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

1.1. Product identifier

Product's name:	Urea
	CAS No: 57-13-6
	REACH Registration number: 01-2119463277-33-XXXX

1.2. Relevant identified uses of	of the substance or mixture and uses advised against
Identified uses:	Fertilizer, antifreeze agent, food and feed additive, pH
	control agent, semi-finished product in the
	pharmaceutical and medical industries.
Uses advised against:	Not specified

1.3. Details of the supplier of the	e safety data sheet
Supplier:	"Aurepio" Sp. z o. o.
	Al. Jana Pawła II 11
	00-828 Warszawa, Poland
Supplier's phone number:	+ 48 22 652 90 61 to 64
E-mail of person responsible for	the safety data sheet: <a>aurepio@aurepio.pl

1.4. Emergency telephone number
Emergency telephone number in Poland:
112 (24 h) or
+48 22 652 90 61 to 64 (Monday -Friday, at hours: 8 a.m. – 4 p.m.).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 as amended.

The substance does not meet the criteria for classification.

Human health effects

In case of significant dust concentrations or direct product penetration into eyes, irritation, redness, tearing, burning, itching may occur. Contact with the skin may cause itching, local redness. Prolonged inhalation of dust may cause slight irritation of the respiratory tract, irritation of the nasal mucosa and mouth, coughing. Swallowing may cause damage of mucous membrane of the digestive tract, vomiting and diarrhea.

Environmental effects

It is not harmful for the environment, if used correctly.

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Physical effects

They are not known.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 as amended.

Pictograms:	Not required.
Signal word:	Not required.
Hazard statements:	Not required.
Precautionary statements:	Not required

2.3. Other hazards

The substance does not meet the PBT and vPvB criteria.

SECTION 3: Composition/information on ingredients

3.1. Substances

Product identifier: Urea, No: CAS: 57-13-6 REACH Registration number: 01-2119463277-33-XXXX

Substance's name	Index number	CAS number	EC Number	Mass fraction in %	Hazard classes and category codes	Hazard statement codes
Urea* REACH Registration number:: 01-211946-3277-33-XXXX	-	57-13-6	200-315-5	97.5 - 100	-	-

Impurities:

Biuret	-	108-19-0	203-559-0	0 – ≤ 1.4	-	-
Water	-	7732-18-5	233-149-7	0 – 0.6	-	-
2-phenyl-2-hexenenitrile	-	9011-05-6	618-464-3	0 – 0.35	-	-

* Designated NDS for dusts

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SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:	Move the injured person from the risk area, arrange a comfortable reclining or sitting position, ensure peace, heat. Call a doctor if necessary.
Skin contact:	Take off immediately contaminated clothing and wash the skin thoroughly with lukewarm, running water. Call a doctor if necessary.
Eye contact: `	Rinse immediately with plenty of cold water, preferably running water for at least 15 minutes. Remove contact lenses. Avoid a strong water jet due to the risk of mechanical damage to the cornea. If irritation persists, get medical attention.
Gastrointestinal tract:	If swallowed, do not induce vomiting. Rinse mouth with water and then give a large amount of water to drink. Consult a doctor if necessary.

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

Significant dust concentrations or direct product penetration into eyes may cause irritation, redness, tearing, burning, itching. Contact with skin may cause itching, local redness. Prolonged inhalation of dust may cause slight irritation of the respiratory tract, irritation of the nasal mucosa and mouth, coughing. Swallowing may cause damage of mucous membrane of the digestive tract, vomiting and diarrhea.

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

No special recommendations. Use symptomatic treatment. If swallowed, active carbon is recommended.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: The product is not flammable. Use extinguishing media appropriate for materials that are burning in surrounding area. Unsuitable extinguishing media: Full water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire, toxic fumes may release, containing nitrogen oxides, ammonia, carbon dioxide.

5.3. Advice for firefighters

Wear gas-tight protective clothing and breathing apparatus that is independent of ambient air. Requirements for protective clothing: EN 469

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protective equipment. Mark the hazard area and prevent access to unauthorized persons. Avoid raising dust.

6.2. Environmental precautions

Protect against penetration into sewers, surface and ground waters and soil.

6.3. Methods and material for containment and cleaning up

Place the damaged packaging in the replacement packaging. Collect the released product mechanically, avoiding dust collection, transfer into tightly closed containers and dispose for disposal. Rinse the contaminated surface with large amounts of water.

