taken from ECETOC Technical Report no. 86 (Derivation of Assessment Factors for Human Health Risk Assessment).

Workers exposure

Acute systemic effects - dermal - DNEL: 580 mg/kg bw/day

LOAEL: 6.960 mg/kg bw/day

- inhalation - DNEL: 292 mg/m³

LOAEC: 3.504 mg/m³

Long term systemic effects - dermal - DNEL: 580 mg/kg bw/day

LOAEL: 6.960 mg/kg bw/day

- inhalation - DNEL: 292 mg/m³

NOAEC: 3.504 mg/m³

Public exposure

Acute systemic effects - dermal - DNEL: 580 mg/kg bw/day

LOAEL: 6.960 mg/kg bw/day

- inhalation - DNEL: 125 mg/m³

LOAEC: 1.500 mg/m³

- oral - DNEL: 42 mg/kg bw/day

LOAEL: 504 mg/kg bw/day

Long term systemic effects - dermal - DNEL: 580 mg/kg bw/day

LOAEL: 6.960 mg/kg bw/day

- inhalation - DNEL: 125 mg/m³

LOAEL: 1.500 mg/m³

- oral - DNEL: 42 mg/kg bw/day

LOAEL: 504 mg/kg bw/day

8.2. Exposure control

8.2.1 Appropriate Engineering Controls

General measures at company level

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The CSSM (The Committee for Work Health and Safety) was constituted at the company level, where the risk factors of professional injury and illness in the work place are assessed.

The evaluation of the risks of professional injury and illness at the work place was carried out by committees established by the management; preventive measures were taken to eliminate or to diminish the risks that cannot be avoided, having as purpose the work safety and health, reduction of work injuries and of professional illnesses.

The Chemical Plant:

- Risk evaluation when using dangerous chemical substances
- Ammonium Nitrate Plant II-III-ADEX (operation – chemists, mechanic, electric and automation maintenance, packing machinists)

As a result of the analysis and evaluation of the risks at the work place:

The plan for prevention and protection at company level was elaborated and approved.

A record is held of the work places of great danger and imminent danger of injury.

A situation of the hazardous chemical substances used in the work process is kept.

The toxic gases, released by chemical substances at the work place, are monitored.

The health of the staff exposed to the action of chemical substances is supervised and monitored.

The auditing of the safety and health at the work place is carried out, establishing the noncompliance with the law in force and taking measures to ensure compliance with such laws.

Statistics are drafted, referring to work accidents and professional illnesses caused by hazardous chemical substances.

Intervention teams in case of chemical accident with periodically instructed staff are organized at company level.

Authorized employees of the internal prevention and protection service perform the inspection of the work places according to the operational procedure.

The explosion protection document is elaborated according to Government Ordinance no. 1058/2006 for the following plants: Ammonia, Nitric Acid, and Ammonium Nitrate.

The equipment used in areas with danger of explosion is certified upon availability date.

Workers have access to personal instructions regarding the usage of dangerous chemical substances:

- The staff has individual protection equipment
- Measures of collective protection are ensured.

Collective protection measures for the source of risk – Urea

Technical Measures

Monitoring system of the main functioning parameters for the safety of the equipment (pressure, temperature, concentration, flow capacity, level etc), with acoustic and optical warning signals in case of malfunction.

Toxic gas, fire and explosion detectors.

Protection devices – flange fenders on all the dangerous liquids layouts.

Ammonia and nitric acid layouts painted in conventional colors.

Signaling for work safety health and according to Government Ordinance no. 971/2006 (safety, warning, interdiction, obligation marks, delimitation of danger zones).

Ventilation systems.

Rescue showers for the danger of splashing with corrosive substances.

Water sources with upward jet (for washing the eyes in case of splashing).

Periodical ISCIR inspections of under-pressure equipment.

Toxic gases level control.

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Organization and provision of individual insulating protection equipment.

Endowment and organization of medical help trained in case of gassing.

Administrative measures

Manufacturing regulation, work instructions regarding work safety and health and fire prevention.

Safety data sheets for hazardous substances.

Organization of an information system for surveillance and intervention:

- Action plan in case of fire
- Internal Emergency Plan (PUI).
- Evacuation action plan in emergency situations
- Action plan in case of earthquake
- Action plan for safe road transport (PSTR).

