

CERTIFICATE OF ANALYSIS



PRODUCT NAME: ALLANTOIN

BATCH/LOT NUMBER: 4387512

BEST BEFORE DATE: February 2023

IDENTITY/TEST	SPECIFICATION	RESULT
Composition	5 - ureidohydantoin	
Appearance	White, odourless crystalline powder	Conforms
Purity (potentiometric)	98.0 – 101.0%	99.47
Melting Point	224 – 232°C	228
Moisture Content	0.1% max	Conforms
pH (0.5% solution) @ 25°C	4.0 – 6.0	4.4
Sulphated Ash	0.1% max	Conforms
Heavy Metals (as Pb)	15 ppm max	Conforms
Iron	10 ppm max	Conforms
Arsenic	2 ppm max	Conforms
Bulk Density	0.7 kg / m ³	Conforms
Solubility	Fully miscible with water & ethanol	Conforms
Microbiological purity	< 10 CFU / g. (aerobes & anaerobes) pathogens absent	<10



SAFETY DATA SHEET ALLANTOIN

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

1.1. Product identifier

Product name	ALLANTOIN
Chemical name	5-Ureidohydantoin
Product number	20035
Internal identification	SDS Number 20140
Synonyms; trade names	Glyoxyldiureide
CAS number	97-59-6
EC number	202-592-8

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

Identified uses	Skin protectant
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1.3. Details of the supplier of the safety data sheet

Supplier	Madar Corporation Limited 19 - 20 Sandleheath Industrial Estate Fordingbridge Hampshire Sp6 1PA T: +44(0)1425 655555 E: technical@madarcorporation.co.uk
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1.4. Emergency telephone number

Emergency telephone	+44(0)1425 655555 (0800 - 1700hrs GMT)
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards	Not Classified
Health hazards	Not Classified
Environmental hazards	Not Classified

2.2. Label elements

EC number	202-592-8
Hazard statements	NC Not Classified
Precautionary statements	P262 Do not get in eyes, on skin, or on clothing. P280 Wear protective clothing, gloves, eye and face protection. P403+P233 Store in a well-ventilated place. Keep container tightly closed.

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2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Product name	ALLANTOIN
Chemical name	5-Ureidohydantoin
CAS number	97-59-6
EC number	202-592-8
Ingredient notes	Allantoin

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	First aid personnel should wear appropriate protective equipment during any rescue. Show this Safety Data Sheet to the medical personnel.
Inhalation	Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. For breathing difficulties, oxygen may be necessary. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Do not induce vomiting. Rinse nose, mouth and throat with water. Get medical attention.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

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

Inhalation	May cause respiratory irritation.
Ingestion	May cause discomfort if swallowed.
Skin contact	May cause irritation.
Eye contact	Particles in the eyes may cause irritation and smarting.

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

Notes for the doctor	Treat symptomatically.
Specific treatments	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards	Dust may form explosive mixture with air.
Hazardous combustion products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

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5.3. Advice for firefighters

Protective actions during firefighting	Use special protective clothing. Take precautionary measures against static discharge. Ground container and transfer equipment to eliminate static electric sparks. Control run-off water by containing and keeping it out of sewers and watercourses.
Special protective equipment for firefighters	Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure procedures and training for emergency decontamination and disposal are in place. No smoking, sparks, flames or other sources of ignition near spillage. For personal protection, see Section 8.
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6.2. Environmental precautions

Environmental precautions	Collect and dispose of spillage as indicated in Section 13. Do not discharge into drains or watercourses or onto the ground. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.
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6.3. Methods and material for containment and cleaning up

Methods for cleaning up	Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation. Collect powder using special dust vacuum cleaner with particle filter or carefully sweep into suitable waste disposal containers and seal securely. Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. Avoid generation and spreading of dust. Wash thoroughly after dealing with a spillage.
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6.4. Reference to other sections

Reference to other sections	For personal protection, see Section 8. For waste disposal, see section 13.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions	Avoid inhalation of dust and contact with skin and eyes. Provide adequate ventilation. Dust may form explosive mixture with air. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges.
Advice on general occupational hygiene	Do not eat, drink or smoke when using this product. Eye wash facilities and emergency shower must be available when handling this product. Wash contaminated clothing before reuse. No specific hygiene procedures recommended but good personal hygiene practices should always be observed when working with chemical products.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions	Store in tightly-closed, original container in a dry and cool place. Keep away from food, drink and animal feeding stuffs. Store away from the following materials: Oxidising materials. Strong acids. Strong alkalis.
Storage class	Chemical storage.