6.4. Reference to other sections

Follow the instructions given in section 7. Detailed information on personal protective equipment is given in section 8. Remove as directed in section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Take precautions to avoid contact with skin and eyes when working with the substance. Do not breathe dust. Do not eat, drink or smoke during use. Wash hands during breaks and after work. Remove contaminated clothing immediately, wash before re-use. Use in rooms with general ventilation. Keep away from sources of high temperatures and sources of ignition.

7.2. Conditions for safe storage, including any incompatibilities

Store in original, properly labelled, tightly closed containers in a cool, well-ventilated place accessible only to authorized persons. Keep away from children. Protect against moisture. Do not store together with food, drinks and animal feeds. Do not store with incompatible materials - see section 10.

7.3. Specific end use(s)

No information on applications other than mentioned in subsection 1.2.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Recommended procedures for monitoring air cleanliness in the work environment:

EN 689 Air at workplaces. Guidelines for the assessment of inhalation exposure to chemical agents by comparison with limit values and measurement strategy

EN 1540 Air at workplaces. Terminology PN-Z-04008-7: 2002 / Az1: 2004 and PN-Z-04008-7: 2002 - Polish version. Air purity protection - Sampling - Principles of air sampling in the work environment and interpretation of results

For Poland:

Component	CAS No.:	Normative	Value	Unit	Legal base
Dusts not classified	for toxicity				
- inhalable fraction	-	NDS	10	mg/m ³	O.J.2018.0.1286

DNEL/DMEL values for employees:

292 mg/m³ (inhalation, systemic effects, acute and long-lasting) 580 mg/kg body weight/day (skin, systemic effects, acute and long-lasting)

DNEL/DMEL values for consumers:

125 mg/m³ (inhalation, systemic effects, acute and long-lasting)
580 mg/kg body weight/day (skin, systemic effects, acute and long-lasting)
42 mg/kg body weight/day (oral, systemic, acute and long-lasting)

PNEC values:

0.047 mg/l (fresh water) 0.047 mg/l (sea water)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Use efficient ventilation.

8.2.2. Individual protection measures, such as personal protective equipment

Respiratory system: In the event of a high concentration of dust, use respiratory protection with a particulate filter marked in white and P in accordance with EN 149 or EN 143.

Hands and skin: When handling large quantities, wear protective clothing made of natural materials, gloves made of rubber (thickness ≥ 0.4 mm ± 0.1 mm, breakthrough time> 480 min), protective footwear made of rubber or leather. Gloves must comply with the standard: EN 374. Requirements for protective clothing: ISO 13982.

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Eyes:	Wear safety goggles according to EN 166.
Hygiene at work: `	Observe the general industrial hygiene provisions. Do not allow for to exceeded permissible normative concentrations at work. Remove contaminated clothing after work. Wash hands and face before breaks at work. Wash the entire body thoroughly after work. Do not eat, drink or smoke during work. Do not breathe dust.
0.2.2 Environmental	

8.2.3. Environmental exposure controls

Secure against entering the municipal water, sewage system and watercourses.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical a	and chemical properties
a) Appearance	Crystals measuring 0.1-5 mm
b) Odour	No odour
c) Odour threshold	Not applicable
d) pH	7.5 - 9.5 (10% aqueous solution)
e) Melting / freezing point	132-134 °C
f) Initial boiling point and boiling rar	nge It decomposes before reaching the boiling point.
g) Flash point	No data available. Urea is a solid which decomposes during
	The ignition temperature test is technically not feasible.
h) Evaporation rate	No data available.
i) Flammability (solid, gas)	The substance is non-flammable.
j) Upper / lower flammability limit o	r upper / lower explosion limit
	It does not pose an explosion hazard.
k) Vapour pressure	0.16 kPa (25 °C)
l) Vapour density	No data available.
m) Relative density	1.33 (water = 1) (20 °C)
n) Solubility	Solubility in water 624 g/l (20 °C).
o) Partition coefficient: n-octanol / v	water Log Pow: = - 1.56 to Log Pow = - 1.73 (20 °C)
p) Auto-ignition temperature	During the test the substance was melted at 134 ° C. Below
	this temperature, no self-ignition occurred.
r) Oxidizing properties.	As per the entries in column 2 of Annex VII to the REACH
	Regulation, the study does not need to be performed.
	Based on the chemical structure and taking into account
	the chemical properties, no oxidizing properties are
	expected
s) Decomposition temperature	Decomposes below the boiling point.