Authorization for the job position, employees in the production sector, maintenance, repair (mechanic, electric, automation) in technological installations.

Work safety and health training for Azomures employees, in all stages (upon hiring, at work, periodically, supplementary) and work safety and health instruction for the employees from the companies that perform services based on contract and for the persons that are on the platform with the employer's permission, related to:

- risk of professional injury and illness at the work place
- minimal requests of health and safety of work, stipulated by legal regulations applicable to the specific activity at the work place
- tasks and responsibilities of the employees
- usage of work equipment and individual protection equipment
- prevention and protection measures, action plan in case of danger
- giving first aid to the injured at the work place

Risk management measures for human health

No risk management measures were identified for urea.

8.2.2. Personal protection measures, such as personal protection equipment

(a) Respiratory protection: mask against dust

(b) Hand protection: adequate protection gloves

(c) Eye protection: tight protection goggles (plastic frame, polycarbonate lens) or face mask (polycarbonate)

(d) Skin protection:

Protection clothing:

Dust resistant overalls (breastplate duck overalls, coat).

Winter or summer shirt (natural fibers – duck)

Protective footwear:

Protective boots resistant to corrosive chemical agents (rubber, PVC).

Chemical and mechanical aggression resistant boots, with anti-static properties that allow usage in explosive environments (leather with rubber soles).

8.2.3 Environmental exposure control

Urea is of no concern with regard to human or environmental exposure. No risk management measures were identified for urea. The users will be informed concerning the product safe usage rules.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information concerning the main physical and chemical properties

- (a) Aspect: granules
- (b) Color: white
- (c) Odor: odorless

No.	Properties	Results	Values used for CSA / Discussions
(d)	Melting point/ freezing point	133.3 °C	Value used for CSA: 407K at 1013hPa The melting point of urea at atmospheric pressure is reported to be 133.3 °C
(e)	Boiling point/ boiling temperature interval	Urea decomposes before reaching the boiling point.	The substance is reported to decompose before reaching the boiling point
(f)	Physical state 20 °C and 1013 hPa	solid (tetragonal prisms (alcohol)) Form: crystalline	Crystalline
(g)	Flammability	Urea is not flammable	Value used for CSA: not flammable
(h)	Water solubility	624 g/l at 20 °C	Value used for CSA: 624000 mg/L at 20 °C The water solubility of urea was found to be 624 g/l at 20 °C and is also reported to be 545000 mg/L at 25 °C.
(i)	Partition coefficient n-octanol/water	-1.73	Value used for CSA: log Kow (Pow): -1.73 at 20 °C
(j)	Vapor pressure	1.2 x 10 ⁻⁵ mmHg (0.0016 Pa) at 25 °C.	Value used for CSA: 0.002 Pa at 298K The vapor pressure of urea is reported to be 1.2 x 10 ⁻⁵ mmHg at 25 °C.
(k)	Relative density	1.33 g/cm ³	Value used for CSA: 1330 at 20 °C The relative density of urea was determined to be 1.33 g/cm ³ at 20 °C and is also reported to be 1.323 g/cm ³ at 20 °C.
(l)	Granulometry	The generic specification approved for the consortium specifies a particle size distribution between 0.1-5 mm.	The generic specification approved for the consortium specifies a particle size distribution between 0.1-5 mm. This specification shows that the substance has a very low risk of inhalation under normal conditions of use.

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No.	Properties	Results	Values used for CSA / Discussions
(m)	Dissociation constant	The dissociation constant is lower than 0.6 (pKb)	The dissociation constant is reported to be 0.10 at 21 °C, and is measured to be lower than 0.6 in a modern proprietary study.
(n)	Self-ignition temperature	There was no evidence of autoinflammability in a proprietary study.	There was no evidence of autoinflammability in a proprietary study: the substance melted at 134 °C. below this temperature there was no self-ignition of the sample.

9.2. Additional information

9.2.1. Information with regard to physical hazard classes

Urea is not classified according to Regulation (EC) no. 1272/2008.

9.2.2. Other safety characteristics

No data available.

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable in normal conditions of storage, handling and usage.

10.3. Hazardous reactions potential

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

10.4. Conditions to avoid

Temperature – heating above the melting point of 133 °C

Welding and working with open fire in installations that contain urea, without prior washing and elimination of fertilizer traces.

