

# **Scientific Documentation**

**PO204**, Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP

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



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA Senior Manager of Technical Services techservices@spectrumchemical.com

19.May.2016

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# Specification for Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP (PO204)

Item Number	<u>PO204</u>
Item	Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP
CAS Number	7758-11-4
Molecular Formula	$K_2HPO_4$
Molecular Weight	174.18
MDL Number	
Synonyms	Dipotassium Hydrogen Phosphate ; Dipotassium Phosphate

Test	Specification		
	Min	Max	
ASSAY (K₂HPO₄; DRIED BASIS)	98.0 - 100.5 %		
pH OF A 1 IN 20 SOLUTION	8.5 - 9.6		
LOSS ON DRYING		1.0 %	
INSOLUBLE SUBSTANCES		0.2 %	
CARBONATE	TO PASS TEST		
CHLORIDE (CI)		0.02 %	
SULFATE		0.1 %	
ARSENIC (As)		2 ppm	
IRON (Fe)		0.001 %	
SODIUM (Na)	TO PASS TEST		
HEAVY METALS		0.001 %	
FLUORIDE		0.001 %	
MONOBASIC OR TRIBASIC SALT	TO PASS TEST		
MONOPOTASSIUM PHOSPHATE		2.5 %	
APPEARANCE OF SOLUTION	TO PASS TEST		
REDUCING SUBSTANCES	TO PASS TEST		
IDENTIFICATION	TO PASS TEST		
EXPIRATION DATE			
CERTIFIED KOSHER			
RESIDUAL SOLVENTS	TO PASS TEST		

# Spectrum Chemical Mfg Corp

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

Gardena, CA 90248

732.214.1300

310.516.8000

West Coast Facility:

14422 S. San Pedro St.





# SAFETY DATA SHEET

Preparation Date: 7/27/2014 Revision Date: 7/27/2014 Revision Number: G1

1. IDENTIFICATION

**Product identifier** 

Product code: PO204

Product Name: DIBASIC POTASSIUM PHOSPHATE, ANHYDROUS, USP, EP, BP

Other means of identification

**Synonyms:** Dipotassium Phosphate;

Dipotassium hydrogen phosphate; Dipotassium monohydrogen phosphate; Phosphoric acid, dipotassium salt

CAS #: 7758-11-4
RTECS # TC5580000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Buffer.

Uses advised against No information available

**Supplier:** Spectrum Chemicals and Laboratory Products, Inc.

14422 South San Pedro St. Gardena, CA 90248

(310) 516-8000

Order Online At: https://www.spectrumchemical.com

Emergency telephone numberChemtrec 1-800-424-9300Contact Person:Martin LaBenz (West Coast)Contact Person:Regina Wachenheim (East Coast)

# 2. HAZARDS IDENTIFICATION

### Classification

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

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

#### Label elements

Not classified			

Hazards not otherwise classified (HNOC)

Product code: PO204 Product name: DIBASIC POTASSIUM

PHOSPHATE, ANHYDROUS, USP, EP,

#### Other hazards

Not available

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Potassium Phosphate Dibasic, Anhydrous	7758-11-4	100	*
7758-11-4			

# 4. FIRST AID MEASURES

First aid measures

**General Advice:** Poison information centres in each State capital city can provide additional

assistance for scheduled poisons (13 1126)

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothes and

shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact: Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation. May cause digestive (gastrointestinal) tract irritation. May cause

abdominal discomfort. May cause nausea and vomiting. May cause diarrhea.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

**Protection of first-aiders** 

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of

contaminated clothing and equipment as bio-hazardous waste

# 5. FIRE-FIGHTING MEASURES

### **Extinguishing Media**

Suitable Extinguishing Media: The product is not flammable. If it is involved in a fire,

extinguish the fire using an agent suitable for the type of

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surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: If involved in a fire, the following can be released: oxides of

phosphorus and potassium

Product code: PO204 Product name: DIBASIC POTASSIUM

PHOSPHATE, ANHYDROUS, USP, EP,

Specific hazards: Vapors may travel to areas away from work site before

igniting/flashing back to vapor source

**Special Protective Actions for Firefighters** 

Specific Methods: No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus

pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

# **6. ACCIDENTAL RELEASE MEASURES**

# Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes

and clothing. Avoid dust formation.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways,

sewers.

