

# **Scientific Documentation**

# Potassium Phosphate Tribasic, FCC

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 Phosphate Tribasic,** FCC (P1379)

Item Number	P1379	
Item	Potassium Phosphate Tribasic, FCC	
CAS Number	7778-53-2	
Molecular Formula	$K_3PO_4$	
Molecular Weight	212.27	
MDL Number		
Synonyms	Tripotassium Phosphate	

Test	Specification		
	Min	Max	
APPEARANCE			
IDENTIFICATION	TO PASS TEST		
ASSAY (IGNITED)	97.0 %		
ARSENIC (As)		3 mg/kg	
FLUORIDE		10 mg/kg	
INSOLUBLE SUBSTANCES		0.2 %	
LEAD (Pb)		2 mg/kg	
LOSS ON IGNITION		5.0 %	
CERTIFIED KOSHER			
CERTIFIED HALAL			
EXPIRATION DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			

#### Spectrum Chemical Mfg Corp

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



# **Certificate Of Analysis**

Item Number	P1379	Lot Number	1ML0064
Item	Potassium Phosphate Tribasic, FCC	CAS Number	7778-53-2
Molecular Formula	K <sub>3</sub> PO <sub>4</sub>	Molecular Weight	212.27

TECT	SPECIFICATION		DECLUIT.
TEST	MIN	MAX	RESULT
APPEARANCE			WHITE POWDER
IDENTIFICATION	TO PASS TEST		PASSES TEST
ASSAY (IGNITED)	97.0 %		99.9 %
ARSENIC (As)		3 mg/kg	0.08 mg/kg
FLUORIDE		10 mg/kg	<10 mg/kg
INSOLUBLE SUBSTANCES		0.2 %	<0.2 %
LEAD (Pb)		2 mg/kg	<1 mg/kg
LOSS ON IGNITION		5.0 %	1.5 %
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			08-APR-2026
DATE OF MANUFACTURE			09-APR-2023
MONOGRAPH EDITION			(FCC) 13TH

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 31-JAN-24 17:08:53

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 01-APR-24 14:09:49

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 SPECTRUM®



Revision date 14-November-2022 Revision Number 2

#### 1. Identification

**Product identifier** 

Product Name POTASSIUM PHOSPHATE TRIBASIC, FCC

Other means of identification

Product Code(s) P1379

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** Granular or Crystalline powder or Powder

Physical state Solid

Odor No information available

#### **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**

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

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

May be harmful if swallowed. May be harmful in contact with skin.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
Potassium Phosphate Tribasic	7778-53-2	100

#### 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

**Note to physicians**Treat symptomatically.

#### 5. Fire-fighting measures

surrounding environment.

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

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

Specific hazards arising from the

chemical

No information available.

Hazardous combustion products Chloroform does not burn, but may decompose upon heating to produce the following if

involved in a fire: carbon monoxide, carbon dioxide, hydrogen chloride and chlorine.

Phenols. Sodium 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 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.

Conditions for safe storage, including any incompatibilities

#### 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.

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 Granular or Crystalline powder or Powder

**Color** White

Odor No information available No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH of a 1% solution @ 25 deg. C = None known

11.9

> 1300 °C / 2372 °F Melting point / freezing point None known no data available None known Boiling point / boiling range Flash point no data available None known None known **Evaporation rate** no data available Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure

Vapor density

Relative density

Vapor density

Solubility

None known

Partition coefficient
Autoignition temperature

No data available no data available

None known None known

Decomposition temperature

None known

Kinematic viscosity

Dynamic viscosity

no data available No data available

None known None known

Other information

Explosive properties

Oxidizing properties

No information available

#### 10. Stability and reactivity

**Reactivity** No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to 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 serious 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.

**Acute toxicity** 

**Numerical measures of toxicity** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Potassium Phosphate Tribasic	= 2000 mg/kg (Rat)	> 4640 mg/kg (Rabbit)	-
7778-53-2			

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

Other adverse effects No information available.

Interactive effects No information available.

