according to Regulation (EC) No. 1907/2006 (REACH) and Commission Regulation

**ALLANTOIN** 

(EU) No. 2020/878 ALLANTOIN

 Revision:
 E

 Date of publication:
 26/01/2009

 Revision date:
 27/09/2022

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

1.1 Product identifier Chemical /		

**Ekokoza s.r.o** Distributor:

Address: Fryčovice 297, 73945, Fryčovice ID: 07508247, eshop@ekokoza.cz

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

Intended uses: Cosmetic and pharmaceutical industry.

Not recommended uses: Not listed.

# 1.3 Detailed data on the supplier of the safety data sheet

Business name:

trade name:

Residence:

Identification number: Ekokoza s.r.o

 Phone:
 Fryčovice 297, 73945, Fryčovice ID:

 www:
 07508247, eshop@ekokoza.cz

BL Processor: 1.4

Telephone number for emergency situations

Toxicology Information Centre, Na Bojišti 1, 120 00 Prague 2. Emergency telephone: +420 224 91 92 93 or +420 224 91 54 02, www.tis-cz.cz

# **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or

mixture Classification according to Regulation (EC) No. 1272/2008 (CLP):

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

# 2.2 Marking elements

Labeling according to Regulation (EC) No. 1272/2008

(CLP): Warning symbol: Not classified.

Signal word: Not classified.

Contains: Urea, N-(2,5-dioxo-4-imidazolidinyl)

H-phrases: Not classified.

P-instructions: Not classified.

Additional information: They are not

#### 2.3 Another danger

This mixture does not contain any substances that are assessed as PBT or vPvB.

This product does not contain SVHC substance.

This product does not contain endocrine disruptors in a concentration of 0.1% by weight or higher.

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#### SECTION 3: Composition / information on ingredients

#### 3.1 Substances

Folder name	Content (wt%)	TIME EINECS Index N° Reg. number	Classification according to regulation (EC) no. 1272/2008 (CLP)
Urea, N-(2,5-dioxo-4-imidazolidinyl)	100	97-59-6 202-592-8 - 01-2119953242-43-0000	Not classified.

Full text of H-phrases in section 16.

#### **SECTION 4: First aid measures**

## 4.1 Description of first aid

General instructions: In case of accident or if you feel unwell, seek medical attention immediately (show this SDS or the label if

possible).

When inhaling: Move the victim to fresh air, keep him calm, prevent hypothermia.

In case of skin contact: Take off the stained clothing, wash the affected area thoroughly with soap and water, treat with a suitable

cream.

In case of eye contact: Immediately rinse the eyes with a stream of running water, open the eyelids. If contact lenses are worn, carefully

remove them and continue rinsing, the affected eye wide open from the inner corner to the outer, so as not to affect the other eye and also under the lids for min. 15 minutes. If difficulties persist, seek professional medical help.

If ingested: Rinse mouth with water, do not induce vomiting. Do not give anything by mouth to an unconscious person; put the

person in a stable position and call for medical help immediately.

Protection of first responders: Pay attention to personal safety during rescue operations.

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

If first aid procedures are effectively applied, no acute or delayed symptoms or effects are expected.

## 4.3 Indication of immediate medical attention and special treatment

It is generally recommended for ingestion.

## **SECTION 5: Firefighting measures**

#### 5.1 Fire extinguishers

Suitable extinguishing agents: Foam, extinguishing powder, CO2, water mist.

Unsuitable extinguishing agents: Direct stream of water - fire could spread.

# 5.2 Special hazards arising from the substance or mixture

Combustion products and hazardous gases: smoke, carbon monoxide, carbon dioxide. Remove closed containers as far as possible from the fire and cool them with water mist.

# 5.3 Instructions for firefighters

Emergency responders exposed to smoke or vapors must be equipped with respiratory and eye protection, protective clothing. When working in closed spaces, it is necessary to use a self-contained breathing apparatus. Cool containers exposed to fire with water mist. Do not spray water directly into the container to avoid excessive foaming. Collect extinguishing water separately and prevent it from entering water and soil.