#### Methods and material for containment and cleaning up

**Methods for containment**Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up

Sweep up and shovel into suitable containers for disposal. Clean contaminated

surface thoroughly.

#### 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

# Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

# Conditions for safe storage, including any incompatibilities

# **Technical Measures/Storage Conditions:**

Hygroscopic. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

# **Incompatible Materials:**

Oxidizing agents.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Control parameters**

#### National occupational exposure limits

U.S Occupational Exposure Limits: Not determined

**United States** 

Product code: PO204 Product name: DIBASIC POTASSIUM

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Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	None	None	None	None
Potassium Phosphate Dibasic,				
Anhydrous - 7758-11-4				

#### Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
	None	None	None	None
Potassium Phosphate Dibasic,				
Anhydrous - 7758-11-4				

#### **Australia and Mexico**

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Potassium Phosphate Dibasic,	None	None
Anhydrous		
7758-11-4		

# Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit

# Individual protection measures, such as personal protective equipment

**Personal Protective Equipment** 

Product code: PO204

**Eye protection:** Safety glasses. Safety glasses with side-shields.

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

**Respiratory protection:** Effective dust mask. Wear respirator with dust filter..

**Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and

immediately after handling the product. When using, do not eat, drink or smoke.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

**Product name:** DIBASIC POTASSIUM PHOSPHATE, ANHYDROUS, USP, EP,

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color

Solid. Crystalline powder. Granular White. Off-white.

powder.

Odor:TasteFormula:Odorless.No information availableK2HPO4

Molecular/Formula weight:Flash point (°C):Flashpoint (°C)°F):174.18No data availableNo information available.

Flash Point Tested according to: Lower Explosion Limit (%): Upper Explosion Limit (%):

Not available No information available No information available

Autoignition Temperature (°C/°F): pH: Melting point/range(°C/°F):

Boiling point/range(°C/°F): Decomposition temperature(°C/°F): Specific gravity:

No information available >465 °C/869 °F No information available

Density (g/cm3): Vapor pressure @ 20°C (kPa):

2.3 No information available No information available

Evaporation rate: Vapor density: VOC content (g/L):
No information available No information available No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available

No information available

Miscibility: Solubility:

No information available Very soluble in water

Slightly soluble in alcohol

# 10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable at normal conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

**Conditions to avoid:** Exposure to moisture. Incompatible materials.

Incompatible Materials: Oxidizing agents.

**Hazardous decomposition products:** Phosphorus oxides. Oxides of potassium.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

#### 11. TOXICOLOGICAL INFORMATION

Product code: PO204 Product name: DIBASIC POTASSIUM

PHOSPHATE, ANHYDROUS, USP, EP,

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# 11. TOXICOLOGICAL INFORMATION

# Information on likely routes of exposure

#### **Principal Routes of Exposure:**

Ingestion. Inhalation.

# **Acute Toxicity**

# **Component Information**

Potassium Phosphate Dibasic, Anhydrous - 7758-11-4

LD50/oral/rat = No information available
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No infomation available

Other LD50 or LC50information = No information available

#### **Product Information**

LD50/oral/rat =

**VALUE- Acute Tox Oral =** No information available

LD50/oral/mouse =

Value - Acute Tox Oral = No information available

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

**VALUE -Acute Tox Dermal =** No information available

LC50/inhalation/rat

**VALUE-Vapor** = No information available

**VALUE-Gas** = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

Product code: PO204

**VALUE-Vapor** = No information available

**VALUE - Gas =** No information available

**VALUE - Dust/Mist =** No information available

**Symptoms** 

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause irritation of respiratory tract.

