CERTIFICATE OF ANALYSIS



PRODUCT NAME: ALLANTOIN **BATCH/LOT NUMBER:** 4459203

BEST BEFORE DATE JANUARY 2025

IDENTITY/TEST	SPECIFICATION	RESULT
Composition	5 - ureidohydantoin	
Appearance	White, odourless crystalline powder	Conforms
Purity (potentiometric)	98.0 – 101.0%	99.49
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	$0.7 \text{ kg} / \text{m}^3$	Conforms
Solubility	Fully miscible with water & ethanol	Conforms
Microbiological purity	< 10 CFU / g. (aerobes & anaerobes) pathogens absent	<10



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.

Page 1 of 3



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 AROMOATIC HYDROCARBONS (PAH) and POLYCHLORINATED BIPHENYL (PCB) STATEMENT

ALLANTOIN does not contain polycylic 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.

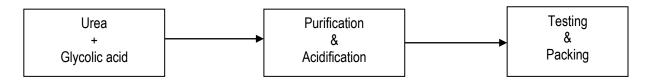
MOSH/MOAH STATEMENT

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

1.3. Details of the supplier of the safety data sheet

Supplier Madar Corporation Limited

19 - 20 Sandleheath Industrial Estate

Fordingbridge United Kingdom T: +44(0)1425 655 555

E: technical@madarcorporation.co.uk

1.4. Emergency telephone number

Emergency telephone +44(0)1425 655 555 (0900 - 1700hrs GMT)

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

ALLANTOIN

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.

IngestionNo adverse effects known.Skin contactNo 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

Do not use water jet as an extinguisher, as this will spread the fire.

media

ALLANTOIN

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.

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.

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.

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.

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

ALLANTOIN

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

Crystalline powder. **Appearance**

Colour White.

Odour Characteristic.

> 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK Tel: 01425 655555 Email: technical@madarcorporation.co.uk

> > Page 8 of 15

ALLANTOIN

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/m³

Solubility(ies) Slightly soluble in water. 1 g/190 ml water.

Auto-ignition temperatureNot available.Decomposition TemperatureNot available.ViscosityNot 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

None known.

reactions

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

ALLANTOIN

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

10.6. Hazardous decomposition products

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

products 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 LD₅o) LD₅o 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 sensitisationBased on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity - in vitroBased 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 LC₅o, 96 hours: >5000 mg/l, Fish

Acute toxicity - aquatic

EC₅₀, 48 hours: >100 mg/l, Daphnia magna

invertebrates

Acute toxicity - aquatic plants EC₅₀, 72 hours: >100 mg/l, Desmodesmus subspicatus 19-20 Sandleheath nutstrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

ALLANTOIN

Acute toxicity -

NOEC, : >1000 mg/l, Microorganisms, (OECD 209)

microorganisms

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

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

coefficient

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.

ALLANTOIN

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

Revision: 2 Revision date: 20/05/2021

ALLANTOIN

Classific	cation	abbre	viations	3
and acr	onym	3		

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 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

Tel: 01425 655555 Email: technical@madarcorporation.co.uk

ALLANTOIN

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



PRODUCT SPECIFICATION SHEET

ALLANTOIN

PROPERTY SPECIFICATION

CTFA Name Allantoin

Synonyms 1-(2,5-dioxoimidazolidin-4-yl)urea

Composition Glyoxyldiureide, 5 - ureidohydantoin

Empirical Formula C₄H₆O₃N₄

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/m³

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.