spectrum®

Scientific Documentation

P9110, Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED [™]

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> 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

Ver4.06 04.February.2022

P9110, Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED ™

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Spectrum[®]



Specification for Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED (TM) (P9110)

Item Number	P9110
Item	Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED (TM)
CAS Number	127-08-2
Molecular Formula	C ₂ H ₃ KO ₂
Molecular Weight	98.14
MDL Number	
Synonyms	

Test	Speci	fication
	Min	Max
ASSAY	99 %	
pH OF A 5% SOLUTION	7.5	9.0
LOSS ON DRYING		1 %
ARSENIC		3 mg/kg
Formic Acid, Formates, Other Oxidizable Substances		1000 mg/kg
MERCURY		1 mg/kg
LEAD		2 mg/kg
MICROBIAL LIMITS:		
ТАМС		1000 CFU/g
ТҮМС		100 CFU/g
BACTERIAL ENDOTOXINS		6.0 EU/g
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		

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

Spectrum® CHEMICAL MFG CORP Trusted Since 1971

Certificate Of Analysis

Item Number	P9110	Lot Number	4KH0013
Item	Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED (TM)	CAS Number	127-08-2
Molecular Formula	C ₂ H ₃ KO ₂	Molecular Weight	98.14

TECT	SPECIFICATION		
TEST	MIN	ΜΑΧ	RESULT
ASSAY	99 %		101%
pH OF A 5% SOLUTION	7.5	9.0	8.6
LOSS ON DRYING		1 %	0.6%
ARSENIC		3 mg/kg	<0.05 mg/kg
Formic Acid, Formates, Other Oxidizable Substances		1000 mg/kg	<1000 mg/kg
MERCURY		1 mg/kg	<0.05 mg/kg
LEAD		2 mg/kg	<0.05 mg/kg
MICROBIAL LIMITS:			
ТАМС		1000 CFU/g	<1000 CFU/g
ТҮМС		100 CFU/g	<100 CFU/g
BACTERIAL ENDOTOXINS		6.0 EU/g	<6.0 EU/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			31-DEC-2022
DATE OF MANUFACTURE			01-DEC-2020
APPEARANCE			WHITE POWDER

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ Certificate of Analysis Results Certified By:

isha. Pate

Jigisha Patel VP Regulatory Compliance & Technical Services, Regulatory

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.



SAFETY DATA SHEET

Revision date 25-January-2022

1. Identification	
Product identifier	
Product Name	POTASSIUM ACETATE, ENDOTOXIN TESTED, cGMP, bioCERTIFIED™
Other means of identification	
Product Code(s)	P9110
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

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

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

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

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Crystals or Crystalline powder

Physical state Solid

Odor Odorless



Revision Number 1

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Potassium Acetate	127-08-2	100	*

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

4. First-aid measures
4. First-aid measures

Description of first aid measures

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	Clean mouth with water and drink afterwards plenty of water.	
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 Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. 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	he 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.
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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
 Handle in accordance with good industrial hygiene and safety practice.

 Conditions for safe storage, including any incompatibilities
 Deliquescent. Protect from moisture. Keep container tightly closed in a dry and well-ventilated place.

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 Eyewash stations Ventilation systems.	
Individual protection measures, such as personal protective equipment		
Eye/face protection	No special protective equipment required.	
Skin and body protection	No special protective equipment required.	
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	Handle in accordance with good industrial hygiene and safety practice.	

9. Physical and chemical properties

Information on basic physical and chemical properties Physical state Solid

Appearance Color Odor Odor threshold	Crystals or Crystalline powder Colorless; White Odorless No information available	
Property	Values	Remarks • Method
рН	7.8-8.5 (5% solution @ 25)	None known
Melting point / freezing point	292 °C / 557.6 °F	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	1.57	None known
Water solubility	Easily soluble in cold water Easily soluble in hot water	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		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	98.14	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	No information available.	
Chemical stability	Stable under recommended storage conditions.	
Possibility of hazardous reactions	None under normal processing.	
Conditions to avoid	None 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

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.