10.5. Incompatible materials

Contamination with strong acids (nitric, perchloric) or nitrates, strong oxidizers, bases, nitrates, sodium or calcium hypochlorite.

10.6. Hazardous decomposition products

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When heated, it may release toxic gases (ammonia, nitrogen oxides).

SECTION 11.	TOXICOLOGICAL INFORMATION
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Toxicokinetics (absorption, metabolism, distribution and elimination)

Absorption: Method – female rat - exposure 5 days

Result – percentage of absorbed urea in the in vivo experiments was low, less than 3% of the applied dose was absorbed per day, with a total absorbed dose of 8.1%. Similar results were obtained in vitro, with the total absorbed dose after 5 days being 7.2%.

Human information – no available data. The handling of urea by the human body is well characterized as it is a normal product of protein catabolism and is normally produced in large quantities.

Dermal absorption – values of 7.2 – 9.5% are reported for urea.

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

The relevant hazard classes for which information is provided are:

- (a) Acute toxicity
- (b) Skin corrosion / irritation
- (c) Eye irritation / damage
- (d) Sensitization of the skin or the respiratory system
- (e) Mutagenicity germ cell
- (f) Carcinogenicity
- (g) Toxicity for reproduction
- (h) STOT (specific target organs of toxicity) – unique exposure
- (i) STOT (specific target organs of toxicity) – repeated exposure
- (j) Aspiration hazard

11.1.1 Information for each hazard class

(a) Acute toxicity

Oral – male/female rat - LD50: 14300 mg/kg bw (male)

LD50: 15000 mg/kg bw (female)

- male/female mouse - LD50: 11500 mg/kg bw (male)

LD50: 13000 mg/kg bw (female)

- cattle (Holstein & Shorthorn) male/female - LDLo: 600 mg/kg bw (male/female)

- pig (cross-Landrace) male - LDLo: > 16000 mg/kg bw (male)

Value used for CSA: LD50 (oral): 14300 mg/kg bw

Inhalation – the substance is a non-volatile solid, produced as crystals with a particle size of >100 µm. there is therefore no potential for inhalation exposure. In addition, the substance has been demonstrated to be of very low toxicity by other routes of exposure. Testing for acute inhalation toxicity is therefore not justified on scientific grounds or based on exposure considerations.

Dermal - Urea is demonstrated to be of very low acute toxicity by the oral, subcutaneous and intravenous routes in the rat and mouse. Testing for acute dermal toxicity is not justified on scientific grounds and for reasons of animal welfare.

Other routes – male/female rat (subcutaneous) - LD50: 9400 mg/kg bw (mle)

LD50: 8200 mg/kg bw (female)

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- male/female rat (Wistar) (intravenous) - LD50: 5400 mg/kg bw (male)
5300 mg/kg bw (female)
- male/female mouse (subcutaneous) - LD50: 9200 mg/kg bw (mle)
LD50: 10700 mg/kg bw (female)
- male/female mouse (intravenous after a single dose)
LD50: 4600 mg/kg bw (male)
LD50: 5200 mg/kg bw (female)

Information on humans – no available data.

Justification for classification or non-classification

Urea is of inherently very low toxicity by all routes investigated. No data are available for the inhalation route, however low toxicity can also be predicted for this route. No classification is proposed for acute toxicity according to CLP.

Repeated dose toxicity

Oral - NOAEL: 45000 ppm (male/female rat (Fischer 344))

- NOAEL: 45000 ppm (male/female mouse (C57BL))

No effects were observed at the highest dose level (4.5 % in the diet).

Value used for CSA (route: oral): NOAEL: 2250 mg/kg bw/day

Inhalation - the substance is a non-volatile solid, produced as crystals with a particle size of > 0.1 mm. There is therefore no potential for inhalation exposure.

Dermal – no dose-dependant toxic effects were observed.

Other routes - urea was administered for 45 days (every 8 hours) to dogs - subchronic (subcutaneous) 3000 - 4000 mg/kg bw.

Low toxicity: causes increased diuresis and drowsiness.

(b) Skin corrosion / irritation

Non-human information: studies indicate that urea is not irritant.

Human information: urea is formulated into skin creams for the treatment of irritant skin conditions and is therefore considered unlikely to be a primary skin irritant in humans.

