

SAFETY DATA SHEET

Allantoin

(according to Regulation 878/2020)

ALLANTOINE



1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier:

Product name : Allantoin
Chemical product name : 1-(2,5-dioxoimidazolidin-4-yl)urea
Synonyms : UreidoHydantoin – Glyoxildiureide – Hemocane – 5-ureidohydantoin
CAS Nr. : 97-59-6
EC Nr. : 202-592-8
Chemical formula : $C_4H_6N_4O_3$
REACH Registration Number : 01-2119953242-43-0001

Intended use : This product is used in the chemical/pharmaceutical industry as raw material for the manufacturing of toothpaste, cosmetics, polymers and active pharmaceutical ingredients.

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

1.2.1. Relevant identified uses

This product is used in the chemical/pharmaceutical industry as raw material for the manufacturing of toothpaste, cosmetics, polymers and active pharmaceutical ingredients..

1.2.2. Uses advised against: Those different from the relevant identified uses.

1.3. Details about the supplier of the Safety Data Sheet:

Manufacturer : Deretil, S.A.
Villaricos s/n – 04616
Cuevas del Almanzora (Almería)
Spain
Phone: +34 950 61 80 00
<http://www.deretil.com>

1.4. Emergency phones: +34 950 61 80 28 Deretil Villaricos (available 24 hours)

2. Hazards identification

2.1. Classification of the substance or mixture

Unclassified.

2.2. Label elements

Labelling in accordance with Regulation (EC) No. 1272/2008

Pictogram : Unclassified

Signal word : Unclassified

Hazard statements:
: No hazard warnings

Precautionary statements:
: No hazard warnings

2.3. Other hazards

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In normal conditions of use and its original shape, the product has no negative effect neither on health, nor on environment.

3. Composition/information on ingredients

3.1. Substances

Substance/Mixture : Substance

Chemical Name	CAS Nr.	%	EC Nr.	Classification	REACH Registration Number
1-(2,5-dioxoimidazolidin-4-yl)urea	97-59-6	≥ 99 %	202-592-8	Unclassified	01-2119953242-43-0001

3.2. Mixtures

Not applicable

4. First-aid measures

4.1 Description of first aid measures:

General	: Move the exposed person to fresh air.
Inhalation	: If inhaled, move the exposed person to fresh air. Ask for medical attention in case of symptoms.
Skin contact	: Wash with plenty water and soap Remove contaminated clothing and shoes immediately. Ask for medical attention in case of symptoms.
Eye contact	: Flush with plenty of water for several minutes. Ask for medical attention in case of symptoms.
Ingestion	: If swallowed, rinse the mouth with water (only if the person is conscious). Ask for medical attention in case of symptoms.
First aid facilities	: Ensure that eyewash stations and safety showers are close to the workstation location.

4.2 Most important symptoms and effects, both acute and delayed

Harmful product, a prolonged exposure through inhalation may cause anesthetic effects, requiring immediate medical attention.

4.3 Indication of any immediate medical attention and special treatment needed

When there is any doubt or if the symptoms of discomfort persist, always consult a doctor. Never give anything by mouth to an unconscious person. Do not induce vomiting. In case of spontaneous vomiting, make sure the affected persons' airways are clear.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Use dry chemical powder or CO₂. In case of larger fires, water spray or alcohol resistant foam can also be used.

Unsuitable extinguishing media:

Avoid direct water jet. In case of electrical voltage, water or foam should not be used.

5.2 Special hazards arising from the substance or mixture

Special hazards

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In case of fire, a thick black smoke can be generated. As a consequence of thermal decomposition, the following hazardous products can be produced: carbon monoxide, carbon dioxide, nitrogen oxides (NO, NO₂), ammonia (NH₃), amines. The exposure to combustion and decomposition products may be harmful for health.

5.3 Advice for firefighters

Cool with water the tanks, truck tankers or containers which are close to the sources of heat or fire. Observe wind direction. Avoid that the products used for fire extinguishing enter the sewerage system or water streams.