7.3. Specific end use(s)

Specific end use(s)	The identified uses for this product are detailed in Section 1.2.
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SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

ALLANTOIN

Occupational exposure limits

No exposure limits noted for the ingredient(s).

8.2. Exposure controls

Protective equipment



Appropriate engineering controls

Provide adequate general and local exhaust ventilation.

Eye/face protection

Use approved safety goggles or face shield.

Hand protection

The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material.

Other skin and body protection

Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures

Use engineering controls to reduce air contamination to permissible exposure level. Eye wash facilities and emergency shower must be available when handling this product. Wash contaminated clothing before reuse. No specific hygiene procedures recommended but good personal hygiene practices should always be observed when working with chemical products.

Respiratory protection

If ventilation is inadequate, suitable respiratory protection must be worn.

Environmental exposure controls

Take all necessary precautions to avoid the accidental release of the product into environment.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Crystalline powder.
Colour	White.
Odour	Characteristic.
Odour threshold	Not available.
pH	pH (diluted solution): 4.0 - 6.0 (0.5%)
Melting point	230°C
Initial boiling point and range	Not available.
Flash point	Not available.
Evaporation rate	Not applicable.
Evaporation factor	Not applicable.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not available.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.

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Relative density	Not available.
Bulk density	~ 0.7 kg/m ³
Solubility(ies)	Slightly soluble in water. 1 g/190 ml water.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Product is not explosive. However formation of explosive air/dust mixtures is possible.
Explosive under the influence of a flame	Not determined
Oxidising properties	Not determined.

9.2. Other information

Molecular weight 158.12

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Not available. Will not polymerise.

10.4. Conditions to avoid

Conditions to avoid Avoid exposure to high temperatures or direct sunlight. Avoid heat, flames and other sources of ignition. Avoid dust close to ignition sources. Water, moisture.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents. Strong acids. Strong alkalis.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

Notes (oral LD₅₀) LD50 Oral (Rat) >5000 mg/kg

Acute toxicity - dermal

Notes (dermal LD₅₀) No information available.

Acute toxicity - inhalation

Notes (inhalation LC₅₀) No information available.

Skin corrosion/irritation

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Skin corrosion/irritation	Not irritating., (Rabbit)
<u>Serious eye damage/irritation</u>	
Serious eye damage/irritation	Slightly irritating. (Rabbit)
<u>Respiratory sensitisation</u>	
Respiratory sensitisation	Not sensitising.
<u>Skin sensitisation</u>	
Skin sensitisation	Not sensitising.
<u>Germ cell mutagenicity</u>	
Genotoxicity - in vitro	Not classified (based on available data, the classification criteria are not met)
<u>Carcinogenicity</u>	
Carcinogenicity	Not classified (based on available data, the classification criteria are not met)
<u>Reproductive toxicity</u>	
Reproductive toxicity - fertility	No information available.
<u>Specific target organ toxicity - single exposure</u>	
STOT - single exposure	No specific test data are available.
<u>Specific target organ toxicity - repeated exposure</u>	
STOT - repeated exposure	No specific test data are available.
<u>Aspiration hazard</u>	
Aspiration hazard	No data available
<u>Inhalation</u>	
Inhalation	May cause respiratory irritation.
<u>Ingestion</u>	
Ingestion	May cause discomfort if swallowed.
<u>Skin contact</u>	
Skin contact	May cause skin irritation.
<u>Eye contact</u>	
Eye contact	May cause irritation.

SECTION 12: Ecological Information

12.1. Toxicity

Acute toxicity - fish	LC ₅₀ , : >5000 mg/l, Brachydanio rerio (Zebra Fish)
Acute toxicity - aquatic invertebrates	EC ₅₀ , : >100 mg/l, Daphnia magna
Acute toxicity - aquatic plants	NOEC, 72 hours: 100 mg/l, Desmodemus subspicatus
Acute toxicity - microorganisms	Not available.
Acute toxicity - terrestrial	Not available.

12.2. Persistence and degradability

Persistence and degradability The product is readily biodegradable. >70% 10 days

12.3. Bioaccumulative potential

Bioaccumulative potential	No information available.
Partition coefficient	Not available.

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12.4. Mobility in soil

Mobility The product has poor water-solubility.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This product does not contain any substances classified as PBT or vPvB.

