

Scientific Documentation

Allantoin, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Allantoin, USP (A2721)

Item Number	A2721
Item	Allantoin, USP
CAS Number	97-59-6
Molecular Formula	C ₄ H ₆ N ₄ O ₃
Molecular Weight	158.12
MDL Number	
Synonyms	5-Ureidohydantoin ; (2,5-Dioxo-4-imidazolidinyl)urea

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY	98.5	101.0 %
ACIDITY OR ALKALINITY	A YELLOW COLOR IS OBSERVED SOLUTION TURNS RED	
LOSS ON DRYING		0.1 %
ORGANIC IMPURITIES		0.5 %
RESIDUE ON IGNITION (SULPHATED ASH)		0.1 %
REDUCING SUBSTANCES	THE SOLUTION REMAINS VIOLET FOR AT LEAST 10 MIN.	
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
COBALT (Co)	AS REPORTED	
VANADIUM (V)	AS REPORTED	
NICKEL (Ni)	AS REPORTED	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	Rf VALUE CORRESPONDS STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		

Test	Specification	
	Min	Max
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	A2721	Lot Number	1NA0132
Item	Allantoin, USP	Manufacturer Lot	023/ALL/0322
CAS Number	97-59-6	Manufacturer Code	14912
Molecular Formula	C ₄ H ₆ N ₄ O ₃	Molecular Weight	158.12

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
ASSAY	98.5	101.0 %	100.5 %
ACIDITY OR ALKALINITY	A YELLOW COLOR IS OBSERVED SOLUTION TURNS RED		A YELLOW COLOR IS OBSERVED SOLUTION TURNS RED
LOSS ON DRYING		0.1 %	0.1 %
ORGANIC IMPURITIES		0.5 %	<0.5 %
RESIDUE ON IGNITION (SULPHATED ASH)		0.1 %	0.1 %
REDUCING SUBSTANCES	THE SOLUTION REMAINS VIOLET FOR AT LEAST 10 MIN.		THE SOLUTION REMAINS VIOLET FOR AT LEAST 10 MIN.
ELEMENTAL IMPURITIES:			.
CADMIUM (Cd)	AS REPORTED		<0.1 µg/g
ARSENIC (As)	AS REPORTED		<0.05 µg/g
COBALT (Co)	AS REPORTED		<0.01 µg/g
VANADIUM (V)	AS REPORTED		<0.5 µg/g
NICKEL (Ni)	AS REPORTED		<0.1 µg/g
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE

TEST	SPECIFICATION		RESULT
	MIN	MAX	
IDENTIFICATION (B)	Rf VALUE CORRESPONDS STANDARD		Rf VALUE CORRESPONDS STANDARD
EXPIRATION DATE			01-FEB-2025
DATE OF MANUFACTURE			01-MAR-2022
MONOGRAPH EDITION			(USP-NF) 2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT (M)
NOTE: All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

AMENDEZ
Ana Mendez
22-APR-24 11:49:53

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA



Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
22-APR-24 11:51:17

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by SALICYLATES & CHEMICALS PRIVATE LIMITED at A-25, Road No 18, IDA, Nacharam, Hyderabad, Telangana 500076, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 8/23/2016

Revision date 1/30/2019

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: A2721
Product Name: ALLANTOIN, USP, EP

Other means of identification

Synonyms: 5-Ureidohydantoin
 (2,5-Dioxo-4-imidazolidinyl)urea
CAS #: 97-59-6
RTECS # YT1600000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Tom Tyner (USA - West Coast)

Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Allantoin	97-59-6	100

4. FIRST AID MEASURES

First aid measures

General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. If symptoms persist, call a physician.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause skin irritation May cause eye irritation
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media:	Dry powder. Carbon dioxide (CO ₂). Water spray. Foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO _x).
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Specific hazards	May be combustible at high temperatures.
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Special Protective Actions for Firefighters

