

# **Scientific Documentation**

# **SO138**, Dibasic Sodium Phosphate, Dried, USP

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

Ver4.01 12.April.2016



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, Global Supplier Quality Assurance gualityassurance@spectrumchemical.com

SO138, Dibasic Sodium Phosphate, Dried, USP

#### Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Manufacturing Process Flowchart
- Certification of Quality Mangement System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Allergen Statement
- Product Aflatoxin Statement
- General Label Information Sample Label
- Product Certificate of Analysis Sample(s)
- General Lot Numbering System Guidance
- Stability Shelf Life Guidance



Item Number	<u>SO138</u>
Item	Dibasic Sodium Phosphate, Dried, USP
CAS Number	7558-79-4
Molecular Formula	Na <sub>2</sub> HPO <sub>4</sub>
Molecular Weight	141.96
MDL Number	
Synonyms	Sodium Phosphate, Dibasic; Dibasic Sodium Phosphate; Disodium Hydrogen Phosphate;

Test	Specification		
	Min	Max	
ASSAY (DRIED BASIS)	98.0 - 100.5 %		
LOSS ON DRYING		5.0 %	
INSOLUBLE SUBSTANCES		0.4 %	
CHLORIDE (Cl)		0.06 %	
SULFATES $(SO_4)$		0.2 %	
ARSENIC (As)		16 ppm	
HEAVY METALS (as Pb)		0.002 %	
IDENTIFICATION		TO PASS TEST	
EXPIRATION DATE			
RESIDUAL SOLVENTS		TO PASS TEST	

#### Spectrum Chemical Mfg Corp

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

# spectrum



## SAFETY DATA SHEET

Preparation Date: 1/7/2015	·		
	1. IDENTIFICATION		
Product identifier			
Product code:	SO138		
Product Name:	DIBASIC SODIUM PHOSPHATE, DRIED, USP		
Other means of identification			
Synonyms:	Dibasic sodium phosphateDisodium hydrogen phosphate		
	Disodium monohydrogen phosphate		
	Disodium orthophosphate		
	Disodium phosphate Disodium phosphoric acid		
	Phosphoric acid, disodium salt		
	Soda phosphate		
	Sodium hydrogen phosphate		
	Sodium phosphate		
CAS #:	7558-79-4		
RTECS # CI#:	WC4500000 Not available		
Recommended use of the chem	nical and restrictions on use		
Recommended use:	Emulsifying agent. In Foods.		
Uses advised against	No information available		
Supplier:	Spectrum Chemical Mfg. Corp		
	14422 South San Pedro St.		
	Gardena, CA 90248		
	(310) 516-8000		
Order Online At:	https://www.spectrumchemical.com		
Emergency telephone number	Chemtrec 1-800-424-9300		
Contact Person:	Martin LaBenz (West Coast)		
Contact Person:	Ibad Tirmiz (East Coast)		
	2. HAZARDS IDENTIFICATION		

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

	Serious eye damage/eye irritation	Category 2B
--	-----------------------------------	-------------

#### Label elements

#### Warning

Hazard statements Causes eye irritation

#### Hazards not otherwise classified (HNOC) Not Applicable

Other hazards

Causes mild skin irritation

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

Wash face, hands and any exposed skin thoroughly after handling

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 skin irritation occurs: Get medical advice/attention

#### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

	Components	CAS-No.	Weight %
ĺ	Sodium Phosphate, Dibasic	7558-79-4	100
	7558-79-4		

#### 4. FIRST AID MEASURES

First aid measures General Advice:	Poison information centers 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.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If breathing is difficult, give oxygen. In case of shortness of breath, give oxygen. Obtain 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 effec	ts, both acute and delayed
Symptoms	May cause eye/skin irritation. Mild skin irritation. Mild eye irritation. May cause digestive (gastrointestinal) tract irritation. May cause purging.
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

Product name: DIBASIC SODIUM PHOSPHATE, DRIED, USP

#### **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 surrounding fire.
Unsuitable Extinguishing Media:	No information available.
Specific hazards arising from the chemical	
Hazardous Combustion Products:	No information available.
Specific hazards:	No information available.
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. Avoid contact with skin, eyes and clothing. Use personal protective equipment.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let this chemical enter the environment. Do not let product enter drains.
Methods and material for contain	ment 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. Keep away from incompatible materials.

#### Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe vapours/dust. Keep away from heat and sources of ignition. 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. Acids. Bases.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Control parameters**

#### National occupational exposure limits

U.S Occupational Exposure Limits: Not determined

#### **United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Sodium Phosphate, Dibasic	None	None	None	None
7558-79-4				

#### Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
Sodium Phosphate, Dibasic 7558-79-4	None	None	None	None

#### Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Sodium Phosphate, Dibasic	None	None
7558-79-4		

#### 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**

Eye protection:	Goggles. Safety glasses with side-shields.			
Skin and body protection:	Long sleeved clothing. Chemical resistant apron. Gloves.			
Respiratory protection:	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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.

Odor: Odorless.

**Molecular/Formula weight:** 141.96

Flashpoint (°C/°F): No information available.

Lower Explosion Limit (%): No information available

Melting point/range(°C/°F): No information available

Bulk density: No information available

Vapor pressure @ 20°C (kPa): No information available

**VOC content (g/L):** No information available

Viscosity: No information available Appearance: Powder. Crystalline powder.

**Taste** Saline.

Flammability: No information available

Flash Point Tested according to: Not applicable

Upper Explosion Limit (%): No information available

**Boiling point/range(°C/°F):** No information available

Density (g/cm3): 1.7

**Evaporation rate:** No information available

Odor threshold (ppm): No information available

**Miscibility:** No information available Color: White.

Formula: Na2HPO4

Flash point (°C): No data available

Autoignition Temperature (°C/°F): No information available

**pH:** 9.1 (for a 1% aqueous solution at 25 deg. C)

Decomposition temperature(°C/°F): Converted to sodium pyrophosphate at about 240 deg. C Specific gravity: No information available

Vapor density: No information available

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

Solubility: Easily soluble in water Soluility in Water: 11.8 g/100 g (or 120 g/l) @ 25 deg. C

#### **10. STABILITY AND REACTIVITY**

#### Reactivity

Incompatible with magnesium, alkaloids, antipyrine, chloral hydrate, lead acetate, pyrogallol, resorcinol, strong mineral acids, strong organic acids

Chemical stability Stability:	Stable under recommended storage conditions
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur
Conditions to avoid:	Heat. Exposure to moist air. Exposure to moisture. Incompatible materials.
Incompatible Materials:	Oxidizing agents. Acids. Bases.
Hazardous decomposition products:	Phosphorus oxides. Sodium oxides.
Other Information Corrosivity:	No information available
Special Remarks on Corrosivity:	No information available

#### Information on likely routes of exposure

**Principal Routes of Exposure:** Ingestion. Inhalation.

#### Acute Toxicity

#### **Component Information**

Sodium Phosphate, Dibasic - 7558-79-4 LD50/oral/rat = 17000 mg/kg oral LD50 rat LD50/oral/mouse = No information available LD50/dermal/rat = No information available LD50/dermal/rabbit = >7940 mg/kg dermal LD50 rabbit LC50/inhalation/rat = No information available LC50/inhalation/mouse = No information available Other LD50 or LC50information = No information available

**Product Information** 

LD50/oral/rat = VALUE- Acute Tox Oral = 17000mg/kg

LD50/oral/mouse = Value - Acute Tox Oral = No information available

LD50/dermal/rabbit VALUE-Acute Tox Dermal = >7940mg/kg

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 VALUE-Vapor = No information available VALUE - Gas = No information available VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:	May cause skin irritation. Mild skin irritation				
Eye Contact:	Causes eye irritation. Mild eye irritation.				
Inhalation	May cause irritation of respiratory tract.				

