

# **Scientific Documentation**

**S9401**, Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED TM

Not appropriate for regulatory submission. Please visit <a href="www.spectrumchemical.com">www.spectrumchemical.com</a> 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

#### **S9401,** Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED™

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#### Specification for Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED (TM) (S9401)

Item Number	S9401
Item	Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED (TM)
CAS Number	7601-54-9
Molecular Formula	$Na_3PO_4$
Molecular Weight	163.94
MDL Number	
Synonyms	Tribasic Sodium Phosphate ; Trisodium Phosphate

Test	Spe	cification
	Min	Max
Assay (Na3PO4; Ignited Basis)	97.0 %	
ARSENIC		3 ppm
INSOLUBLE SUBSTANCES		0.2 %
LOSS ON IGNITION		2.0 %
ELEMENTAL IMPURITIES		AS REPORTED
MICROBIAL LIMITS:		
TAMC		1000 CFU/g
TYMC		100 CFU/g
Endotoxins		10 IU/g
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

#### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901

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West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

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# SAFETY DATA SHEET SPECTRUM®



Revision date 11-June-2021 Revision Number 1

#### 1. Identification

**Product identifier** 

Product Name SODIUM PHOSPHATE TRIBASIC, ANHYDROUS, NF, BIOCERTIFIED(TM)

Other means of identification

Product Code(s) S9401

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 2A
Specific target organ toxicity (single exposure)	Category 3

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Warning

#### Hazard statements

Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



**Appearance** Crystalline powder or Crystals or Granular

Physical state Solid

Odor Odorless

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area Wear protective gloves/eye protection/face protection

#### **Precautionary Statements - Response**

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

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Call a POISON CENTER or doctor if you feel unwell

#### **Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed 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
Sodium Phosphate Tribasic	7601-54-9	100	*

<sup>\*</sup>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. IF exposed or concerned: Get medical advice/attention. 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. Do not rub affected area.

**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** 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.

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** May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

#### 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. Use personal protective equipment as required. Evacuate

personnel to safe areas. Avoid contact with skin, eyes or clothing.

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. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

Conditions for safe storage, including any incompatibilities

Storage Conditions Hygroscopic. It absorbs moisture from the air. Protect from moisture. Keep containers

#### 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** If splashes are likely to occur, wear safety glasses with side-shields.

**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 Crystals or Granular

Color White Odor Odorless

Odor threshold No information available

Property	<u>Values</u>	Remarks • Method
pH	11.5-12 (1% solution)	None known
Melting point / freezing point	1583 °C / 2881.4 °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	No data available	
limits		
l fl	Nie dete evelleble	

Lower flammability or explosive No data available

limits

No data available None known Vapor pressure Vapor density no data available None known Relative density 1.62 None known Water solubility Soluble in water None known Solubility(ies) no data available None known No data available Partition coefficient None known Autoignition temperature

**Decomposition temperature** 

no data available None known

None known

Kinematic viscosity Dynamic viscosity

no data available No data available None known None known

Other information

**Explosive properties** No information available No information available Oxidizing properties No information available Softening point

Molecular weight 163.94

**VOC Content (%)** No information available **Liquid Density** No information available No information available **Bulk density** 

#### 10. Stability and reactivity

Reactivity No information available.

**Chemical stability** Stable under recommended storage conditions.

Possibility of hazardous reactions None under normal processing.

None known based on information supplied. Conditions to avoid

Strong acids. Strong bases. Strong oxidizing agents. Incompatible materials

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 serious eye irritation.

Skin contact Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

Specific test data for the substance or mixture is not available. Ingestion may cause Ingestion

gastrointestinal irritation, nausea, vomiting and diarrhea.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. May cause redness and tearing of the eyes.

Acute toxicity

**Numerical measures of toxicity** 

**Component Information** 

	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
[	Sodium Phosphate Tribasic 7601-54-9	> 2000 mg/kg (Rat)	> 300 mg/kg (Rabbit)	> 2.16 mg/L (Rat)1 h

Skin corrosion/irritation

Serious eye damage/eye irritation Respiratory or skin sensitization

Germ cell mutagenicity

Classification based on data available for ingredients. Irritating to skin.

Classification based on data available for ingredients. Causes serious eye irritation.

No information available. No information available.

Reproductive toxicity No information available.

STOT - single exposure STOT - repeated exposure **Aspiration hazard** 

May cause respiratory irritation. No information available. No information available.

Other adverse effects No information available.

Interactive effects No information available.

#### 12. Ecological information

**Ecotoxicity** 

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Sodium Phosphate	-	LC50 220 mg/l 96 h	-	177 mg/l 50 h Daphnia
Tribasic		Bluegill sunfish		
7601-54-9		LC50 120 mg/l 96 h		
		Rainbow trout		

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

not regulated MEX

ICAO (air) not regulated

not regulated <u>IATA</u>

<u>IMDG</u> not regulated

<u>RID</u> not regulated

not regulated ADR

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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Sodium Phosphate Tribasic	5000 lb final RQ	-
7601-54-9	2270 kg final RQ	

#### **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 3 Flammability 0 Instability 0

Physical and chemical properties -

HMIS

Health hazards 3
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 11-June-2021

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
S9401	Sodium Phosphate Tribasic, Anhydrous, NF, 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: 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

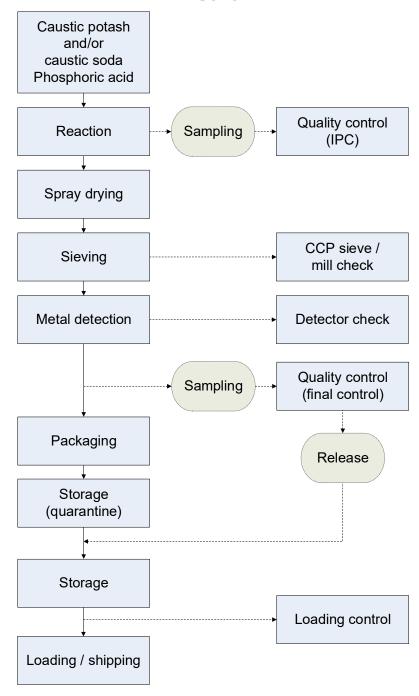
Quality Assurance Specialist

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#### **Manufacturing Process Flowchart**

Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED™
- S9401



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Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



# **S9401**, Sodium Phosphate Tribasic, Anhydrous, NF, 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
- 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 for cosmetic purposes. Animal testing has been conducted only for regulatory compliance purposes.

#### **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 - Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED ™ (Cat# S9401)

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	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 1 ppm
Cobalt	Co	2A	< 5 ppm
Vanadium	V	2A	< 3 ppm
Nickel	Ni	2A	< 6 ppm

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

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

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

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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## RE: Residual Solvents - Sodium Phosphate Tribasic, Anhydrous, NF, bioCERTIFIED ™ (Cat# S9401)

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
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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.



- Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Size/Quantity

- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Nosher Certified by Kosher Supervision of America (KSA).
- Storage Color Band
- Halal Certified by IFANCA
- bioCertified

This color-coded band indicates the hazard most likely to be posed by that material under storage 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

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#### **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 928<sup>th</sup> 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 706<sup>th</sup> 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 quality\_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,

**Quality Assurance Specialist** 

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