#### Ingestion

Phosphates are toxic because of their abillity to sequester calcium, but they are slowly and incompletey absorbed when ingested, and seldom result in systemic effects. Furthermore, acute potassium poisoning by mouth is rare because large single doses usually induce vomiting and because in the absence of pre-existing kidney damage, potassium is rapidly excreted. However, such effects have occured. Symptoms may include gastrointestinal tract irritation (gastroenteritis) with nausea, vomiting, abdominal discomfort, diarrhea. May affect behavior/central nervous system(somnolence, listlessness, mental confusion, convulsions), metabolism (anorexia), cardiovascular system (fall of blood pressure, cardiac arrythmias, heart block), kidneys (polyuria, polydipsia). May cause mineral imbalance and affect osmotic pressure of body fluids. Other clinical signs and symptoms of oral overdosage may include: paresthesias of the extremities, weakness or heaviness of the legs, flaccid paralysis, cold skin, gray pallor.

Aspiration hazard No information available

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

Chronic Toxicity
Sensitization:

No information available
No information available

Mutagenic Effects:

No information available

Carcinogenic effects: Not considered carcinogenic.

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Potassium Phosphate Dibasic, Anhydrous	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity

No data is available

Reproductive Effects:No information availableDevelopmental Effects:No information availableTeratogenic Effects:No information available

**Specific Target Organ Toxicity** 

STOT - single exposure
STOT - repeated exposure
Target Organs:

No information available
No information available

# 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

**Ecotoxicity effects:** No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

**Mobility:** No information available

Product code: PO204 Product name: DIBASIC POTASSIUM

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# 13. DISPOSAL CONSIDERATIONS

# **Disposal Methods**

#### Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

#### Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Potassium Phosphate Dibasic, Anhydrous	None	None	None	None

# 14. TRANSPORT INFORMATION

DOT

UN-No: Not regulated

Proper Shipping Name: No information available Hazard Class: No information available

Subsidiary Risk: Not applicable

Packing Group: None

Marine Pollutant No data available

ERG No: No information available DOT RQ (lbs): No information available

TDG (Canada)

UN-No: Not regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
No information available

**ADR** 

UN-No: Not regulated

Proper Shipping Name:
Hazard Class:
Packing Group:
Subsidiary Risk:
Classification Code:
Description:
No information available

IMO / IMDG

UN-No: Not regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Description:
No information available

Product code: PO204 Product name: DIBASIC POTASSIUM

PHOSPHATE, ANHYDROUS, USP, EP,

BP

# 14. TRANSPORT INFORMATION

Marine Pollutant
MFAG:
No information available
No information available
No information available

RID

UN-No: Not regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Classification Code:
Description:
No information available

**ICAO** 

UN-No: Not regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
No information available

**IATA** 

**UN-No:** Not regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
No information available

#### 15. REGULATORY INFORMATION

### International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Potassium Phosphate Dibasic,	Present	Present KE-	Present	Present (1)-	Present	Present	Present 231-834-5
Anhydrous		12167		452			

# **U.S. Regulations**

Potassium Phosphate Dibasic, Anhydrous

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 182.6285

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

# Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

## Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity		Female Reproductive Toxicity:
Potassium Phosphate Dibasic, Anhydrous	Not Listed	Not Listed	Not Listed	Not Listed

#### **CERCLA/SARA**

**Product code:** PO204 **Product name:** DIBASIC POTASSIUM PHOSPHATE, ANHYDROUS, USP, EP,

· ·	Substances and their	Hazardous	Section 302 Extremely Hazardous Substances and RQs	<b>Chemical Category</b>	Section 313 - Reporting de minimis
Potassium Phosphate Dibasic, Anhydrous	None	None	None	None	None

# U.S. TSCA

•	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Potassium Phosphate Dibasic, Anhydrous	Not Applicable	Not Applicable