Ingestion	May cause irritation of the digestive tract and may cause purging. It is slowly absorbed. Expected to be a low ingestion hazard for usual industrial handling. If ingestion of large doses occur and if a significant amount of phosphate is absorbed, severe electrolyte disturbances including hyperphosphatemia, hypocalcemia, hyperkalemia, hypernatremia and hypermagnesemia may also occur with symptoms such as increased thirst, decrease in the amount of urine or in frequency of urination, renal failure, troubled breathing and shortness of breath, headache, tetany, seizures/convulsions, tremor, muscle cramps, numbness or tingling, pain around the lips, hands or feet, weakness in the hands or feet, bradycardia (slow heartbeat) or tachycardia (fast heartbeat), dysrhythmias (cardiac arrhythmias), cardiac arrest.
Aspiration hazard	No information available
Delayed and immediate effects as	s well as chronic effects from short and long-term exposure
Chronic Toxicity	Prolonged skin contact may cause skin irritation and/or dermatitis
Sensitization:	No information available
Mutagenic Effects:	No information available

Carcinogenic effects: Not considered carcinogenic

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

Reproductive toxicity	No data is available
Reproductive Effects:	No information available
Developmental Effects:	No information available
Teratogenic Effects:	No information available
Specific Target Organ Toxicity	
STOT - single exposure	No information available
STOT - repeated exposure	No information available
Target Organs:	No information available

#### **12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

Ecotoxicity effects:	Aquatic environment.
Sodium Phosphate, Dibasic - 7558- Freshwater Fish Species Data: Water Flea Data:	<i>79-4</i> >=100 mg/L LC50 fish 3580 mg/l LC50 48 hr
Persistence and degradability:	No information available

#### Bioaccumulative potential:

No information available No information available

**Mobility:** 

#### **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
Sodium Phosphate, Dibasic	None	None	None	None

#### **14. TRANSPORT INFORMATION**

#### DOT

UN-No:	Not regulated (although listed Table 1 to Appendix A - Hazardous Substances Than Radionuclides, it is not regulated for transport in sold quantities, which a below the Reportable Quantity (RQ))	
Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: ERG No: Marine Pollutant DOT RQ (Ibs):	No information available No information available No information available None No information available No data available 5000 lbs./2270 kg	
TDG (Canada) UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: Description:	Not Regulated No information available No information available No information available No information available No information available	
ADR		
UN-No: Proper Shipping Name: Hazard Class: Packing Group: Subsidiary Risk: Classification Code: Description: CEFIC Tremcard No:	Not Regulated No information available No information available No information available No information available No information available No information available	
IMO / IMDG UN-No: Proper Shipping Name: Hazard Class:	Not Regulated No information available No information available	
Product code: SO138	Product name: DIBASIC SODIUM PHOSPHATE, DRIED, USP	8 / 11

#### **14. TRANSPORT INFORMATION**

	Subsidiary Risk:	No information available
	Packing Group:	No information available
	Description:	No information available
	IMDG Page:	No information available
	Marine Pollutant	No information available
	MFAG:	No information available
	Maximum Quantity:	No information available
RID		
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Subsidiary Risk:	No information available
	Packing Group:	No information available
	Classification Code:	No information available
	Description:	No information available
	_	
ICAC	-	Net Demulated
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Subsidiary Risk:	No information available
	Packing Group:	No information available
	Description:	No information available
ΙΑΤΑ		
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Subsidiary Risk:	No information available
	Packing Group:	No information available
	Description:	No information available
	•	
		15. REGULATORY INFORMATION

#### **International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Sodium Phosphate, Dibasic	Present	Present KE- 12344	Present	Present (1)- 497	Present	Present	Present 231-448-7

