

Scientific Documentation

Potassium Sorbate, Granular, NF

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 Sorbate, Granular, NF (PO301)

Item Number	PO301
Item	Potassium Sorbate, Granular, NF
CAS Number	24634-61-5
Molecular Formula	$C_6H_7KO_2$
Molecular Weight	150.22
MDL Number	
Synonyms	2,4-Hexadienoic Acid Potassium Salt

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION (A)	POSITIVE FOR POTASSIUM	
IDENTIFICATION B (FTIR)	SPECTRUM MATCHES REFERENCE	
POTASSIUM SORBATE CONTENT (DRIED BASIS)	98.0	102.0 %
POTASSIUM CONTENT	24.5	27.6 %
ACIDITY		1.1 ML NAOH
ALKALINITY		0.80 ML HCl
LOSS ON DRYING		1.0 %
ALDEHYDE (as ACETALDEHYDE)		0.15 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)		AS REPORTED
LEAD (Pb)		AS REPORTED
ARSENIC (As)		AS REPORTED
MERCURY (Hg)		AS REPORTED
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

Test	Specification	
	Min	Max
CLASS 3 (solvent) / ACETONE	.	
CLASS 3 (solvent) / 2-PROPANOL	.	
MONOGRAPH EDITION		

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	PO301	Lot Number	1NB0082
Item	Potassium Sorbate, Granular, NF	CAS Number	24634-61-5
Molecular Formula	C ₆ H ₇ KO ₂	Molecular Weight	150.22

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE GRANULES
IDENTIFICATION (A)	POSITIVE FOR POTASSIUM		POSITIVE FOR POTASSIUM
IDENTIFICATION B (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
POTASSIUM SORBATE CONTENT (DRIED BASIS)	98.0	102.0 %	100.1 %
POTASSIUM CONTENT	24.5	27.6 %	26.026 %
ACIDITY		1.1 ML NAOH	<1.1 ML
ALKALINITY		0.80 ML HCl	<0.80 ML
LOSS ON DRYING		1.0 %	0.15 %
ALDEHYDE (as ACETALDEHYDE)		0.15 %	<0.15 %
ELEMENTAL IMPURITIES:			.
CADMIUM (Cd)		AS REPORTED	<0.02 µg/g
LEAD (Pb)		AS REPORTED	<2 µg/g
ARSENIC (As)		AS REPORTED	<3 µg/g
MERCURY (Hg)		AS REPORTED	<1 µg/g
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			01-JAN-2026
DATE OF MANUFACTURE			01-JAN-2024
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 3 (solvent) / ACETONE	.		<5000 ppm
CLASS 3 (solvent) / 2-PROPANOL	.		<5000 ppm
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
28-FEB-24 14:31:05

Certificate of Analysis Results Approved By:

AMENDEZ
Ana Mendez
29-FEB-24 10:14:54

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

spectrum®



Revision date 09-February-2022

Revision Number 4

1. Identification

Product identifier

Product Name POTASSIUM SORBATE, GRANULAR, NF

Other means of identification

Product Code(s) PO301

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

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2B

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes skin irritation
Causes eye irritation



Appearance Crystalline powder or
Granular or Powder

Physical state Solid

Odor Characteristic

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Wear protective gloves

Precautionary Statements - Response

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

IF ON SKIN: Wash with plenty of water and soap

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Potassium Sorbate	590-00-1	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. Get medical attention immediately if symptoms occur.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Skin contact

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider

Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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 physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the 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.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Potassium oxides.
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	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.
Other information	Refer to protective measures listed in Sections 7 and 8.

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. Take off contaminated clothing and wash before reuse.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
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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
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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
 Eyewash stations
 Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline powder or Granular or Powder
Color White
Odor Characteristic
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	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
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.363	None known
Water solubility	Easily soluble in cold water	None known
Solubility(ies)	Soluble in Alcohol	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature	270 - °C 518 °F	None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties No information available
Oxidizing properties No information available
Softening point No information available
Molecular weight 150.22 g/mol

VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	0.67 g/L

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.
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. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. May cause redness and tearing of the eyes.
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Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Potassium Sorbate 590-00-1	= 3800 mg/kg (Rat)	-	-

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

Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Irritating to eyes.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.

Aspiration hazard	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	No information available.
Bioaccumulation	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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

15. Regulatory information

International Inventories

TSCA	Complies
DSL/NDL	Complies
EINECS/ELINCS	Does not Comply
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies

AICS

This product does not comply with 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 does not contain any Proposition 65 chemicals.