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t) Viscosity

According to point 2 of Annex XI to the REACH Regulation, the test need not to be carried out due to the properties of the substance. The substance is a solid. Not explosive.

u) Explosive properties

9.2. Other information

Molar mass: 60.06 g/mol

Dissociation constant: 0.10 (21 °C), (in the published database) 0.6 at (21 °C) temperature, (in own study)

SECTION 10: Stability and reactivity

10.1. Reactivity

It polymerizes, hydrolyzes, oxidizes, reacts with acids and their anhydrides.

10.2. Chemical stability

The substance is stable under the recommended conditions of transport or storage.

10.3. Possibility of hazardous reactions

It reacts with nitric acid to form urea nitrate, which has explosive properties. In aqueous solutions it reacts with acids and bases, undergoing hydrolysis and dissociation to produce ammonia and carbon dioxide.

10.4. Conditions to avoid

Moisture (caked). Sources of ignition, open fire, high temperature (above the melting point).

10.5. Incompatible materials

Strong acids, sodium hypochlorite, calcium hypochlorite, sodium nitrate, nitrile perchlorate, strong oxidants, dichromates, liquid chlorine, nitrates, permanganates, chromyl chloride, other fertilizers.

10.6. Hazardous decomposition products

Urea heated to 200 °C decomposes into biuret, cyanic acid, ammonia and carbon dioxide. The product of thermal decomposition of urea - ammonia - reacts with oxidants and under certain conditions with presence of an open flame, ammonia can produce nitrogen oxides. Urea stored for some time at elevated temperatures (especially in hot climates) may be partially decomposed to biuret and ammonia.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

Based on available data, the classification criteria are not met. **Acute oral toxicity:** LD₅₀ - oral rat 14300 - 15000 mg/kg LD₅₀ - oral mouse 11500 - 13000 mg/kg LD₅₀ - subcutaneously rat 8200 - 9400 mg/kg LD₅₀ - subcutaneous mouse 9200 - 10700 mg/kg LD₅₀ - intravenously rat 5300 - 5400 mg/kg LD₅₀ - intravenous mouse 4600 - 5200 mg/kg

Acute inhalation toxicity

The substance is a non-volatile solid and it is produced in the form of crystals with a particle size > 100 μ m. Therefore, there is no possibility of inhalation exposure. In addition, it has been shown that the substance shows very low toxicity through other routes of exposure. An acute inhalation toxicity study is not scientifically justified or based on considerations related to exposure.

Acute dermal toxicity:

Urea shows a very low acute toxicity after oral, subcutaneous and intravenous administration in rats and mice. The study of acute dermal toxicity is not scientifically justified or because of reasons of animal welfare.

Skin corrosion / irritation:

Based on available data, the classification criteria are not met.

Serious eye damage / eye irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization:

Based on available data, the classification criteria are not met.

Urea occurs naturally in relatively high concentrations in human skin and is widely used in skin creams without any reports of allergic reactions. Therefore, it is very unlikely that it will have a skin sensitizing effect.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Urea is produced by the body in large quantities as a normal metabolic product and is found in the bloodstream at high concentrations.

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Carcinogenicity:

Based on available data, the classification criteria are not met.

From animal studies it is not result that urea is carcinogenic. The physiological role of urea and the level of production in the human body indicate that this substance is not carcinogenic. In NCI screening tests in rats and mice no evidence of carcinogenicity was observed. NOAEL: 2250 mg/kg body weight/day (rat, oral, 12 months, NCI screening), Fleischman and partners (1980)).

Reproductive toxicity:

Based on available data, the classification criteria are not met.

No standard tests available. It is considered unlikely that occupational exposure to urea, whether primary or secondary, will result in developmental toxicity, since exposure levels will be negligible compared to levels found in maternal and fetal blood as a result of protein catabolism.

NOAEL: 500 mg/kg body weight/day (oral)

Specific target organ toxicity - single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Other information:

In the human body, urea is produced in large quantities as a product of normal metabolism and is excreted with the urine. Urea is present in the human epidermis, where it can play the role of a humectant. At very high exposure levels, urea can act as a denaturant and may increase the absorption of other substances through the skin. Bronaugh et al. (1982), give a skin absorption value of 7.2-9.5% based on in vivo rat test results and comparable in vitro results.

