

Scientific Documentation

Amantadine Hydrochloride, 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 Amantadine Hydrochloride, USP (AM102)

Item Number	AM102
Item	Amantadine Hydrochloride, USP
CAS Number	665-66-7
Molecular Formula	C ₁₀ H ₁₇ N•HCl
Molecular Weight	187.71
MDL Number	
Synonyms	Adamantanamine Hydrochloride

Test	Specification		
	Min	Max	
ASSAY	98.0	102.0 %	
pH OF A 20% SOLUTION	3.0	5.5	
ORGANIC IMPURITIES:			
AMANTADINE RELATED COMPOUND A		0.3 %	
AMANTADINE RELATED COMPOUND B		0.3 %	
Any individual unspecified impurity		0.10 %	
TOTAL IMPURITIES		1.0 %	
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		
RETEST DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS	AS REPORTED		

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	AM102	Lot Number	4MH0036
Item	Amantadine Hydrochloride, USP	Manufacturer Lot	120922
CAS Number	665-66-7	Manufacturer Code	15197
Molecular Formula	C ₁₀ H ₁₇ N•HCl	Molecular Weight	187.71

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
ASSAY	98.0	102.0 %	101.0 %	
pH OF A 20% SOLUTION	3.0	5.5	5.4	
ORGANIC IMPURITIES:				
AMANTADINE RELATED COMPOUND A		0.3 %	NONE DETECTED	
AMANTADINE RELATED COMPOUND B		0.3 %	NONE DETECTED	
Any individual unspecified impurity		0.10 %	NONE DETECTED	
TOTAL IMPURITIES		1.0 %	NONE DETECTED	
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
RETEST DATE			01-SEP-2027	
DATE OF MANUFACTURE			01-SEP-2022	
APPEARANCE			WHITE CRYSTALLINE POWDER	
RESIDUAL SOLVENTS	AS REPORTED			
CLASS 2 (solvent) TOLUENE			<890 ppm	
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm	
MONOGRAPH EDITION			USP 2023	
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm	
CLASS 1 (solvent) / BENZENE			<2 ppm	

Certificate of Analysis Results Entered By:

KMORALES Keyla Morales 27-SEP-23 09:39:38

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 29-SEP-23 08:55:57

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 Olainfarm JSC at 5 Rupnicu iela, Olaine, Olaines novads, LV-2114, Latvia (LVA). 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 SPECTRUM®



Revision date 01-June-2021 Revision Number 2

1. Identification

Product identifier

Product Name AMANTADINE HYDROCHLORIDE, USP

Other means of identification

Product Code(s) AM102

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 4
Reproductive toxicity	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful if swallowed

Suspected of damaging fertility or the unborn child



Appearance Crystalline powder Physical state Solid Odor Odorless

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Amantadine Hydrochloride	665-66-7	100	*

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Wash skin with soap and water.

Ingestion Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.

Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physiciansTreat symptomatically.

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children. Store locked up.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

> **Evewash stations** Ventilation systems.

Individual protection measures, such as personal protective equipment

No special protective equipment required. Eye/face protection

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

exceeded or irritation is experienced, ventilation and evacuation may be required.

None known

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Crystalline powder Color White; Off-white Odor Odorless

Odor threshold No information available

Property Values Remarks • Method рΗ no data available None known Melting point / freezing point no data available None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known

No data available

No data available

Flammability Limit in Air

Upper flammability or explosive

limits

Lower flammability or explosive

limits

Vapor pressure No data available Vapor density no data available Relative density no data available Water solubility No data available Solubility(ies) no data available No data available **Partition coefficient Autoignition temperature** no data available

360 - °C 680 °F **Decomposition temperature** no data available Kinematic viscosity No data available Dynamic viscosity

Other information

Explosive properties No information available **Oxidizing properties** No information available Softening point No information available Molecular weight No information available No information available **VOC Content (%) Liquid Density** No information available **Bulk density** No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoidNone known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Harmful if swallowed. (based

on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ī	Amantadine Hydrochloride	= 800 mg/kg (Rat)	-	-
L	665-66-7			

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

Skin corrosion/irritation
Serious eye damage/eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity

No information available.
No information available.
No information available.
No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

No information available.
No information available.
No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity The environmental impact of this product has not been fully investigated.

