

Scientific Documentation

Potassium Gluconate, Anhydrous, 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 Potassium Gluconate, Anhydrous, USP (PO178)

Item Number	PO178
Item	Potassium Gluconate, Anhydrous, USP
CAS Number	299-27-4
Molecular Formula	$C_6H_{11}KO_7$
Molecular Weight	234.25
MDL Number	
Synonyms	D-Gluconic Acid, Monopotassium Salt ; Monopotassium D-Gluconate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0	103.0 %
LOSS ON DRYING		3.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
REDUCING SUBSTANCES		1.0 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	VIOLET COLOR PRODUCED	
IDENTIFICATION (C)	PRINCIPAL SPOT CORRESPONDS TO STANDARD	
CERTIFIED HALAL		
EXPIRATION 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 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	PO178	Lot Number	1LH0685
Item	Potassium Gluconate, Anhydrous, USP	CAS Number	299-27-4
Molecular Formula	C ₆ H ₁₁ KO ₇	Molecular Weight	234.25

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	97.0	103.0 %	99.5 %
LOSS ON DRYING		3.0 %	0.2 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
REDUCING SUBSTANCES		1.0 %	<0.5 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	VIOLET COLOR PRODUCED		VIOLET COLOR PRODUCED
IDENTIFICATION (C)	PRINCIPAL SPOT CORRESPONDS TO STANDARD		PRINCIPAL SPOT CORRESPONDS TO STANDARD
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			31-JAN-2024
DATE OF MANUFACTURE			17-JAN-2021
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 2022

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
02-SEP-22 13:08:17

Certificate of Analysis Results Approved By:

JRUIZ
Jesus Ruiz
02-SEP-22 16:34:30

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



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.

SAFETY DATA SHEET

Preparation Date: 08/26/2015

Revision date 6/18/2019

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: PO178
Product Name: POTASSIUM GLUCONATE, ANHYDROUS, USP

Other means of identification

Synonyms: D-Gluconic acid, potassium salt (1:1)
 D-Gluconic acid, monopotassium salt
 Gluconic acid potassium salt
 Gluconic acid, monopotassium salt
 Kalium Gluconate
 Monopotassium D-gluconate
 Potassium D-gluconate
CAS #: 299-27-4
RTECS # LZ5230000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
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)

Product code: PO178

Product name: POTASSIUM
 GLUCONATE, ANHYDROUS, USP

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Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Potassium Gluconate, Anhydrous	299-27-4	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. Consult a physician if necessary.
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 May cause respiratory irritation Ingestion may cause nausea, vomiting, and diarrhea Abdominal pain Central nervous system effects May affect the urinary system
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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 chemical. Carbon dioxide (CO2). Water spray mist, or 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. Potassium oxides.

Specific hazards

May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods:

No information available

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions:

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

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering 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. 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:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Potassium Gluconate, Anhydrous	299-27-4	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Potassium Gluconate, Anhydrous	299-27-4	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Potassium Gluconate, Anhydrous	299-27-4	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. 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: Safety glasses with side-shields.

Skin and body protection: Chemical resistant apron
Long sleeved clothing
Gloves

Respiratory protection: Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient.

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:
Crystals.

Color:
White to yellowish.

Odor:
Odorless.

Taste
Saline. Slight.

Formula
C₆H₁₁KO₇

Molecular/Formula weight (g/mole): 234.25

Flammability (solid, gas)
no data available

Flash point (°C):
180°C

Flashpoint (°C/°F):
180°C/ 356°F

Flash Point Tested according to:
Closed cup

Autoignition Temperature (°C/°F):
No information available

Lower Explosion Limit (%): No information available	Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): No information available
Decomposition temperature(°C/°F): 180°C/ 356°F	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 7.5-8.5
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): No information available
Viscosity: No information available	Miscibility: No information available	Solubility: Easily soluble in cold water Insoluble in diethyl ether Insoluble in Alcohol Insoluble in Benzene Insoluble in Chloroform

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Oxides of potassium.

Other Information

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion.