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#### SECTION 6: Accidental release measures

#### 6.1 Personal protection measures, protective equipment and emergency procedures

Avoid contamination of clothing and footwear with the product and contact with skin and eyes. Use suitable protective clothing, change soiled clothing. Ensure ventilation of the affected area. Remove all persons not involved in rescue operations to a safe distance.

#### 6.2 Environmental protection measures

Prevent leakage into the environment, soil, prevent entry into surface water and sewage. In the event of a leak, immediately inform the watercourse/sewerage manager and the relevant authorities.

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

In the event of a leak, locate and, if possible, pump out the product or mechanically remove it, remove it from the surface of the water. Allow residues or smaller amounts to soak into a suitable sorbent (diatomaceous earth, sand) and place in suitable marked containers and hand over for recycling / disposal in accordance with applicable regulations.

#### 6.4 Reference to Other Sections

See dept. 7, 8 and 13.

#### **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Use appropriate PPE. Use only in well-ventilated areas with a guaranteed supply of fresh air. Do not eat, drink or smoke while working. Wash your hands after finishing work. Do not inhale fumes. Comply with legal regulations on occupational health and safety. All fire precautions must be observed during handling.

## 7.2 Conditions for safe storage of substances and mixtures, including incompatible substances and mixtures

Store in well-closed containers in a dry and cool place. Protect from light and moisture.

# 7.3 Specific end / specific end uses

see section 1.2

# SECTION 8: Exposure controls / personal protective equipment

### 8.1 Control parameters

Exposure limits:

Government Regulation No. 361/2007 Coll., which establishes the conditions of health protection at work, as amended, establishes the following maximum permissible concentrations (NPK-P) and permissible exposure limits (PEL) of chemical substances in the workplace air:

Cubatana	TIME	PEL	NEW E ( A S) N	
Substance	(mg/m³)	NPK-P (mg/m³) No	e	
No data available				

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Substances for which a Union exposure limit is set:

Substance	TIME	Limit values	s (mg/m³)	Note
	TIME	OEL	STEL	Note
No data available.				

TODAY

Allantoin (CAS: 97-59-6)

Exposed group and route of exposure	Duration of exposure	Effect type	Unit	Value		
Workers	Workers					
Dermal	Long-term (chronic)	systemic	mg/kg bw/d	284		
Consumers						
Dermal	Long-term (chronic)	systemic	mg/kg bw/d	284		
Oral	Long-term (chronic)	systemic	mg/kg bw/d	56.8		

**PNEC** 

Allantoin (CAS: 97-59-6)

Environmental component		PNEC	Unit	Value
	Freshwater	PNEC water, malt.	mg/L	1
		PNEC water, malt.	mg/L	10
Aquatic environment		PNEC sed., malt.	mg/kg sediment dw	0.85
	Marine	PNEC water, sea	mg/L	0.1
		PNEC sed., sea	mg/kg sediment dw	0.085
Microbiological activity, WWTP	Wastewater treatment plant	PNEC CHOV	mg/L	10,000
Terrestrial environment / organisms	Soil	PNEC land	mg/kg soil dw	0.256

## 8.2 Limiting Exposure

Technical measures: Engineering measures and appropriate work procedures take precedence over personal protective

equipment. Observe normal hygiene principles. Do not eat, drink or smoke while working. Wash your hands

with warm water and soap before a work break and after work.

Individual protective measures

Respiratory protection: In case of exceeding the exposure limits, or when creating fog/dust/vapour/aerosol, use a mask with an A/P

filter, according to ÿSN EN 14387+A1.

Hand protection: Protective work gloves resistant to chemicals according to ÿSN EN 374. Protective gloves should in any case

be tested for the specific suitability of their use at the given workplace (e.g. for their mechanical resistance, compatibility with the product and antistatic properties). Follow the exact instructions from

the manufacturer, including the time of use.

Replace damaged gloves.

Eye and face protection:

Use safety glasses with side labels or a face shield, according to ÿSN EN 166.