Skin irritation – urea at concentrations of between 5-10%, but also at concentrations of up to 25% and higher are widely used for the treatment of dry/irritant skin conditions, therefore it can be predicted that urea is not a skin irritant.

Data on humans and animals indicate that urea is not corrosive.

(c) Eye irritation

Non-human information: studies indicate that urea is not irritant.

Human information: no available data.

Eye irritation: the results of a study indicate that urea must not be classified as an eye irritant.

(d) Respiratory sensitization

Studies indicate that urea does not sensitize the skin or the respiratory system.

(e) Mutagenicity

In vitro data – non-human information

Study – bacterial reverse mutation assay (e.g. Ames test) (gene mutation)

- S. typhimurium TA 1538 (metabolic activation: with and without)

- E. coli WP2 uvr A (metabolic activation: with and without)

Doses: 5, 10, 50, 100, 500, 1000 and 5000 µg/plate

- mammalian cell gene mutation (gene mutation)

Evaluation of results: Negative (with and without metabolic activation)

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Tests were positive for - mouse lymphoma L5178Y cells

- in vitro mammalian chromosomal aberration test
- analysis for DNA single strand breaks by alkaline elution

In vivo data - urea is not considered genotoxic.

Value used for CSA: genetic toxicity: negative

No classification is proposed for genotoxicity. Urea is produced by the body in large quantities as a normal product of metabolism and is present in the bloodstream at high concentrations. Urea is therefore considered extremely unlikely to be genotoxic.

(f) Carcinogenicity

Human information – no available data.

Non-human information – no evidence of carcinogenicity was seen in NCI screening studies in the rat and mouse.

Value used for CSA (route: oral): NOAEL: 2250 mg/kg bw/day

No classification is proposed for carcinogenicity. The physiological role of urea and level of production by the human body indicates that the substance is not carcinogenic.

Urea is not included on any list of products susceptible to be carcinogenic.

(g) Toxicity for reproduction

There are no animal studies that indicate clear evidence of effects on reproduction. The results of available studies do not trigger classification.

Value used for CSA (route: oral): LOAEL: 500 mg/kg bw/day

Other effects – there is no evidence of neurotoxicity and immunotoxicity from the standard toxicity studies.

(h) STOT – single exposure - no data available

(i) STOT – repeated exposure - no data available

(j) Aspiration hazard - no data available

11.1.2 The data in this subsection apply to the urea – they are available in the Chemical Safety Report.

11.1.3 The results of *critical studies* by route of exposure:

The acute toxicity after oral administration – experimental studies were done on mice male/female, rats male/female, cattle (Holstein & Shorthorn) male/female and pig (cross-Landrace) male. Urea is of very low acute oral toxicity in the rat and mouse.

LD50: 14.3 – 15.0 g/kg bw for male and female rats.

LD50: 11.5 – 13.0 g/kg bw for mice.

Urea is of generally low acute oral toxicity in most species but higher toxicity is noted in ruminants due to the generation of ammonia by gastric flora.

LD50: approximately 600 mg/kg bw for cattle.

The acute toxicity after administration by inhalation – no data available.

The substance is a non-volatile solid produced as crystals, there is therefore no potential for inhalation exposure.

The acute toxicity after dermal administration – urea is demonstrated to be of very low acute dermal toxicity in the case of rats and mice. Testing for acute dermal toxicity is not justified on scientific grounds and for the reasons of animal welfare.

LD50: 8.2 – 9.4 g/kg bw for rat

LD50: 9.2 – 10.7 g/kg bw for mouse

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11.1.4 For the following hazard classes: STOT – single exposure, STOT – repeated exposure, aspiration hazard - no data available.

11.1.5 Information on the likely routes of exposure

The likely routes of exposure are ingestion, inhalation or skin / eyes exposure.

Systemic - dermal DNEL - 580 mg/kg bw.

- inhalation DNEL - 292 mg/m³.

The details of the exposure they are available in the Chemical Safety Report.

11.1.6 Symptoms related to the physical, chemical and toxicological characteristics

No data available.

11.1.7 The known delayed and immediate effects and the chronic effects of long term exposure and short term exposure

No data available.

11.1.8 Interactive effects

No data available.

11.1.9 Absence of specific data

No data available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Urea has no endocrine disrupting properties.