12.6. Other adverse effects

Other adverse effects Not known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

Waste class Waste key number in accordance with the European Waste Catalogue (EWC) are origin-referred defined. Since this product is used in several industries, no waste key can be provided by the supplier. The waste key number should be determined in arrangement with your waste disposal partner or the responsible authority.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

14.6. Special precautions for user

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

SECTION 15: Regulatory information

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

National regulations Health and Safety at Work etc. Act 1974 (as amended).

EU legislation Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Revision comments This is first issue.

Revision date 28/09/2016

Revision 1

ALLANTOIN

SDS number 20140

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

**PRODUCT SPECIFICATION SHEET****ALLANTOIN****WSB Product Code** 20035

PROPERTY	SPECIFICATION
CTFA Name	Allantoin
Synonyms	Glyoxyldiureide
Composition	5 - ureidohydantoin
Empirical Formula	C ₄ H ₆ O ₃ N ₄
Molecular Weight	158.12
CAS Number	97-59-6
EINECS Number	202-592-8
Pharmacopoeia Status	Conforms to USP, BP & Ph. Eur. monographs
Identification (A-D)	Conforms to the pharmacopoeia monographs
Appearance	White, odourless crystalline powder
Purity (potentiometric)	98.0 – 101.0 %
Melting Point	224 – 232°C
Optical Rotation	-0.10° to +0.1°
Loss on Drying (100-105°C)	0.1% max
pH (0.5% solution) @ 25°C	4.0 – 6.0
Sulphated Ash	0.1% max
Heavy Metals (Total as Pb)	15 ppm max
Iron	10 ppm max
Arsenic	2 ppm max
Bulk Density	0.7 kg/m ³
Solubility	Fully miscible in water & ethanol
Microbiological purity	<10 CFU/g (aerobes & anaerobes); Pathogens absent
Packaging	25 kg net in HDPE drums
Storage Conditions	Store in original containers, tightly closed and properly labelled. Store in a cool, dry, well-ventilated area, away from direct sunlight, heat and sources of ignition.



ALLANTOIN PRODUCT STATEMENT

MATERIAL TRADE NAME: ALLANTOIN
CHEMICAL NAME: Glyoxyldiureide
CAS NUMBER: 97-59-6
EINECS NUMBER: 202-592-8
TARIFF CODE: 29332100
COUNTRY OF ORIGIN: China

REACH (registration, evaluation and authorisation of chemicals) REGULATION STATEMENT

ALLANTOIN is classified as a substance, REACH Registration Number: 01-2119953242-43-XXXX.
In addition, we hereby confirm that ALLANTOIN does not contain any Substances of Very High Concern (SVHC).

ALLERGENS (EU Directive 2003/89/EC and 2006/142/EC amendment) STATEMENT

ALLANTOIN does not contain any of the following products: dairy, egg, wheat, gluten, corn, rye, barley, oat, soy, safflower, sunflower, peanut, nuts, sesame seeds monosodium glutamate, hydrolyzed animal protein, hydrolyzed plant protein, yeast, sulphites, fish, shellfish, molluscs, beef, pork, chocolate, ethyl alcohol, mustard, lupin & celery.

IFRA 49 STATEMENT

ALLANTOIN is purely of synthetic origin and is not classed as fragrance compound.

VEGAN STATEMENT

ALLANTOIN is purely of synthetic origin and is suitable for vegans.

BSE/TSE STATEMENT

ALLANTOIN is purely of synthetic origin and no raw materials or additives used in the manufacture of ALLANTOIN are derived from animal origin. During manufacture or packing ALLANTOIN never comes into contact with animal or bovine material. Therefore, any risk that ALLANTOIN carries Spongiform or BSE viruses can be excluded.

NON-ANIMAL TESTING DECLARATION

ALLANTOIN has not been tested on animals since 31/12/1985.

CARCINOGENIC, MUTAGENIC, REPROTOXIC (CMR) ATTESTATION

(Evaluation in accordance with European Directive 1272/2008/EEC)
ALLANTOIN does not contain any substances listed CMR 1A, 1B and 2 above the threshold limit in accordance with European Directive 1272/2008/EEC.

GMO FREE STATEMENT

ALLANTOIN is purely of synthetic origin and no raw materials or additives used in the manufacture of ALLANTOIN are derived from GMO materials. Therefore, to the best of our knowledge and belief ALLANTOIN is GMO free

CALIFORNIA PROPOSITION 65 DECLARATION

To the best of our knowledge and belief, ALLANTOIN does not contain any contaminants or bi-products known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act.