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
Potassium Acetate	= 3250 mg/kg (Rat)	-	-
127-08-2			

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	No information available.
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

ECOTOXICITY	•			
Chemical name	Algae/aquatic plants	Fish	. Toxicity to	Crustacea
			microorganisms	
Potassium Acetate	-	LC50: =6800mg/L (96h,	-	EC50: =7170mg/L (24h,
127-08-2		Oncorhynchus mykiss)		Daphnia magna)
Persistence and degradabilityNo information available.BioaccumulationInherently biodegradable.				
Other adverse effects	No information	on 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
IATA	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	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
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 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 0 Flammability 0 Instability 0 Physical and chemical properties -HMIS Health hazards 0 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 (time-weighted average) STEL (Short Term Exposure Limit) TWA STEL 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	25-January-2022
Revision Note	No information available.
<u>Disclaimer</u>	

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

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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
P9110	Potassium Acetate, Endotoxin Tested, cGMP
	bioCERTIFIED ™

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:	<u>2246824</u>

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 <u>qualityassurance@spectrumchemical.com</u>

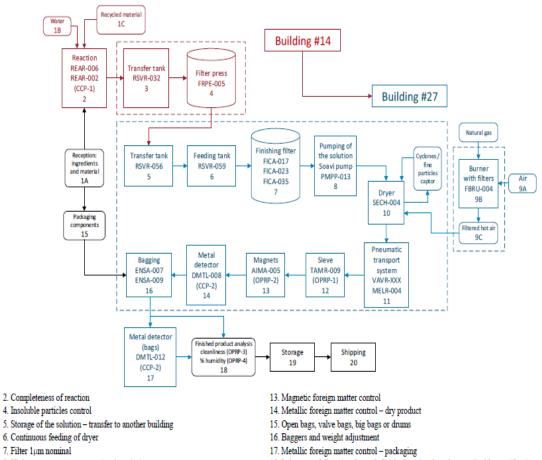
Sincerely,

Oulu Clony

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED™ (Cat# P9110)



- 8. High-pressure pump to vaporize the solution
- 10. Control of drying parameters
- 12. Vibrating sieve (24 mesh) particle size control
- 18. Laboratory full testing for each finished product based on applicable specifications
- 19. Closed warehouse, normal temperature and humidity conditions recorded
- 20. Trailers and containers

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

P9110, Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED[™]

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

spectrum

- 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 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum

RE: Elemental Impurities - Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED™ (Cat# P9110)

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	< 0.06 ppm
Lead	Pb	1	< 0.15 ppm
Arsenic	As	1	< 0.45 ppm
Mercury	Hg	1	< 0.09 ppm
Cobalt	Со	2A	< 0.15 ppm
Vanadium	V	2A	< 0.3 ppm
Nickel	Ni	2A	< 0.6 ppm
Palladium	Pd	2B	< 0.3 ppm
Iridium	lr	2B	< 0.3 ppm
Rhodium	Rh	2B	< 0.3 ppm
Lithium	Li	3	< 7.5 ppm
Antimony	Sb	3	< 2.7 ppm
Copper	Cu	3	< 9 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.

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



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

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

AN ISO 9001:2015 REGISTERED COMPANY



RE: Residual Solvents - Potassium Acetate, Endotoxin Tested, cGMP, bioCERTIFIED™ (Cat# P9110)

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
Acetic Acid	3	< 5000 ppm

No Class 1, Class 2, or 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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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spectrum®

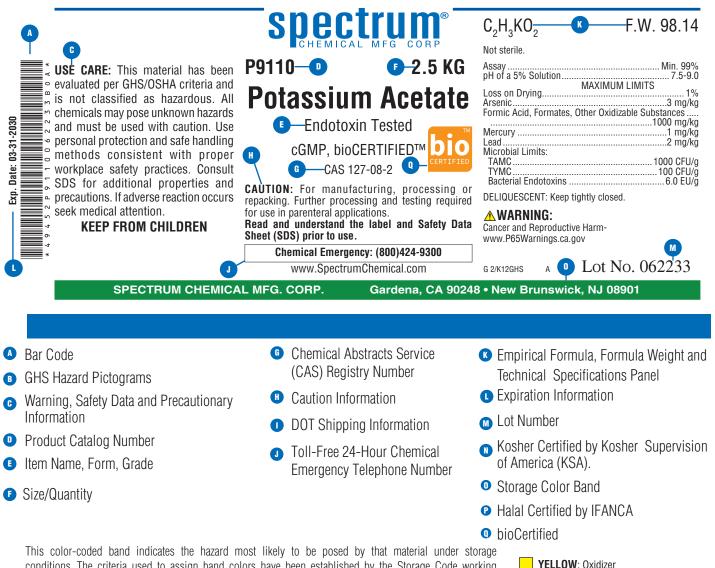
RED: Flammable

GREEN: General Storage

BLUE: Health Hazard WHITE: Corrosive

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.



conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

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

spectrum

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010 The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
 2 = New Brunswick, NJ Facility
 3 = China Facility
 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011 Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at <u>guality_assurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Oulu Clony

Oralia Chavez, Quality Assurance Specialist

CORPORATEHEADQUARTERS

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A N IS O 9 001 : 201 5 R E GI STE R ED C O M P AN Y