Acute Toxicity

Component Information

Product code: PO178

Product name: POTASSIUM
GLUCONATE, ANHYDROUS, USP

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Potassium Gluconate, Anhydrous	
CAS No	299-27-4

LD50/oral/rat = 10380 mg/kg Oral LD50 Rat
LD50/oral/mouse = 9100 mg/kg
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 Toxicity = 10380 mg/kg

LD50/oral/mouse =
Value - Acute Tox = 9100 mg/kg

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

LD50/dermal/rat
VALUE - Acute Tox = 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 May cause digestive (gastrointestinal) tract irritation. May cause nausea, vomiting, diarrhea, abdominal discomfort, and pallor. May cause hypokalemia. May affect behavior/central nervous system/nervous system (altered sleep time, listlessness, weakness, muscular cramps, numbness of extremities, cardiovascular system (hypotension, dysrhythmias), urinary system/kidneys (renal failure, tubular necrosis).

Aspiration hazard No information available.

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

Chronic Toxicity Prolonged and repeated ingestion may cause weight loss or anorexia. Prolonged or repeated ingestion may affect the urinary system.

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
Potassium Gluconate, Anhydrous	299-27-4	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

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: Lungs. Kidneys. Mucous membrane.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

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	RCRA - K Series	RCRA - P Series	RCRA - U Series
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		Wastes	Wastes	Wastes	Wastes
Potassium Gluconate, Anhydrous	299-27-4	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 Number No information available
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 No information available
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.
Potassium Gluconate, Anhydrous	299-27-4	PresentACTIVE	Present KE-17677	Present	Present (2)-3912	Present	Present	Present 206-074-2

U.S. Regulations

Potassium Gluconate, Anhydrous

FDA - 21 CFR - Total Food Additives Present (not regulated under 21 CFR)
- List Sourced from EAFUS

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:
Potassium Gluconate, Anhydrous	299-27-4	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
Potassium Gluconate, Anhydrous	299-27-4	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
Potassium Gluconate, Anhydrous	299-27-4	Not Applicable	Not Applicable

Canada**WHIMIS 2015 - GHS Classifications**

Product code: PO178

Product name: POTASSIUM
GLUCONATE, ANHYDROUS, USP

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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)
Potassium Gluconate, Anhydrous	299-27-4	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Potassium Gluconate, Anhydrous	299-27-4	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Potassium Gluconate, Anhydrous	299-27-4	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Potassium Gluconate, Anhydrous	299-27-4	

EU - CLP (1272/2008)

R-phrases(s)

not determined (not applicable)

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Potassium Gluconate, Anhydrous	299-27-4		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: 08/26/2015
Revision date 6/18/2019
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
PO178	Potassium Gluconate, Anhydrous, 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

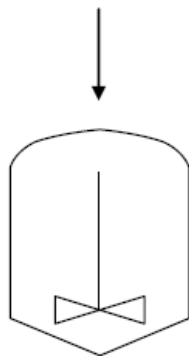
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

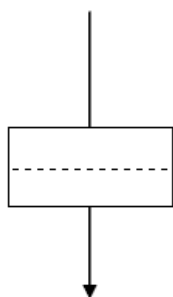
Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Potassium Gluconate, Anhydrous, USP (Cat# PO178)

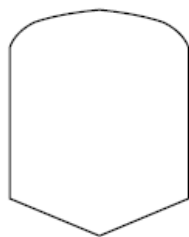
Glucono-delta-lactone, potassium
source, water



neutralization
reactions



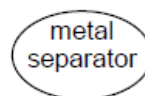
filtration



spray drying



sieving



metal
separator



packaging

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

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WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

PO178, Potassium Gluconate, Anhydrous, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis using plant derived material (fermentation of glucose syrup). No animal 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 or ethylene oxide (EtO).

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 - Potassium Gluconate, Anhydrous, USP (Cat# PO178)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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

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New Brunswick, NJ 08901
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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 - Potassium Gluconate, Anhydrous, USP (Cat# PO178)

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.

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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

P0178

SIZ SY

**Potassium
Gluconate**
(D-Gluconic Acid, Monopotassium Salt; Monopotassium D-Gluconate)
Anhydrous
USP
CAS 299-27-4

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

$C_6H_{11}KO_7$ F.W. 234.25

Assay (Dried Basis)..... 97.0-103.0%
MAXIMUM LIMITS
Loss on Drying.....3.0%
Reducing Substances1.0%
Elemental ImpuritiesAs reported
Residual SolventsTo pass test

Exp. Date: 00-00-0000



G 11/18GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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