11.2.2. Other information

No data available

SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic compartment (including sediments)

Urea has a low toxicity for aquatic organisms.

Short-term toxicity for fish

For acute toxicity to fish and PNEC derivation, the following data are taken into consideration: urea is of very low acute toxicity to fish: LC50 reported values range from > 6810 to 28000 mg/L

Value used for CSA: LC50 for freshwater fish: 6810 mg/L

Long-term toxicity for fish

Urea is of inherently low toxicity for fish: 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 nitrogen cycle.

Toxicity for aquatic invertebrates

Short-term toxicity

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

Value used for CSA: EC50/LC50 for freshwater invertebrates: 10000 mg/L

Long-term toxicity

Urea is of inherently low toxicity for aquatic invertebrates and exposure will be limited by the action of microorganisms and incorporation of urea into the nitrogen cycle.

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Toxicity for algae

Value used for CSA: 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 available data.

PNEC derivation - PNEC aqua (freshwater): 0.047 mg/L

PNEC aqua (marine water): 0.047 mg/L

PNEC aqua (intermittent releases): a separate PNEC derivation is not proposed

PNEC sediments: no available data, PNEC is not derived.

Terrestrial compartment

Urea is of inherently low toxicity and is rapidly assimilated into the nitrogen cycle by soil microorganisms; exposure is therefore limited.

Toxicity to soil macro-organisms, except for arthropods

In the absence of liming, urea fertilizer reduced the number of earth worms and biomass and lowered pH.

Toxicity to soil arthropods

Urea is of inherently low toxicity and is rapidly assimilated into the nitrogen cycle by soil microorganisms.

Toxicity to terrestrial plants

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

Toxicity to soil microorganisms

Urea is of inherently low toxicity for microorganisms as it is used as nutrient and nitrogen source.

Toxicity to other terrestrial organisms

No available data.

Atmospheric compartment - No available data.

Microbiological activity in STP

Toxicity for 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* > 10000 mg/l.

Urea is of inherently low toxicity for microorganisms as it is used as nutrient and nitrogen source.

A PNEC is therefore not proposed.

12.2. Persistence and degradability

Abiotic degradability

Hydrolysis – study scientifically unjustified

Urea is stable in aqueous solution. Based on a theoretical assessment of the molecular structure, hydrolysis is not seen and is not predicted.

Photolysis – no data are available: not required

Phototransformation in air, water and soil - no data are available: not required

Biodegradation - in water and soil – studies indicate that urea is readily biodegradable

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12.3. Potential for bioaccumulation

Aquatic and terrestrial bioaccumulation

A study is not required due to the low log Kow value for urea, it is not likely to undergo bioaccumulation. Additionally, urea is used by fish species as a nutrient and is excreted by some species as a product of protein catabolism. Bioaccumulation is not predicted.

Secondary poisoning

Secondary poisoning is not predicted as urea is rapidly biodegradable and is readily metabolized and excreted by various organisms.

12.4. Mobility in soil

Adsorption/desorption

Urea adsorption by the soil was found to increase with increasing concentration of added urea-N and adsorption coefficients ranged from 0.037-0.064.

Volatilization – no available data, but volatilization is unlikely

Distribution modeling - no data are available: not required.

12.5. PBT and vPvB assessment results

Urea is not a PBT nor a vPvB substance, as the PBT and vPvB criteria are not fulfilled.

12.6. Endocrine disrupting properties

Urea has no endocrine disrupting properties.

12.7. Other adverse effects

There is no information concerning other adverse effects on the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Recycle the product in accordance with local regulations in use.

Packaging wastes contaminated with urea that cannot be reused must be directed to a company authorized for the disposal of packaging wastes.

Relevant provisions of the harmonized EU legislation and domestic legislation regarding waste.

National legislation in force:

Law no. 211/2011 concerning wastes treatment.

Law no. 265/2006 – The Law on environment protection.

Law no. 249/2015 related to the packaging and waste packaging management.

GD no. 856/2002 - The evidence of wastes management, with subsequent modifications.

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Law on labor security and health no. 319/2006, GD no. 1425/2006 on approving the Methodological Norms for the enforcement of the provisions set by the Law on labor security and health no. 319/2006, GD no.355/2007 on the surveillance of workers' health with subsequent modifications. Decision no. 1061/2008 on transport of hazardous or non-hazardous wastes on Romanian territory, with subsequent modifications.