Health effects of local exposure

Inhalation:	Prolonged inhalation of dust may cause slight irritation of the respiratory tract, irritation of the nasal mucosa and mouth, coughing,
Eye contact:	Significant dust concentrations or direct product penetration into
	eyes may cause irritation, redness, tearing, burning, itching.
Skin contact:	It can cause itching, local redness.
Swallowing:	Contact with skin may cause itching, local redness. Swallowing may cause damage of mucous membrane of the digestive tract, vomiting and diarrhea.

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SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

Acute toxicity:

LC₅₀ - fish (Leuciscus idus) 6810 mg/l (96h) (BASF, 1978) LC₅₀ - fish (Leuciscus idus) 6810 - 28000 mg/l (96h) (BASF, 1978) EC₅₀ - invertebrates (Daphnia magna) > 10000 mg/l (24h) (study modified in accordance with DIN 38412 part 11, Bringmann and Kuhn, 1982) EC₅₀ - invertebrates (Daphnia magna) 10000 mg/l (48h) EC₅₀ - bacteria (Pseudomonas putida) > 10000 mg/l (16h) (test for bacterial cell proliferation, Bringmann and Kuhn, 1980) EC₅₀ - bacteria (Entosiphon sulcatum) 29 mg/l (72h) (test for bacterial cell proliferation, Bringmann and Kuhn, 1980)

Chronic toxicity:

NOEC (192h): 47 mg/l - algae (Microcystis aeruginosa) (test for inhibiting cell proliferation, Bringmann and Kuhn, 1978)

12.2. Persistence and degradability

Easily biodegradable.

Degradation of urea was tested in psychrophilic bacteria in an aqueous test system. The maximum decomposition rate per hour at 20 °C was 11.6 mg/l. The average degradation rate per hour at 20 °C was 10.9 mg/l. The maximum degradation rate per hour at 2 °C was 4.0 mg/l. The average degradation rate per hour at 2 °C was 3.2 mg/l.

OECD 302B guideline (Zahn-Wellens / EMPA Test; BASF (1991))

The biodegradation of urea in activated sludge from a laboratory wastewater treatment plant was investigated. Degradation levels of 3% (after 3 hours), 52% (after 7 hours), 60% (after 10 days), 85% (14 days) and 96% (16 days) were observed.

Degradation in soil:

Guideline OECD 304 A (Vlek, P.L.G. and Carter, M.F. (1983)) % Degradation of the test substance: 3 after 30 hours (No. 1) 64 after 30 hours (No. 2) Urea should be expected to biodegrade rapidly.

12.3. Bioaccumulative potential

Due to the low log Kow value, urea is unlikely to bioaccumulate. In addition, urea is used by the fish as a nutrient and is secreted by some species as a product of protein catabolism.

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Octanol / water partition coefficient (Kow): Bioconcentration factor (BCF): Log Pow: = - 1.56 to Log Pow = - 1.73 (20 $^{\circ}$ C) Not determined.

12.4. Mobility in soil

Koc: 0.037 – 0.064

The value Koc suggests that urea has high mobility in soil.

The adsorption coefficient is determined experimentally by testing the diffusion of urea, hydrolyzed urea, and then diffusing NH + 4-N for 30 days in a sterilized and unsterilized Crowley clay soil (Hongprayoon, C. and partners (1991).

12.5. Results of PBT and vPvB assessment

The substance does not meet the criteria PBT and vPvB.

12.6. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product

Do not dispose together with municipal waste. Do not allow contamination of ground and surface water. If possible, use all amount of the product. Possible remnants should be given to an authorized waste recipient.

Package

Empty the packaging thoroughly. Reusable packaging can be reused after thoroughly cleaning. Disposable packaging (after thoroughly cleaning) can be recycled. Proceed in accordance with country and local regulations. Empty and clean packaging can be disposed to municipal waste stream.

Special precautions:

There are no special recommendations.

SECTION 14: Transport information

This product is not classified as dangerous within the meaning of transport regulations.

ADR/RID, IMDG, IATA

14.1. UN number14.2. UN proper shipping name

Not applicable. Not applicable.

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14.3. Transport hazard class(es)14.4. Packing group

Not applicable. Not applicable.

14.5. Environmental hazards

The substance does not pose a risk to the environment in accordance with the criteria contained in the UN Model Regulations.

14.6. Special precautions for user

No special recommendations.

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

Regulation of the Minister of Agriculture and Rural Development of 24 June 2002 on occupational health and safety in the use and storage of plant protection products as well as mineral and organic-mineral fertilizers (Dz.U.2002.99.896), as amended. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorization 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 (OJ EU L series No. 396 of 30 December, 2006), as amended. REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No 1272/2008 of 16 December 2008 on the 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 (OJ EU L Series No. 353 of 31 December, 2008), as amended.