Skin protection:

Work clothes (ÿSN EN ISO13688) and footwear (ÿSN EN ISO 20347).

Thermal hazards: No data available.

Limiting environmental exposure: Prevent unnecessary leaks into the environment.

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#### **SECTION 9: Physical and chemical properties**

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

solid (powder)

Color:

Odor: Odorless. No

data available No data Odor Threshold: pH:

available

about 225 Melting point/freezing point (°C):

Boiling point or initial boiling point and

boiling point range (°C):

No data available.

No data available. No Flash point (°C): Evaporation rate: data available. No data

Flammability (solids, gases, liquids): available.

Lower and upper explosive limits: No data available.

No data available. No Vapor pressure (20°C): Vapor data available. No data

pressure (50°C): Relative available. 1.7

vapor density: Density and/or relative density (kg/

5 20°C): Solubility in water (g/l, 20°C):

Partitioning n-octanol/water coefficient (log No data available.

value): Autoignition

No data available. temperature (°C): Decomposition

> 225 temperature (°C): Kinematic

viscosity: No data available. No data available. No data Refractive index (20°C): Oxidizing properties: available. No data Explosive properties: available. No data

Particle characteristics: available.

#### 9.2 Additional Information

VOC content (%): No data available. No data available. No data Dry matter content:

Additional information: available.

# 9.2.1 Information regarding physical hazard classes

The product is not physically dangerous.

#### 9.2.2 Other safety characteristics:

Mechanical sensitivity: No data available. No data available. Self-accelerating polymerization temperature:

Creation of explosive dust-air mixtures: No data available.

Acid/alkaline reserve: No data available. No Evaporation rate: data available. No data

Miscibility: available.

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Conductivity: No data available.
Corrosivity: No data available.
Gas class: No data available.
Oxidation-reduction potential: No data available.
Radical formation potential: No data available.
Photocatalytic properties: No data available.

# **SECTION 10: Stability and reactivity**

**10.1** Reactivity It is stable under normal storage and use.

**10.2** Chemical stability It is stable under normal storage and use.

10.3 Possibility of hazardous reactions No data available.

**10.4** Conditions to avoid No data available.

10.5 Incompatible materials No data available.

**10.6** Hazardous decomposition products No data available.

# **SECTION 11: Toxicological information**

# 11.1 Information on hazard classes defined in Regulation (EC) No. 1272/2008 Allantoin (CAS: 97-59-6)

Acute toxicity:

Test type	Result	Exposure route	Test organism
key study	> 5,000 mg/kg body weight, LD50 > 5000 mg/kg body weight, LD0 probe	orally: gastric rat	
supporting study	>= 5,000 mg/kg body weight, LD50	dermal	rat

#### Serious eye damage/irritation:

Test type	The result	Exposure route	Test organism
OECD 405, Key Study	is non-irritating	eye	rabbit

### Skin corrosion/irritation:

Test type	Result	Exposure route	Test organism
OECD 404, Key Study	non-irritating	dermal	rabbit

## Respiratory/Skin Sensitization:

Test type	Result	Exposure route	Test organism
OECD 429, Key Study	not sensitizing	dermal	mouse

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# STOT - single exposure:

Test type	Result	Exposure route	Test organism
	No data available.	-	

# STOT - repeated exposure:

Test type	Result	Exposure route	Test organism
	No data available.		

### Carcinogenicity:

Test type	Result	Exposure route	Test organism
	No data available.		

#### Germ cell mutagenicity:

Test type	Result	Exposure route	Test organism
	No data available.		

#### Reproductive toxicity:

Test type	Result	Exposure route	Test organism
	No data available.		

## Inhalation hazard:

Test type	Result	Exposure route	Test organism
	No data available.		

Acute toxicity: The product does not meet the criteria for classification. Serious eye damage/irritation: The product does not meet the criteria for classification. Skin corrosion/irritation: The product does not meet the criteria for classification. Respiratory/Skin Sensitization: The product does not meet the criteria for classification. STOT - single exposure: The product does not meet the criteria for classification. STOT - repeated exposure: The product does not meet the criteria for classification. Carcinogenicity: The product does not meet the criteria for classification. Germ cell mutagenicity: The product does not meet the criteria for classification. Reproductive toxicity: The product does not meet the criteria for classification. Inhalation hazard: The product does not meet the criteria for classification.