Specific Methods:	No information available
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Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Allantoin	97-59-6	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Allantoin	97-59-6	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Allantoin	97-59-6	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles or Safety glasses with side-shields.
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White.
Odor: Odorless.	Taste Tasteless.	Formula C ₄ H ₆ N ₄ O ₃
Molecular/Formula weight (g/mole): 158.12	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 238-239°C/460.4-462.2 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm³): No information available
Specific gravity: No information available	pH No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): -3.82	Viscosity: No information available

Miscibility:

No information available

Solubility:

Soluble in Alcohol
 Soluble in Methanol
 Soluble in Ethanol
 Soluble in pyridine
 Very slightly soluble in water

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

Chemical stability**Stability:**

Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur**Conditions to avoid:**

Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials:

Strong oxidizing agents

Hazardous decomposition products:

Carbon oxides. Nitrogen oxides (NOx).

Other Information**Corrosivity:**

No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Principal Routes of Exposure:**

None.

Acute Toxicity**Component Information**

Allantoin

CAS No	97-59-6
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LD50/oral/rat = No information available

LD50/oral/mouse = No information available

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

Value - Acute Tox = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
Value - Acute Tox = No information available

LD50/dermal/rat
VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.
Eye Contact: May cause eye irritation.
Inhalation May cause respiratory tract irritation.
Ingestion Health injuries are not known or expected under normal use.
Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity No information available.
Sensitization: No information available.
Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Allantoin	97-59-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available

Product code: A2721

Product name: ALLANTOIN, USP, EP

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Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: Potential for bioconcentration in aquatic organisms is low.

Mobility in soil No information available

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Allantoin	97-59-6	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name: No information available

Hazard Class No information available

Subsidiary Class No information available

Packing group: No information available

Emergency Response Guide No information available

Number

Marine Pollutant No data available

DOT RQ (lbs): No information available

Special Provisions No Information available

Symbol(s): No information available

Description: No information available

TDG (Canada)

UN-No: Not Regulated

Proper Shipping Name: No information available

Hazard Class No information available

Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available
Description: No information available

ADR

UN Number Not regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Packing group No information available
Subsidiary Risk: No information available

IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available

ICAO (air)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response IF exposed or concerned
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Allantoin	97-59-6	PresentACTIVE	PresentKE-12023	Present	Present(9)-199	Present	Present	Present202-592-8

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Allantoin	97-59-6	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Allantoin	97-59-6	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Allantoin	97-59-6	Not Applicable	Not Applicable

Canada**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Allantoin	97-59-6	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Allantoin	97-59-6	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Allantoin	97-59-6	Not listed

EU Classification**EU GHS - SV - CLP 1272/2008**

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Allantoin	97-59-6	

EU - CLP (1272/2008)**R-phrases)**

not determined (not applicable)

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Allantoin	97-59-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

None

16. OTHER INFORMATION

Preparation Date: 8/23/2016
Revision date 1/30/2019
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
A2721	Allantoin, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