Fire protection equipment

Depending on the fire size, the use of protective suits against heat, self-contained breathing apparatus, gloves, protective goggles, facial masks and boots could be necessary.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use the suitable protective equipment (section 8).

6.2 Environmental precautions

Avoid the contamination of sewers, surface or subterranean airways or the soil.

6.3 Methods and materials for containment and cleaning up

Small spills or leaks

: Vacuum or sweep-up material and place in a designated labelled waste container. Clean-up the affected area with a large amount of water.

Big spills or leaks

: Vacuum or sweep-up material and place in a designated labelled waste container. Clean-up the affected area with a large amount of water. Use explosion-proof electrical (ventilating, lighting and material handling) equipment.

6.4. Reference to other sections

For exposure control and personal protective measures, see section 8

For waste disposal, follow the recommendations of section 13.

7. Handling and Storage

7.1 Precautions for safe handling

For personal protection, see section 8.

Smoking, eating and drinking must be prohibited in the application area.

Comply with the legislation related to safety and hygiene in the workplace.

Do not use pressure to empty packaging containers, these containers are not pressure-resistant.

Store the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities

Store according to the local legislation. Follow the label indications. Store the containers, at a temperature between 5 and 35°C, in a dry and a well ventilated area, away from heat and direct sunlight. Keep far from ignition points. Keep away from oxidizing agents and from highly acidic or alkaline materials. Prohibit smoking. Avoid the entry of non-authorized people. After opening the containers, close them carefully again and place them vertically to avoid leakages. The product is not affected by Directive 2012/18/UE (SEVESO III).

Suitable packaging material: cardboard box with inner polyethylene liner.

7.3. Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

Note: See section 10 for Stability and Reactivity

8. Exposure Controls/Personal Protection

8.1. Control parameters

The product does not contain substances with Occupational Exposure Limit Values. The product does not contain substances with Biological Limit Values.

The product has a DNEL value of 284 mg/kg/day (on long term). The product has no PNEC value.

8.2. Exposure controls

Appropriate technical controls : Provide an adequate ventilation, by means of local and general air extraction systems.

Concentration:	100%
Uses:	This product is used in the chemical/pharmaceutical industry as raw material for the manufacturing of active pharmaceutical ingredients.

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Respiratory protection		
PPE	Self-filtering mask against particles.	
Characteristics	«CE» marking Cat. III. Made of filtering material, covering nose, mouth and chin	
CEN Norms	EN 149	
Preservation	Before use, check the absence of breakage, deformation, etc. As disposable personal protective equipment, it will be renewed for each use	
Observations	If not properly adjusted, does not protect the worker. Follow the manufacturer's instructions for a proper use of the PPE.	
Type of filter needed	P2	
Hand protection:		
PPE	Protective gloves against chemical products	
Characteristics	«CE» marking Cat. III.	
CEN Norms	EN 374-1, En 374-2, EN 374-3, EN 420	
Preservation	Storage in a dry place, far from heat sources and avoiding the exposure to solar rays. Do not introduce any modification which could alter the resistance of the gloves. Do not apply paints, solvents or adhesives.	
Observations	The gloves have to be of the correct size, fitting properly the hand, without being too loose or too tight. Always use them with clean and dry hands.	
Material	PVC (polyvinyl chloride)	
Breakthrough time	>480 min	
Material thickness (mm)	0,35	
Recommended material	>8 hours (breakthrough time): Practical experience has shown that gloves of polychloroprene (neoprene), nitrile rubber, butyl rubber, fluor rubber (Viton) and polyvinyl chloride (PVC) offer sufficient protection against (undissolved) solids. Replace damaged gloves.	
Eye protection		
PPE	Protective goggles against impact of particles	
Characteristics	«CE» marking Cat. II. Protecting eyes against powder and fumes.	
CEN Norms	EN 165, EN 166, EN 167, EN 168	
Preservation	Visibility through the eyepieces should be optimal for which these items should be cleaned daily. The protectors should be disinfected periodically following the manufacturer's instructions	
Observations	Indicators of damage can be: yellow coloration of the eyepieces, superficial scratches on the eyepieces, tears, etc.	
Skin protection:		
PPE	Protective clothing	
Characteristics	«CE» marking Cat. II. Protective clothing should not be narrow or loose so that it does not interfere with the user's movements.	
CEN Norms	EN 340	
Preservation	Washing and storage instructions provided by the manufacturer must be followed to ensure consistent protection.	
Observations	Protective clothing should provide a level of comfort consistent with the level of protection it should provide against the risk against which it protects, taking into account the environmental conditions, the level of activity of the user and the expected time of use.	
PPE	Safety shoes	
Characteristics	«CE» marking Cat. II.	
CEN Norms	EN ISO 13287, EN 20347	
Preservations	These articles adapt to the shape of the first user's foot. For this reason, as for hygiene, the reuse by another person should be avoided.	
Observations	Work footwear for professional use is that incorporating protective elements intended to protect the user from injuries that could cause accidents. Work for which it is suitable should be reviewed.	