# 11.2 Information on additional hazards Endocrine-disrupting properties

This product does not contain endocrine disruptors in a concentration of 0.1% by weight or

higher.

More information: No data available.

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# SECTION 12: Ecological information 12.1 Toxicity

The product does not meet the criteria for classification.

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Toxicity	Test organism	Result	Test type
Acute toxicity to fish	Danio rerio (previous name: Brachydanio rerio)	> 5000 mg/L, LC50 / 2 h > 5000 mg/L, LC50 / 24 h > 5000 mg/L, LC50 / 48 h > 5000 mg/L, LC50 / 72 h > 5000 mg/L, LC50 / 96 h	OECD 203
Acute toxicity to invertebrates	Daphnia magna	> 100 mg/L, NOEC / 48 h	OECD 202
Acute toxicity to algae	Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)	100 mg/L, NOEC / 72 h	OECD 201

## 12.2 Persistence and Deployability

No data available.

#### 12.3 Bioaccumulative potential

No data available.

#### 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

Based on the results of the assessment, this substance is not PBT or vPvB.

# 12.6 Properties causing disruption of the endocrine system

This product does not contain endocrine disruptors in a concentration of 0.1% by weight or higher.

#### 12.7 Other Adverse Effects

# **SECTION 13: Disposal considerations**

# 13.1 Waste management methods

Waste substance catalog number: No data available.

Packaging catalog number: No data available.

Recommended procedure for disposal of substance No data available.

waste:

Recommended procedure for disposal of

Empty packaging must be disposed of by the waste generator in accordance with applicable waste

waste packaging contaminated with the substance: legislation. After thorough cleaning, the packaging can be used as a secondary raw material for the same purpose.

The recommended method of disposal is recycling, burning in a hazardous waste incinerator or landfilling

hazardous waste.

Physical/chemical properties that may

affect waste management:

No data available.

Prevention of disposal of wastes

No data available.

through sewers:

Special precautions for waste management: Dispose in accordance with applicable legislation.

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#### **SECTION 14: Transport information**

	Transport type	Land transport ADR/RID	Sea transport IMDG	Air transport ICAO / IATA
14.1	UN number or ID number	Not applicable.	Not applicable.	Not applicable.
14.2	Official (UN) shipping name	It is not a dangerous item in terms of transport.	It is not a dangerous item in terms of transport.	It is not a dangerous item in terms of transport.
14.3	Transport hazard class/classes	Not applicable.	Not applicable.	Not applicable.
	Identification number danger	Not applicable.	Not applicable.	Not applicable.
	Safety signs	Not applicable.	Not applicable.	Not applicable.
14.4	Packaging group	Not applicable.	Not applicable.	Not applicable.

14.5 Environmental hazard

Not applicable.

14.6 Special security measures for users

Not applicable.

14.7 Maritime bulk transport according to IMO instruments

Does not apply.

#### More information

Transport type	Land transport ADR/RID Not	Sea transport IMDG Not	Air transport ICAO / IATA
Limited amount:	applicable.	applicable.	Not applicable.
Excluded quantity:	Not applicable.	Not applicable.	Not applicable.
Transport category:	Not applicable.	Not applicable.	Not applicable.
Restriction code for tunnels:	Not applicable.	Not applicable.	Not applicable.
Segregation group:	Not applicable.	Not applicable.	Not applicable.

#### **SECTION 15: Regulatory Information**

# 15.1 Safety, health and environmental regulations / specific legislation relating to the substance or mixture

all as amended and including implementing regulations

Act No. 350/2011 Coll., on chemical substances...

Act No. 258/2000 Coll., on the protection of public health...

Act No. 185/2001 Coll., on waste...

Act No. 201/2012 Coll., on air...

Act No. 254/2001 Coll., on waters...