NANO MATERIALS DECLARATION

We confirm that to the best of our knowledge and belief ALLANTOIN does not contain any materials defined as nanomaterials in accordance with the Cosmetic Regulation 1223/2009/EC.

CERTIFICATE OF ORIGIN

We hereby confirm that ALLANTOIN is purely of synthetic origin.

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COSMETIC REGULATION EC 1223/2009 COMPLIANCE

We hereby confirm that ALLANTOIN complies with the Cosmetic Regulation EC 1223/2009 (as amended) and can be used as an ingredient in cosmetic applications. In addition:

- ALLANTOIN is not listed in Annex II to VI of the cosmetic legislation 1223/2009 (as amended).
- ALLANTOIN does not contain any significant levels of forbidden /restricted substances (listed in annex II to VI of 1223/2009/EC and its amendments) at detectable level. However, according to art.17, traces levels (technically unavoidable in good manufacturing practices) of non-intended prohibited substance could be present but are not expected.

HEAVY METALS STATEMENT

ALLANTOIN contains heavy metals (as Pb): 15 ppm max.

ICH/VICH/USP GUIDELINES ON RESIDUAL SOLVENTS

In accordance with ICH-guideline CPMP/ICH/283/95, VICH guideline CVMP/VICH/502/99 and USP requirements stated in Residual Solvents <467> together with information on Impurities in Official Articles <1086> the following residual solvents are present:

Class 1, 2, 3: none

USP Residual Solvents <467> table 4 (not limited to class 1, 2, 3 and table 4 solvents listed in USP <467> document): none

COLOURS STATEMENT

ALLANTOIN does not contain the colours E102, E104, E110, E122, E124 or E129.

MICROBIOLOGY STATEMENT

ALLANTOIN is not expected to contain any microbes due to the nature of the product.

MYCOTOXINS STATEMENT

ALLANTOIN does not contain any mycotoxins.

PESTICIDE RESTICIDE STATEMENT

ALLANTOIN does not contain any pesticides.

IRRADIATION STATEMENT

ALLANTOIN is not subjected to irradiation during the manufacturing process

DIOXIN STATEMENT

ALLANTOIN does not contain any raw material contaminated with dioxin nor do we believe that the product is contaminated with dioxin by way of the manufacturing process.

LATEX STATEMENT

ALLANTOIN does not contain any raw material contaminated with latex nor do we believe that the product is contaminated with latex by way of the manufacturing process.

POLYCYCLIC AROMATIC HYDROCARBONS (PAH) and POLYCHLORINATED BIPHENYL (PCB) STATEMENT

ALLANTOIN does not contain polycyclic aromatic hydrocarbons (PAH) or polychlorinated biphenyl (PCB).

PHthalATE STATEMENT

ALLANTOIN does not contain phthalates.

VOLATILE ORGANIC COMPOUND STATEMENT

ALLANTOIN does not contain volatile organic compounds (VOCs).

SECONDARY AMINES, NITROSAMINES & PETROLEUM STATEMENT

We hereby confirm ALLANTOIN does not contain any secondary amines, nitrosamines or petroleum products.



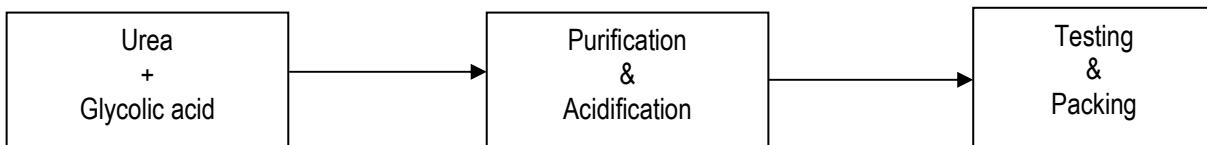
MOSH/MOAH STATEMENT

ALLANTOIN is purely of synthetic origin and no raw materials or additives used in the manufacture of ALLANTOIN are derived from Mineral Oils Saturated Hydrocarbons (MOSH)/Mineral Oils Aromatic Hydrocarbons (MOAH). During manufacture or packing ALLANTOIN never comes into contact with MOSH/MOAH.

ISO 16128-1:2016

We hereby confirm that ALLANTOIN is purely of synthetic origin and no natural and/or organic ingredients are used in the manufacturing process. Therefore ISO 16128-1:2016 is not applicable.

MANUCATURING FLOW CHART



MANUFACTURING PLANT CERTIFICATION

The manufacturing plant is ISO 9001:2015 certified.