#### Canada

# WHMIS hazard class:

Non-controlled

#### Potassium Phosphate Dibasic, Anhydrous

Uncontrolled product according to WHMIS classification criteria

# **Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

#### Inventory

Components	Canada (DSL)	Canada (NDSL)
Potassium Phosphate Dibasic,	Present	Not Listed
Anhydrous		

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandito	
		Reporting	
Potassium Phosphate Dibasic,	Not listed	Not listed	
Anhydrous			

# **EU Classification**

# R-phrase(s)

not determined

# S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Potassium Phosphate Dibasic,		No information	
Anhydrous			

# The product is classified in accordance with Annex VI to Directive 67/548/EEC

# Indication of danger:

Not dangerous

**Product code:** PO204 **Product name:** DIBASIC POTASSIUM PHOSPHATE, ANHYDROUS, USP, EP,

# 16. OTHER INFORMATION

NFPA HMIS Personal Protective Equipment



Health Hazard	1
Fire Hazard	0
Reactivity	0



See Section 8.

Preparation Date:7/27/2014Revision Date:7/27/2014Prepared by:Sonia Owen

Disclaimer:

Product code: PO204

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Material Safety Data Sheet** 

**Product name:** DIBASIC POTASSIUM PHOSPHATE, ANHYDROUS, USP, EP,



# Manufacturer

Product Covered: PO204, Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA Senior Manager of Technical Services techservices@spectrumchemical.com

# **Certificate of Registration**



This is to certify that the quality management system of

# Spectrum Chemicals and Laboratory Products, Lac

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA 755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

**California and New Jersey sites:** The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

**Arizona site:** Supporting Spectrum's two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01

Initial Certification Date: 27 December 1994 Certificate Issue Date: 29 January 2016 Certificate Expiry Date: 14 September 2018

Calin Moldovean, President Intertek Testing Services NA, Inc. 900 Chelmsford Street, Suite 301-3, Lowell, MA, USA ARAB
ACCREDITED
ISO/IEC17021
MANAGEMENT SYSTEMS
CERTIFICATION BODY



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <a href="mailto:certificate.validation@intertek.com">certificate.validation@intertek.com</a> or by scanning the code to the right with a smartphone.

# **Certificate of Registration**



This is to certify that the quality management system of

# Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018







Authorised Signature: Calin Moldovean – President, Business Assurance Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <a href="mailto:certificate.com">certificate.com</a> or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website <a href="http://www.cnca.gov.cn">http://www.cnca.gov.cn</a> of CNCA in China.





March 28, 2016

# **Certificate of cGMP**

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are 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.

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
Spectrum -Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. 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> if we may be of further assistance.

Sincerely,

Michelle Weston

Quality Assurance Specialist

Michelle Weston



April 25, 2016

# **Certificate of cGMP**

#### **Dear Valued Customer:**

Spectrum Chemicals and Laboratory Products certify 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	
	Dibasic Potassium Phosphate, Anhydrous, USP, EP,	
PO204	ВР	

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
Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. 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> if we may be of further assistance.

Sincerely,

Michelle Weston

Quality Assurance Specialist

Michelle Wester



April 28, 2016

Re: Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP-PO204

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP- PO204

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <a href="mailto:techservices@spectrumchemical.com">techservices@spectrumchemical.com</a>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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



May 18, 2016

Re: Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP-PO204

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP-PO204

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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



May 19, 2016

Re: Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP-PO204

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP-PO204

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <a href="mailto:techservices@spectrumchemical.com">techservices@spectrumchemical.com</a>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. 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.



- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Storage Color Band

- 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
- Kosher Certified by Kosher Supervision of America (KSA).

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.

YELLOW: Oxidizer **RED**: Flammable **GREEN**: General Storage **BLUE**: Health Hazard

WHITE: Corrosive

# Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.