Act No. 477/2001 Coll., on packaging...

Act No. 111/1994 Coll., on road transport

Act No. 224/2015 Coll., on the prevention of serious accidents...

NV No. 361/2007 Coll., Health protection conditions at work...

Decree No. 432/2003 Coll., which establishes the conditions for classifying works into categories...

Regulation (EC) No. 1272/2008 (CLP) on classification, labeling and packaging of substances and mixtures,...

Regulation (EC) No. 1907/2006 (REACH) on the Registration, Evaluation, Authorization and Restriction of Chemicals....

Regulation of the European Parliament and the Council (EC) No. 648/2004 on detergents

Regulation (EC) No. 528/2012 on biocides Regulation (EC) No. 2003/2003, on fertilizers

# 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

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#### **SECTION 16: Further information**

#### Full text of all classifications and hazard classes listed in Section 3:

They are not

#### Abbreviations:

ADN Inland waterways European

ADR Agreement on the International Carriage of Dangerous Goods by Road Chemical

TIME Abstracts Service Derived no-

TODAY effect level Effect concentration for 50%

EC50

EINECS European Inventory of Existing Commercial Chemical Substances Effective

EL50 level for 50% (effect level for 50%)

IATA International Air Transport Association Inhibition

IC50 concentration for 50%

ICAO Technical instructions for the safe air transport of dangerous goods Inhibition load for 50%

IL 50 (inhibition load for 50%)

IMDG International regulation on the carriage of dangerous goods by sea Lethal

LC50 concentration for 50% (lethal concentration for 50%)
LD50 Lethal dose for 50% of individuals (lethal dose for 50%)

LL50 Lethal load for 50% (lethal load for 50%)
LOAEC Lowest observable adverse effect concentration

LOAEL Lowest observable adverse effect level
LOEC Lowest observable effect concentration
LOL Lowest observable effect level

NO Exposure without effect (no effect level) No

NOAEC observable adverse effect concentration (no observable adverse effect concentration) No observable adverse effect

NOAEL level (no observable adverse effect level) No observable effect concentration (no observable effect

NOEC concentration) No observable effect level)

CHRISTMAS

NPK-P The highest permissible concentration at the workplace

OEL Occupational Exposure Limit (exposure limit at the workplace - 8 hours/shift)

PBT Persistent, bioaccumulative, toxic
PEL Permissible exposure limit

PNEC Expected concentration without effect (predicted no-effect concentration) Regulation

RID for international rail transport of dangerous goods Specific concentration

SCL limits Short Term Exposure Limit

STEL (short-term exposure - corresponds to approx. 15 min.)

TT Toxic threshold

VOCs Volatile organic substances

vPvB Highly persistent and highly bioaccumulative Water WGK hazard classes (Wassergefährdungsklassen)

#### Changes against the previous version of BL:

This revision follows on from version D of 19/06/2019 and is in accordance with Regulation (EC) No. 1272/2008 (CLP).

The following materials were used for the revision of the safety data sheet: MSDS of the supplier, CASEC program, ECHA

#### Training instructions:

Workers who come into contact with dangerous substances must be familiarized with the effects of these substances, how to handle them, and protective measures to the extent necessary.

Furthermore, they must be familiarized with the principles of first aid, with the necessary sanitation procedures and with the procedures for liquidating malfunctions and accidents.

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The person who handles this chemical product must be familiar with the safety rules and information given in the safety data sheet.

If the hazardous chemical substance/mixture is classified as corrosive or toxic, workers must be familiar with the Rules for Handling Corrosive/Toxic Chemical Substance/Mixture

Persons transporting dangerous substances must be familiar with the instructions in the event of an accident in accordance with ADR/RID regulations.

#### More information:

The above information describes the conditions for safe handling of the product and corresponds to the current knowledge of the manufacturer, serves as instructions for the training of persons handling the product.

The manufacturer bears a guarantee for the above-described properties of the product in the recommended way of use.

The user is responsible for determining the suitability of the product for specific purposes and adapting safety measures if this use is contrary to the manufacturer's recommendations.