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

<u>IATA</u> not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

ENCS IECSCThis product complies with ENCS:
This product does not comply with china:

KECL Does not Comply **PICCS** Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Amantadine Hydrochloride - 665-66-7	developmental toxicity

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 0 Flammability 0 Instability 0

Physical and chemical properties -

HMIS

Health hazards *
Flammability 0
Physical hazards 0
Personal protection X

Chronic Hazard Star Legend *= Chronic Health Hazard

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 01-June-2021

Revision NoteNo information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The 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, unless specified in the text.

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
AM102	Amantadine Hydrochloride, 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,

Oralia Chavez

Quality Assurance Specialist

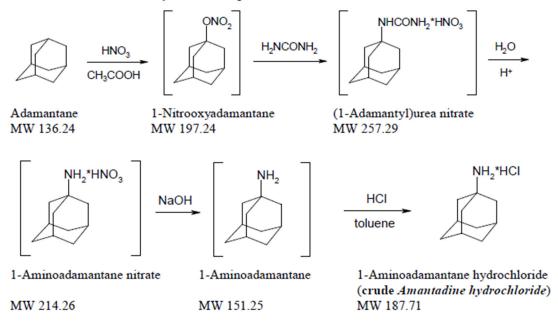
Order Clony



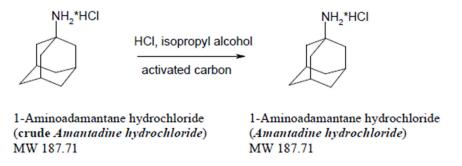
Manufacturing Process Flowchart

Amantadine Hydrochloride, USP (Cat# AM102)

TP-1. Crude Amantadine hydrochloride production



TP-2. Recrystallization of crude Amantadine hydrochloride



CORPORATE HEADQUARTERS

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



AM102, Amantadine Hydrochloride, 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

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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Amantadine Hydrochloride, USP (Cat# AM102)

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
Cadmium	Cd	1	< 0.05 ppm
Lead	Pb	1	< 0.05 ppm
Arsenic	As	1	< 0.05 ppm
Mercury	Hg	1	< 0.05 ppm
Cobalt	Со	2A	< 0.05 ppm
Vanadium	V	2A	< 0.45 ppm
Nickel	Ni	2A	< 0.05 ppm
Thallium	TI	2B	< 0.05 ppm
Gold	Au	2B	< 0.05 ppm
Palladium	Pd	2B	< 0.05 ppm
Ruthenium	Ru	2B	< 0.05 ppm
Selenium	Se	2B	< 0.05 ppm
Silver	Ag	2B	< 0.05 ppm
Platinum	Pt	2B	< 0.05 ppm
Lithium	Li	3	< 0.05 ppm
Antimony	Sb	3	< 0.05 ppm
Barium	Ba	3	< 0.05 ppm
Molybdenum	Мо	3	< 0.05 ppm
Copper	Cu	3	< 0.05 ppm
Chromium	Cr	3	< 0.05 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

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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.

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RE: Residual Solvents - Amantadine Hydrochloride, USP (Cat# AM102)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Benzene	1	< 2 ppm
Toluene	2	< 890 ppm
Acetic Acid	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

No other solvents are used or produced in the manufacturing process of this material.

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

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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

Sodium Acetate

Anhydrous

FCC



CAS 127-09-3

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

 $C_2H_3NaO_2$

F.W. 82.03

Assay (C ₂ H ₃ NaO ₂ ; Dried Basis)	
	. 99.0-101.0%
MAXIMUM LIMIT	S
Alkalinity (as NaOH)	0.2%
Lead	2 mg/kg
Loss on Drying	
Potassium Compounds	To pass test

HYGROSCOPIC: Keep tightly closed.

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 8/L5GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

West Coast Facility:

732.214.1300