#### 12. Ecological information

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

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

#### 13. Disposal considerations

Waste treatment methods

Waste from residues/unused products

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

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

#### 14. Transport information

**DOT** not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

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

<u>NFPA</u>

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 14-November-2022 Revision Note 14-November-2022 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
P1379	Potassium Phosphate Tribasic, FCC

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

Sincerely,

Oralia Chavez

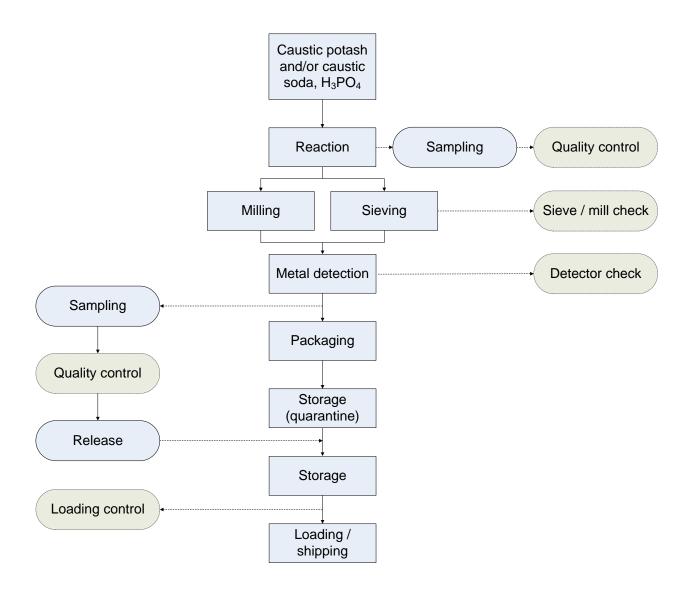
**Quality Assurance Specialist** 

Order Clony



## **Manufacturing Process Flowchart**

# **Potassium Phosphate Tribasic, FCC - P1379**



#### 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



# P1379, Potassium Phosphate Tribasic, FCC

#### **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.

#### **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

#### **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

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

- Parabens
- Pesticides
- Phthalates
- Preservatives



#### **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.





0000-00-00

Date:

• Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation • Mav be harmful if swallowed.

· Wear protective gloves, eye protection, face protection . Avoid breathing dust . Use only outdoors or in a well-ventilated area . 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. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

**KEEP FROM CHILDREN** 

#### SIZ SY P1379 **Potassium Phosphate Tribasic**

KSA

**FCC** CAS 7778-53-2



**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

 $K_3PO_4$ 

F.W. 212.27

Assay (K<sub>3</sub>PO<sub>4</sub>; Ignited Basis) .....Min. 97.0% MAXIMUM LIMITS Arsenic (as As) ...... 3 mg/kg Fluoride ...... 10 mg/kg Insoluble Substances ......0.2% Lead ......2 mg/kg Loss on Ignition ......5.0%

DELIQUESCENT: Keep tightly closed.

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

G 10/L1GHS

Lot No. XQ####

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

732.214.1300

New Brunswick, NJ 08901

West Coast Facility:

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000





The following product(s) prepared by the named company are certified kosher with the stated requirements:

#### **Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA

**Product Name** P1379, Potassium Phosphate Tribasic, FCC

**Brand** Spectrum

UKD-ID KSAV3-L5N7J94

D/P/M P

Symbol Required KSA

**Special Conditions** 

This certificate expires on **Feb 01, 2025** 

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.



This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: September 01, 2023

Document #: 11205.11206.II235543

Company Name & Address: Spectrum Laboratory Products, Inc. 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA

Plant Name & Address: Spectrum Laboratory Products, Inc. 769-Jersey Ave New Brunswick, New Jersey 08901 USA

ProductNameProduct CodeHalal-IDProduct Certificate #1. Potassium Phosphate Tribasic, FCCP1379C54245HC-23SP9K50

Muhammad Munir Chaudry, Ph.D. President





This Certificate is valid until **August 31, 2024** and subject to renewal at that time.



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