Advice on personal protection is applicable for high exposure levels. Select proper personal protection base on a risk assessment of the actual exposure situation.
For environmental precautions, see section 6.

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

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Colour	: White
Odour – Odour threshold	: Odourless
pH	: 4 to 6 (concentration 0,5%)
Melting point/freezing point	: 225 to 236°C (decomposition)
Boiling point or initial boiling point and boiling range	: Not applicable
Flammable point	: Not flammable
Flash point	: > 420°C
Relative evaporation rate	: Not applicable
Flammability	: Non flammable
Lower and Upper explosion limits	: Non explosive
Vapour pressure	: < 0,001 Pa (20°C)
Relative vapour density	: Not applicable
Relative density (g/cm ³)	: 1,7 g/cm ³
Density (g/cm ³)	: 800 kg/m ³
Solubility in water	: 0,49 g/100 ml (25°C)
Solubility	: Very slightly soluble in cold water
Partition coefficient: n-octanol/water (Log Pow)	: - 2,26 (20°C)
Relative self-ignition temperature	: Non flammable
Decomposition temperature	: > 229°C
Viscosity	: Not applicable
Explosive properties	: Non explosive
Oxidising properties	: Non oxidising
Surface tension	: Not applicable
Conductivity	: Not applicable
Molecular weight	: 158.14 g/mole
Minimum ignition energy	: Not available
Particle Characteristics	: Not applicable

9.2. Other Information

Drop point	: Not relevant for this type of product
Scintillation	: Not relevant for this type of product
Kinematic Viscosity	: Not relevant for this type of product

10. Stability and Reactivity

10.1 Reactivity.

No hazard due to the product reactivity.

10.2 Chemical Stability

Stable under recommended storage and handling conditions (see section 7).

10.3 Possibility of hazardous reactions

The product should not undergo hazardous reactions.

10.4 Conditions to avoid

Avoid any incorrect handling. Keep far from heat, sparkles of flames. Avoid the formation of dust clouds.

10.5 Incompatible materials

Keep away from oxidizing agents or strongly alkaline or acidic materials, to prevent exothermic reactions.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses. In case of fire: see section 5

11. Toxicological information

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

Toxicological information on the substances present in the product

Ingredient Name	Test	Species	Route	Result
Allantoin	LD ₅₀	Rat	Oral	> 5000 mg/kg
	LD ₅₀	Rat	Skin	> 5000 mg/kg
	No study available	No study available	Inhalation	No study available

a) Acute Toxicity

Under the toxicity study conditions, the acute oral exposure LD₅₀ of the test substance is >5000 mg/kg. Therefore, it has no acute toxicity.

b) Skin corrosion/irritation

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

c) Serious eye damage/irritation

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

d) Respiratory or skin sensitization

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

e) Germ cell mutagenicity

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

f) Carcinogenicity

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

g) Reproductive toxicity

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

h) STOT-single exposure

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

i) STOT-repeated exposure

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

j) Aspiration hazard

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

Note: See section 4 for effects and symptoms

11.2 Information on other hazards (Endocrine disrupting properties):

The product has no endocrine disrupting properties.