UE Legislation in force:

Regulation (EC) no. 1907/2006 of the European Parliament and of the Council regarding the Registration, evaluation authorization and restriction of chemicals (REACH), *with subsequent modifications*.

Regulation (EC) no. 1272/2008 of the European Parliament and of the Council on the classification, labeling and packaging of substances and mixtures, *with subsequent modifications*.

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

European Agreement concerning the International Carriage of Dangerous Goods by Rail (RID).

SECTION 14. TRANSPORT INFORMATION

Urea is not classified according to UN Orange Book, RID, ADR, AND(R) și IMDG and it is not considered dangerous for transportation.

Chapters 14.1; 14.2; 14.3; 14.4 are not applicable.

14.5. Environmental hazards

No available information.

14.6. Special precautions for users

Users must ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15. REGULATORY INFORMATION

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

Relevant information regarding the domestic legislation

Law on labor security and health no. 319/2006, GD no.1425/2006 on approving the Methodological Norms for the enforcement of the provisions set by the Law on labor security and health no. 319/2006, GD no. 355/2007 on the surveillance of workers' health with subsequent modifications. Law no. 265/2006 for the amendment of GEO no.195/2005 on environment protection

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Decision no. 1391/2006 for the approval of the Regulation concerning the application of Government Emergency Ordinance no. 195/2002 regarding traffic on public roads, with subsequent amendments and supplements.

Government Ordinance no. 651/2003 for the modification and completion of Government Decision no. 716/2001 for establishing trading conditions for chemicals fertilizers coming from domestic production and import.

Law no. 278/2013 on industrial emissions.

Law no. 49/2018 on explosives precursors, as well as for amending and supplementing some normative acts.

Relevant information regarding the EU legislation

Regulation (EC) no. 1907/2006 of the European Parliament and of the Council regarding the Registration, evaluation authorization and restriction of chemicals (REACH), *with subsequent modifications.*

Regulation (EC) no. 1272/2008 of the European Parliament and of the Council on the classification, labeling and packaging of substances and mixtures, *with subsequent modifications.*

Regulation (EU) no. 286/2011 by the Commission from 10.03.2011 amending Regulation (EC) no. 1272/2008.

Regulation (EU) No. 2019/521 by the Commission from 27 March 2019 amending, for the purposes of its adaptation to technical and scientific progress Regulation (EC) No. 1272/2008.

Regulation (EC) No. 2020/878 of 18.06.2020 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the registration, evaluation and restriction of chemicals (REACH).

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013.

EC no. 2003/2003 regulation of the European Parliament regarding fertilizers with its subsequent amendments relating to EN standards drawn up by the European Committee for Standardization.

Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003.

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), 2021 edition.

Regulation referring to the International Carriage of Dangerous Goods by Rail (RID), 2021 edition
International Maritime Dangerous Goods (IMDG), 2020 edition.

Other regulations

“This product is not regulated by Regulation (EU) 2019/1148, but all suspicious transactions, and significant disappearances and thefts should be reported to the relevant national contact point”.

15.2 Chemical safety assessment

A chemical safety assessment (CSA) was conducted and a chemical safety report (CSR) was elaborated for urea.

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SECTION 16.	ADDITIONAL INFORMATION
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a) A clear evidence of added, deleted or modified information
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Version (revision, edition) number	Date	Page number	Evolution of the information
edition 6, revision 0	06.01.2014	7, 16	At page 7 chapter 8.2.1. - Organizational measures, Monitoring and intervention plans were modified At page 16 section 15.1 – information regarding national legislation was modified
version 7	05.11.2014	1, 2, 5, 15	All pages were replaced edition and revision with version. At page 1 was modified the form number. At page 2, section 2.2 – labeling nitrogen content was mentioned fixed value. At page 5, section 7.2 – safe storage conditions were added 500 kg bags. At page 15, section 14 – transport information were added 500 kg bags.
version 8	06.01.2015	5	At page 5, section 7, chapter 7.2 was modified the number of rows it is stored bags.
version 9	01.06.2015	1, 2, 14	At page 1, section 1.4 emergency telephone number was modified. At page 2, in section 2.1 it was removed classification in accordance with directive 67/548/ EEC. At page 14, chapter 13.1 - Waste treatment methods national legislation was modified.
version 10	08.07.2016	5, 10, 17	At page 5, section 7.2 – safe storage conditions were added 600 kg bags At page 10, section 11 they have introduced additional toxicological data. At page 16, section 15.1 it was introduced Regulation no.830/2015.
version 11	24.04.2018	3	At page 3, section 3.1 - Chemical identity of the substance the concentration limits and degree of purity for urea have changed.
version 12	15.10.2018	6	At page 6, section 7.2 has changed in accordance with current legislation.