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 2

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 0

Physical hazards 0

Personal protection X

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 09-February-2022

Revision Note No 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
PO301	Potassium Sorbate, Granular, NF

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

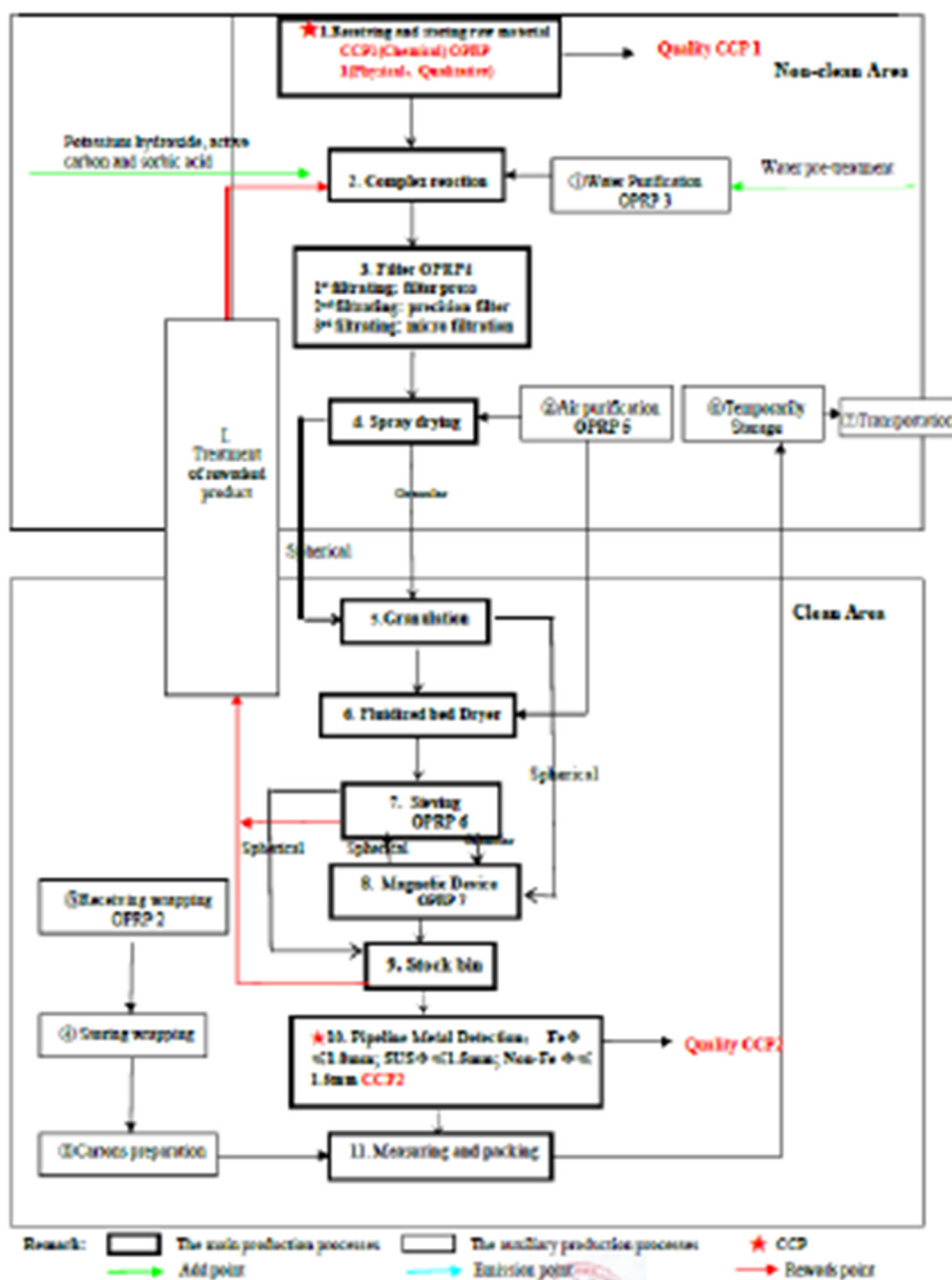
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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

Manufacturing Process Flowchart - Potassium Sorbate, Granular, NF (Catalog No. PO301)

Process Flow Chart of Potassium Sorbate



PO301, Potassium Sorbate, Granular, NF

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

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 the above-mentioned 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 24 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 |

Elemental Impurities - Potassium Sorbate, Granular, NF (Catalog No. PO301)

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	< 0.02 ppm
Lead	Pb	1	< 2 ppm
Arsenic	As	1	< 3 ppm
Mercury	Hg	1	< 1 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 the 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.

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.



Exp. Date: 00-00-0000

* 4 9 4 5 2 0 3 0 1 *



P0301 **SIZ SY**

Potassium Sorbate

(2,4-Hexadienoic Acid Potassium Salt)

Granular, NF

CAS 590-00-1



$C_6H_7KO_2$ F.W. 150.22

Assay:

Potassium Sorbate Content (Dried Basis)	98.0-102.0%
Potassium Content	24.5-27.6%
Acidity or Alkalinity	To pass test

MAXIMUM LIMITS

Loss on Drying	1.0%
Aldehyde (as Acetaldehyde)	0.15%
Elemental Impurities	As reported
Residual Solvents	To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

WARNING

- Causes skin and eye irritation • May be harmful if swallowed.
- Wear protective gloves • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention.

KEEP FROM CHILDREN

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

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

G 11/J4GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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