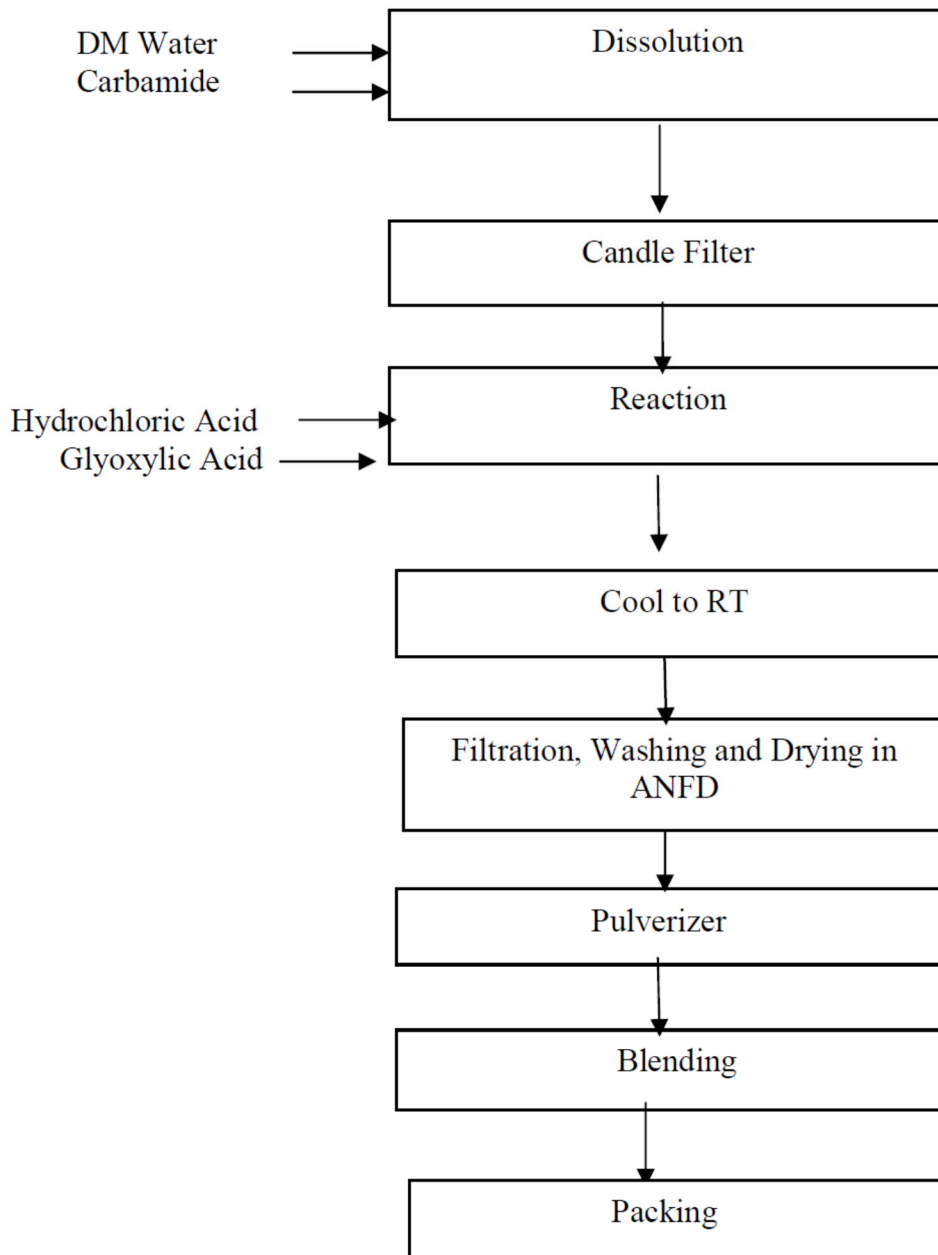
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Allantoin, USP (Cat# A2721)



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

A2721, Allantoin, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Allantoin, USP (Cat# A2721)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cobalt	Co	2A	< 5 ppm
Molybdenum	Mo	3	< 2 ppm
Chromium	Cr	3	< 5 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents - Allantoin, USP (Cat# A2721)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

A2721

SIZ SY

Allantoin

[(2,5-Dioxo-4-imidazolidinyl)-
urea; 5-Ureidohydantoin]

USP

CAS 97-59-6

CAUTION: For manufacturing, processing or repacking.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_4H_6N_4O_3$ F.W. 158.12

Manufacturer/Supplier Code ?
Manufacturer Lot Number..... ?

Assay 98.5-101.0%
Acidity or Alkalinity To pass test
MAXIMUM LIMITS

Loss on Drying 0.1%
Organic Impurities 0.5%
Residue on Ignition 0.1%
Reducing Substances To pass test
Elemental Impurities As reported
Residual Solvents To pass test

Repackaged by Spectrum as:

G 5/16GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000