



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 AND INTOLERANCES (EU Directive 1169/2011)

We hereby confirm that ALLANTOIN does not contain any substances or products that cause allergies or intolerances listed in Annex II of EU Directive 1169/2011.

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.

HALAL STATEMENT

ALLANTOIN is purely of synthetic origin and meets the following requirements:
Does not contain any traces of pork (porcine).
Does not contain any animal products.
No ethanol is used in the manufacturing process.

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.

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.

POLYCYLIC 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.

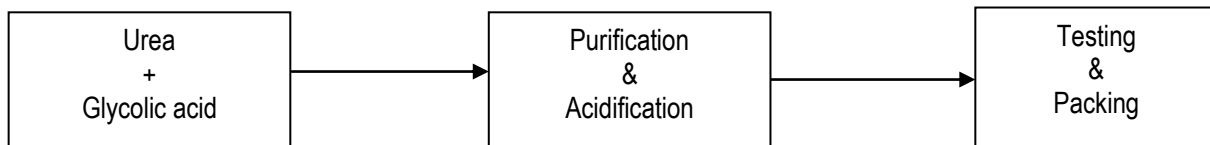
MOSH/MOAH STATEMENT

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.

10th November 2020



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	1-(2,5-dioxoimidazolidin-4-yl)urea
Product number	20035
Internal identification	SDS Number 20140
Synonyms; trade names	5-Ureidohydantoin; Glyoxyldiureide
REACH registration number	01-2119953242-43-XXXX
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	Naturally Balmy Ltd 8 Benson Road Nuffield Industrial Estate Poole, BH17 OGB
Telephone:	01202 567046
E-Mail:	sales@naturallybalmy.co.uk

1.4. Emergency telephone number

Emergency telephone	Use your local or national emergency contact number
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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

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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.

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Product name	ALLANTOIN
Chemical name	1-(2,5-dioxoimidazolidin-4-yl)urea
REACH registration number	01-2119953242-43-XXXX
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	Dust may irritate the respiratory system.
Ingestion	No adverse effects known.
Skin contact	No adverse effects known.
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.

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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.

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	See section 1 for emergency contact information. See section 2 for hazard identification. See section 7 for information on safe handling. See section 8 for information on personal protective equipment. See section 12 for additional information on ecological hazards. See section 13 for information on disposal.
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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

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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.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

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. Personal protective equipment for eye and face protection should comply with European Standard EN166.

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. To protect hands from chemicals, gloves should comply with European Standard EN374.

Other skin and body protection

Wear appropriate clothing to prevent any possibility of skin contact. Wear chemical protective clothing (overall with long sleeves, two piece suit resistant to chemical splashes or chemical resistant disposable coveralls) according to EN 465.
Wear chemical resistant safety shoes according to EN 13832.

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.
Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136.
Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.

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.

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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.
Relative density	Not available.
Bulk density	~ 0.7 kg/m ³
Solubility(ies)	Slightly soluble in water. 1 g/190 ml water.
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.
<u>9.2. Other information</u>	
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 None known.

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

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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 5000 mg/kg bw, Oral, Rat

Acute toxicity - dermal

Notes (dermal LD₅₀) LD₅₀ 5000 mg/kg bw, Dermal, Rabbit

Acute toxicity - inhalation

Notes (inhalation LC₅₀) No information available.

Skin corrosion/irritation

Skin corrosion/irritation Based on available data the classification criteria are not met.

Serious eye damage/irritation

Serious eye damage/irritation Based on available data the classification criteria are not met.

Respiratory sensitisation

Respiratory sensitisation Not available.

Skin sensitisation

Skin sensitisation Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity - in vitro Based on available data the classification criteria are not met.

Carcinogenicity

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

Reproductive toxicity

Reproductive toxicity - fertility Based on available data the classification criteria are not met.

Specific target organ toxicity - single exposure

STOT - single exposure Endpoint waived according to REACH Annex VII, IX or XI.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure LOELs 989 mg/kg/day, Category approach: 1743 mg/kg/day trend analysis for rat; 1000 mg/kg/day read-across for rat., Rat, Mouse

Aspiration hazard

Aspiration hazard No data available

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity

Acute toxicity - fish LC₅₀, 96 hours: >5000 mg/l, Fish

Acute toxicity - aquatic invertebrates EC₅₀, 48 hours: >100 mg/l, Daphnia magna

Acute toxicity - aquatic plants EC₅₀, 72 hours: >100 mg/l, Desmodemus subspicatus

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Acute toxicity - microorganisms NOEC, : >1000 mg/l, Microorganisms, (OECD 209)

Acute toxicity - terrestrial Scientifically unjustified.