Act of 25 February 2011 on chemical substances and mixtures (Book of Acts 2011.63.322), as amended.

Regulation of the Minister of Health of 30 December, 2004 on occupational health and safety connected with chemical agents at work (Book of Acts 2005.11.86), as amended.

Regulation of the Minister of Health of 2 February, 2011 on the testing and measurement of agents harmful to health in the work environment (Book of Acts 2011.33.166).

The Act of 14 December 2012 on waste (Book of Acts 2013.0.21), as amended.

Act of 13 June 2013 on the management of packaging and packaging waste (Book of Acts 2013.0.888), as amended.

Regulation of the Minister of Labor and Social Policy of 14.03.2000 on the safety and hygiene of work on manual transport work (Book of Acts 2000.26.313), as amended.

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Regulation of the Minister of Labor and Social Policy of 6 June, 2014 on the highest allowable concentrations and intensities of agents harmful to health in the work environment (Book of Acts 2018.0.1286.

REGULATION (EC) No 2003/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 October 2003 on fertilizers, as amended.

Act of 10 July 2007 on fertilizers and fertilization, Book of Acts 1997, No.147.1033, as amended. Regulation of the Minister of Agriculture and Rural Development of 16 April 2008 on the detailed method of fertilizer application and conducting training in the field of their application, Dz.U.2008.80.479, as amended..

Regulation of the Minister of Economy of 8 September 2010 on the method of packaging mineral fertilizers, placing information on fertilizer components on these packaging, the method of testing mineral fertilizers and types of lime fertilizer, Dz.U.2010.183.1229. Regulation of the Minister of Agriculture and Rural Development of 18 June 2008 on the implementation of certain provisions of the Act on fertilizers and fertilization, OJ 2008.119.765, as amended.

15.2. Chemical safety assessment

A chemical safety assessment for this substance has been carried out.

SECTION 16: Other information

Sources:

• Safety data sheet in Polish, date of compilation: 04.12.2017.

Recommendations for training

As a minimum there is recommended a safety training. Prior to working with the product the user is required to know the safety rules for safe handling of chemicals, and above all, hold appropriate workplace training.

Abbreviations:

NDS - Highest permissible concentration - value of weighted average of concentration, which impact on the employee during an 8-hour daily and average weekly working time, during the duration of its professional activity should not cause negative changes in his state of health and the health of the future generations

DNEL - level that does not cause harm to human health - the level of exposure to the substance not causing harmful effects to human health

PNEC - predicted concentration causing changes in the environment - the concentration of the substance below which there are no expected adverse effects on the environment

vPvB - substance very persistent and very bioaccumulative

NOEC - the highest concentration at which no changes are observed

PBT – substance persistent, bioaccumulative and toxic

NOAEL — *Highest dose* at which there *was not* an observed toxic or adverse effect.

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LOAEL — *Lowest dose* at which there *was* an observed toxic or adverse effect. DMEL - Derived Minimal Effect Level

LD₅₀: Lethal Dose 50 %. The LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval.

LC₅₀: Lethal Concentration 50 %. The LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval.

EC₅₀: Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50% changes in response (e.g. on growth) during a specified time interval. BCF - bioconcentration factor - the ratio of the concentration of substances in the body to its concentration in water at equilibrium

ADR- Agreement on Dangerous Goods by Road

RID - Regulations Concerning the International Transport of Dangerous Goods by Rail IMDG - International Maritime Dangerous Goods Code

IATA - International Air Transport Association

CAS - number assigned to a chemical substance on the list of Chemical Abstracts Service EC - the reference number used in the European Union in order to identify hazardous substances, in particular, registered in the European Inventory of Existing Commercial Chemical Substances (EINEC) or the European List of Notified Chemical Substances (ELINCS) or the list of chemical substances listed in the publication of "No-longer polymers"

UN number - four-digit identification number of the material in the list of dangerous materials of the United Nations, based on the "UN Model Regulations", which classified material is an individual, mixture or article

The information contained in this safety data sheet are based on the current state of knowledge and data from a supplier. They are not a guarantee of specific properties of the product and does not relieve users of responsibility for the appropriate use of this information. The supplier will not be liable for any damages or losses that might arise from the use of this product.

Changes

Changes to the previous version are marked with a vertical bold line on the left of the text.