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12. Ecological Information

12.1. Toxicity

No information available concerning ecological toxicity. :

12.2 Persistence and degradability

Ingredient name	Aquatic half-life	Photolysis	Biodegradability
Allantoin	-	-	Readily

12.3 Bioaccumulative potential

Ingredient name	LogP _{ow}	Bio-concentration factor	Bioaccumulative potential
Allantoin	- 2,26	-	Low

12.4 Mobility in soil

No data available about mobility in soil.
Avoid the entry of the product in sewers or waterways.
Prevent any ground penetration.

12.5 Results of PBT and vPvB assessment

Based on the available data, the product is not PBT/ vPvB.

12.6 Endocrine disrupting properties

The product has no endocrine disrupting properties.

12.7 Other adverse effects

No data available about other adverse effects on environment.

13. Disposal considerations

13.1 Appropriate treatment methods for the substance waste

Prohibit the waste discharge into sewers or waterways. Waste and packaging material must be disposed of in accordance with the national and local regulations.

Follow the provisions of the 2008/98/CE Directive about the waste disposal.

14. Transport information

Not hazardous for transport. In case of accident and leakage of the product, react according to point 6.

14.1 UN Number or ID Number

Not hazardous for transport.

14.2 UN proper shipping name

Description:

ADR: Not hazardous for transport.

IMDG: Not hazardous for transport.

ICAO/IATA: Not hazardous for transport.

14.3 Transport hazard class(es)

Not hazardous for transport.

14.4 Packaging group

Not hazardous for transport.

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14.5 Environmental hazards

Not hazardous for transport.

14.6 Special precautions for user

Not hazardous for transport.

14.7 Transport in bulk by sea or inland waterways according to IMO instruments

Not hazardous for transport.

15. Regulatory information

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

The product is not affected by the Regulation (EC) n° 1005/2009 from the European Parliament and Council, dated Sept. 16, 2009, about substances depleting the ozone layer.

Classification of the product according to the Annex I of the Directive 2012/EU (SEVESO III): N/A

The product is not affected by the Regulation (EC) N° 528/2010 related to the marketing and use of biocides.

The product is not affected by the procedure established in the Regulation (EU) N° 649/2012 related to the export and import of hazardous chemical products.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment was carried out for this substance.

16. Other Information

16.1 Changes from the previous SDS version

Updating according to REACH content.

History

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:

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Elaboration

: Deretil's own electronic format

16.2 Legend to any abbreviations and acronyms used

CAS: Chemical Abstracts Service NUMBER

CEN: European Committee for Standardisation

PBT: Persistent, bioaccumulative and toxic

vPvB: Very Persistent and Very Bioaccumulative

PPE: Personal Protective Equipment.

LD50: Lethal Dose, 50%

16.3 Key literature references and sources for data

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

16.4 Mixtures: Procedure used to derive the classification

Not applicable

16.5 Relevant risk phrases, hazard statements, safety phrases and/or precautionary statements

H and P statements: See section 2

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16.6 Advice on training, for those handling the chemical

Before handling this substance/preparation, the personnel involved should be instructed by means of the present safety data sheet.

Sources of key data : Literature data and/or investigation reports are available through the manufacturer.

The information provided in the present SDS has been written according to the REGULATION (EU) 2020/878 FROM THE EUROPEAN COMMISSION, issued on June 18, 2020, to modify the Appendix II of the Regulation (EC) nr. 1907/2006 from the European Parliament and Council, related to the registry, evaluation, authorization and restrictions of the chemical substances and mixtures (REACH) and the following directives: Directive 76/769/EEC from the Council and Directives 91/155/EEC, 93/67/EEC, 93/105/EC y 2000/21/EC from the Commission.

Notice to reader

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The product must not be used for any purposes other than those specified under heading 1, without first obtaining written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information given on this safety data sheet must be regarded as a description of the safety requirements relating to our product and not a guarantee of its properties.

END OF THE SAFETY DATA SHEET