#### **U.S. Regulations**

 Sodium Phosphate, Dibasic

 Massachusetts RTK: Present

 New Jersey RTK Hazardous Substance List: 1723

 New Jersey - Discharge Prevention - List of Hazardous Substances: Present

 Pennsylvania RTK: Environmental hazard

 Pennsylvania RTK - Environmental Hazard List Present

 New York Release Reporting - List of Hazardous Substances:

 5000 lb RQ

 100 lb RQ

 Louisana Reportable Quantity List for Pollutants: 5000lbfinal RQ

 2270kgfinal RQ

 California Directors List of Hazardous Substances: Present

 FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 182.1778 21 CFR 182.6778 21 CFR 182.8778

Product name: DIBASIC SODIUM PHOSPHATE, DRIED, USP **FDA - 21 CFR - Total Food Additives** 133.169 133.173 133.179 135.110 137.305 139.110 150.141 150.161 173.310 175.210 175.300 181.29 182.1778 182.6290 182.6778 182.8778 73.85

#### 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:
Sodium Phosphate, Dibasic	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

•	CERCLA - Hazardous Substances and their Reportable Quantities	Hazardous	Hazardous	Chemical Category	Section 313 - Reporting de minimis
	5000 lb final RQ 2270 kg final RQ	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
Sodium Phosphate, Dibasic	Not Applicable	Not Applicable

#### Canada

#### WHMIS hazard class:

Non-controlled

#### **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)
Sodium Phosphate, Dibasic	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Sodium Phosphate, Dibasic	Not listed	Not listed

#### **EU Classification**

R-phrase(s) none

S -phrase(s) none

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

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

Indication of danger: Not dangerous

#### **16. OTHER INFORMATION**

Preparation Date:	1/7/2015
Revision Date:	1/14/2016
Prepared by:	Sonia Owen
Disclaimer:	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 Safety Data Sheet



#### Manufacturer

Product Covered: SO138, Dibasic Sodium Phosphate, Dried, USP

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.

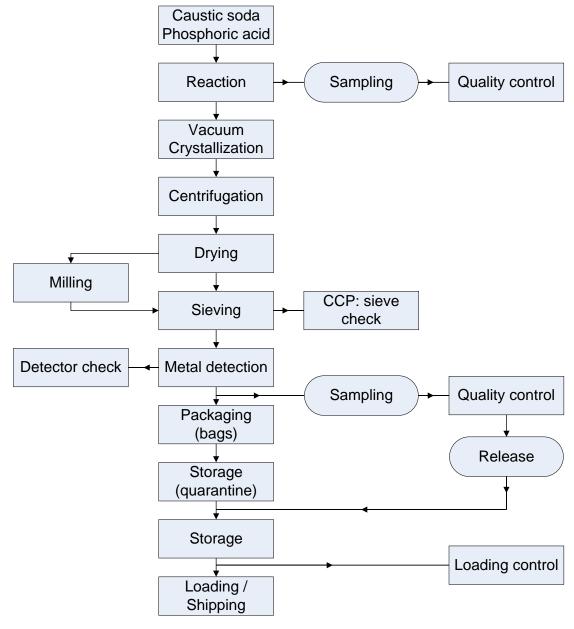
Sincerely,

Alan Wang, MSQA, ASQ CQA Senior Manager, Global Supplier Quality Assurance <u>qualityassurance@spectrumchemical.com</u>



### **Manufacturing Process Flowchart**

### **Dibasic Sodium Phosphate, Dried, USP - SO138**



#### 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

# **Certificate of Registration**



This is to certify that the quality management system of

## Spectrum Chemicals and Laboratory Products, Frc

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 gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01 Initial Certification Date: 27 December 1994 Certificate Issue Date: Certificate Expiry Date:

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



CERTIFICATION



Intertek Intertek

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 certificate.validation@intertek.com 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: Certificate Number: Certificate Issue Date: Certificate Expiry Date: 77762704-8 111310001-01 17 November 2015 14 September 2018



014

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 <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone. The annual validity of the certificate a also be checked through the website <u>http://www.cnca.gov.cn</u> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.