12.2. Persistence and degradability

Persistence and degradability The product is readily biodegradable. >76% 28, days

12.3. Bioaccumulative potential

Bioaccumulative potential Bioaccumulation is unlikely. log Kow: ≤ 3, Aquatic organisms

12.4. Mobility in soil

Mobility The product has poor water-solubility.

Adsorption/desorption coefficient The substance is readily biodegradable, therefore requirement to test for adsorption/desorption is waived.

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 Any other adverse effects on the environment are not expected.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods The generation of waste should be minimised or avoided wherever possible. Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal 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 REACH etc. (Amendment etc.) (EU Exit) Regulations 2019
The CLP Regulation
Health and Safety at Work etc. Act 1974 (as amended).
EH40/2005 Workplace exposure limits.

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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).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

15.2. Chemical safety assessment

A chemical safety assessment has been carried out.

Inventories

Remarks:

SECTION 16: Other information

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Classification abbreviations and acronyms

AND – European Agreement concerning the Carriage of Dangerous Good by inland Waterways

ADR – European Agreement concerning the Carriage of Dangerous Good by Road

AICS – Australian Inventory of Chemical Substances

ANSI – American National Standards Institute

ATE – Acute Toxicity Estimate

ASTM – American Society of Testing and Materials (US)

BCF – Bio-concentration factor

BOD – Biochemical Oxygen Demand

BODIS – Biodegradability of Insoluble Substances

CAS – Chemical Abstract Service

Catpe – Converted Acute Toxicity Point Estimate

CLP – Regulation on Classification, Labelling and Packaging of Substances and Mixtures

COD – Chemical Oxygen Demand

DIN – Deutsches Institut für Normung (German institute of standardisation)

DMEL – Derived Minimal Effect Level

DNEL – Derived No-Effect Level

DSL – Domestic Substances List

EC... – Effect concentration ... %

EINECS – European Inventory of Existing Commercial Substances

ELINCS – European Inventory of Notified Substances

ENCS – Existing Notified Chemical Substances (Japan)

EWC – European Waste Catalogue

IARC – International Agency for Research on Cancer

IATA – International Air Transport Association

IBC – Intermediate Bulk Container

ICAO – International Civil Aviation Organization

IECSC – Chinese Chemical Inventory of Existing Chemical Substances

IMDG – International Maritime Dangerous Goods

IMO – International Maritime Organization

ISHL – Industrial Safety and Health Law (Japan)

ISO – International Organization for Standardization

IUAPC – International Union of Pure and Applied Chemistry

KECI – Korea Existing Chemicals Inventory

Koc – Organic-water Partition Coefficient

Kow – Octanol-water Partition Coefficient

LC... – Lethal Concentration, ...%

LD... – Lethal Dose, ...%

MARPOL – International Convention for the Prevention of Pollution From Ships

MITI – Ministry of International Trade and Industry (Japan)

NDSL – Non-Domestic Substances List

NECI – National Existing Chemical Inventory (Taiwan)

NOAEL – No observable adverse effect level

NOEL/NOEC – No Observed-effect level/concentration

NTP – National Toxicity Program

NZIoC – New Zealand Inventory of Chemicals

OECD – Organisation for Economic Co-operation and Development

PBT – Persistent, bioaccumulative, toxic

PICCS – Philippine Inventory of Chemicals and Chemical Substances

PNEC – Predicted No-Effect Concentration

Pow – Octanol-water Partition Coefficient

PSN – Proper Shipping Name

REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals

RID – Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT – Specific Target Organ Toxicity

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TG – Test Guideline
TRGS – The Technical Rules for Hazardous Substances
TSCA – Toxic Substances Control Act
vPvB – very Persistent, very Bioaccumulative
WGK – German Water Hazard Class

Revision comments	All sections updated.
Revision date	20/05/2021
Revision	2
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**

PROPERTY	SPECIFICATION
CTFA Name	Allantoin
Synonyms	1-(2,5-dioxoimidazolidin-4-yl)urea
Composition	Glyoxyldiureide, 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	1 ppm max
Bulk Density	0.7 kg/m ³
Solubility	Slightly soluble in water; very slightly soluble in alcohol
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.