New Brunswick, NJ 08901

West Coast Facility:

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300



# **Certificate Of Analysis**

Item Number	PO204	Lot Number	1EJ0514
Item	Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP		
CAS Number	7758-11-4		
Molecular Formula	K <sub>2</sub> HPO <sub>4</sub>	Molecular Weight	174.18

Test	Specification		Result
	min	max	
ASSAY (K,HPO,; DRIED BASIS)	98.0 - 100.5 %		99.9 %
pH OF A 1 IN 20 SOLUTION	8.5 - 9.6		8.9
LOSS ON DRYING		1.0 %	0.03 %
INSOLUBLE SUBSTANCES		0.2 %	0.00 %
CARBONATE	TO PASS TEST		PASSES TEST
CHLORIDE (CI)		0.02 %	<0.02 %
SULFATE		0.1 %	<0.1 %
ARSENIC (As)		2 ppm	<2 ppm
IRON (Fe)		0.001 %	<0.001 %
SODIUM (Na)	TO PASS TEST		PASSES TEST
HEAVY METALS		0.001 %	<0.001 %
FLUORIDE		0.001 %	0.0001 %
MONOBASIC OR TRIBASIC SALT	TO PASS TEST		PASSES TEST
MONOPOTASSIUM PHOSPHATE		2.5 %	1.6 %
APPEARANCE OF SOLUTION	TO PASS TEST		PASSES TEST
REDUCING SUBSTANCES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			14-SEP-2018
CERTIFIED KOSHER			KOSHER
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED
MANUFACTURE DATE			14-SEP-2015
APPEARANCE			WHITE GRANULES

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

Certificate of Analysis Results Certified By:

Adan Hernandez Quality Control Manager

Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.



# **Certificate Of Analysis**

Item Number	PO204	Lot Number	2EG0180
Item	Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP		
CAS Number	7758-11-4		
Molecular Formula	K <sub>2</sub> HPO <sub>4</sub>	Molecular Weight	174.18

Test	Spe	Specification	
	min	max	
ASSAY (K <sub>2</sub> HPO <sub>4</sub> ; DRIED BASIS)	98.0 - 100.5 %		98.5 %
pH OF A 1 IN 20 SOLUTION	8.5 - 9.6		8.5
LOSS ON DRYING		1.0 %	0.15 %
INSOLUBLE SUBSTANCES		0.2 %	0.01 %
CARBONATE	TO PASS TEST		PASSES TEST
CHLORIDE (Cl)		0.02 %	<0.02 %
SULFATE		0.1 %	<0.1 %
ARSENIC (As)		2 ppm	<2 ppm
IRON (Fe)		0.001 %	<0.001 %
SODIUM (Na)	TO PASS TEST		PASSES TEST
HEAVY METALS		0.001 %	<0.001 %
FLUORIDE		0.001 %	0.0001 %
MONOBASIC OR TRIBASIC SALT	TO PASS TEST		PASSES TEST
MONOPOTASSIUM PHOSPHATE		2.5 %	0.75 %
APPEARANCE OF SOLUTION	TO PASS TEST		PASSES TEST
REDUCING SUBSTANCES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			20-APR-2018
CERTIFIED KOSHER			KOSHER
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE CRYSTALS
DATE OF MANUFACTURE			20-APR-2015

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:

Mulbah F. Dwanah Laboratory Supervisor

Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.



January 26, 2016

# 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**: Zl0928 = 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

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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a> if we may be of further assistance.

Sincerely,

Michael Dang

Manager, GMP Compliance



# Stability - Shelf Life Guidance

Product Covered: PO204, Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, PO204, Dibasic Potassium Phosphate, Anhydrous, USP, EP, BP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

Corporate Headquarters 769 Jersey Avenue

New Brunswick, NJ 08901-3605

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

# **Spectrum Laboratory Products, Inc.**

S-0032

14422 S. San Pedro Street Gardena CA 90248 **USA** 

**Product Name** Potassium Phosphate Dibasic, Anhydrous, USP, EP, BP - PO204

**Brand Spectrum** 

**UKD-ID** KSAV3-B5F4X5

P D/P/M

**Symbol Required KSA** 

**Special Conditions** 

This certificate expires on Feb 28, 2017

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.