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Version (revision, edition) number	Date	Page number	Evolution of the information
version 13	12.04.2019	5	At page 5, section 7.2 has been reformulated.
version 14	25.06.2019	18	At page 18, section 15.1 "Other regulations" have been introduced.
version 15	08.07.2020	17	At page 17, section 14.6 has been reformulated.
version 16	17.02.2021	10, 14, 18	Change of the drafting framework annex. At page 10 section 9.2 changes due to legislation. At page 14 section 11.2 other hazards information was introduced. At page 18 section 15.1 new legislation has been introduced.

b) List of abbreviations and acronyms used throughout the Safety Data Sheet

ADR	- European Agreement referring to the International Carriage of Dangerous Goods by Road, 2021 edition
b/w	- body weight
CSA	- Chemical Safety Assessment
CSR	- Chemical Safety Report
DMEL	- Derived minimal effect level
DNEL	- Derived no effect level
EC	- European Commission
EC50	- Concentration of toxic material for which 50% of the tested organisms survive
ECETOC	- European Center for Ecotoxicology and Toxicology of Chemicals
ECHA	- European Chemicals Agency
(FE) EFMA	- Fertilizers Europe (European Fertilizer Manufacturers Association)
ES	- Exposure Scenario
ESIS	- European Chemical Substances Information System
EUSES	- The European Union System for the Evaluation of Substances
FPE	- Fire Prevention and Extinction
GD	- Government Decision
GEO	- Government Emergency Ordinance
GESTIS	- Information system on hazardous substances of the German Social Accident Insurance
HSW	- Health and Safety at Work
IMDG	- Regulations referring to the maritime transportation of hazardous Substances, 2020 edition
IPPC	- Integrated pollution prevention and control
ISCIR	- State Inspection for the Control of Boilers, Under-Pressure Vessels and Lifting Devices

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LC50	- Lethal concentration for 50% of the tested population
LD50	- Lethal dose for 50% of the tested population
LOAEC	- Lowest observed adverse effect concentration
LOAEL	- Lowest observed adverse effect level
NA	- Not applicable
NOAEL	- No Observed Adverse Effect Level
OMI	- <i>International Maritime Organization</i>
OEL	- Limit values allowed for occupational exposure
PBT	- Persistent, Bioaccumulative, Toxic
PNEC	- Predicted No Effect Concentration
VC	- Polyvinyl chloride
REACH	- EC Regulation No. 1907/2006 of the European Parliament and Council concerning the registration, evaluation, authorization and restriction of chemical substances
RID	- Regulation referring to the International Carriage of Dangerous Goods by Rail (RID), 2021 edition
RMM	- Risk Management Measures
RPE	- Respiratory protection equipment
SDS	- Safety Data Sheet
SEVESO III	- European Council Directive no. 2012/18/UE of July 4, 2012 on the control of major-accident hazards involving dangerous substances
STOT	- Specific target organs of toxicity
UN	- United Nations
vPvB	- Very Persistent, very Bioaccumulative
w/w	- mass unit

c) Bibliography

Studies according to the Chemical Safety Report

Guidance on safe use – The joint/individual ECHA Registration file for the substance

Official Journal of the European Union – EU Regulation no. 2020/878 of the European Council of 18.06.2020

EFMA - Guidance for the Compilation of Safety Data Sheets for Fertilizer Materials.

ESIS - European Chemical Substances Information System

Official Journal of the European Union – EC Regulation no. 1907/2006 of the European Parliament and Council concerning the registration, evaluation, authorization and restriction of chemical substances (REACH)

Note:

The information included in this safety data sheet is based on the data available at the time of publication.

The client and the user assume all risks regarding usage, handling and storage of this product.

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There are no guarantees for the product in case of improper handling, transport and storage of the product, not complying with the specifications of the Technical Specification and the Safety Data Sheet.