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: Spectrum-New Brunswick, NJ: Spectrum -Shanghai, China: 2020632 2246824 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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



April 8, 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	
SO138	Dibasic Sodium Phosphate, Dried, USP	

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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



March 31, 2016

Re: Dibasic Sodium Phosphate, Dried, USP-SO138

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 Sodium Phosphate, Dried, USP-SO138

is BSE/TSE free.

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

March 31, 2016



Re: Dibasic Sodium Phosphate, Dried, USP-SO138

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 (Cereals containing gluten, namely: wheat, rye, barley, oats or their hybridized strains, and products thereof, Crustaceans/Shellfish and products thereof, Eggs and products thereof, Fish and products thereof, Lupin and products thereof, Molluscs and products thereof, Peanut and products thereof, Legumes/pulses and products thereof, Soybeans and products thereof, Milk and products thereof (including lactose), Nuts and products thereof, Coconut and coconut derivatives, Cocoa and products thereof, Celery and products thereof, Mustard and products thereof, Seeds (Sesame & sesame derivatives, poppy and sunflower), Sulphur dioxide and sulphites in concentrations of more than 10 mg/kg or 10 mg/litre in terms of total SO2, Fruit & fruit derivatives (e.g. Banana, Peach, Apple, Kiwi fruit, Orange), Umbellifers and products thereof (e.g. parsley, coriander, dill), Carrots and products thereof Animal and animal derivatives (others than dairy products), Hydrolysed vegetable protein, Preservatives (incl. SO2, sulphite, benzoates), Flavourings, Colours, Sweeteners, Glutamate / MSG, BHT / BHA, Yeast / yeast extract, Yams, Rice, Matsutake mushrooms, Buckwheat, Gelatine, Bee products and Corn & products thereof)

Dibasic Sodium Phosphate, Dried, USP-SO138

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

April 1, 2016



Re: Dibasic Sodium Phosphate, Dried, USP- SO138

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 Sodium Phosphate, Dried, USP- SO138

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,

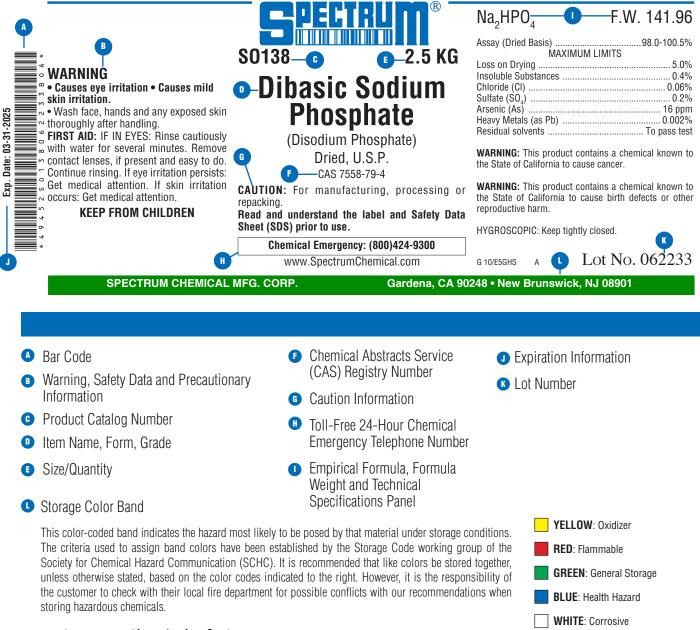
Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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



### **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.



#### Spectrum Chemical Mfg Corp

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

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

West Coast Facility:

732.214.1300

# Spectrum®

# **Certificate Of Analysis**

Item Number	SO138	Lot Number	1EJ0339
Item	Dibasic Sodium Phosphate, Dried, USP		
CAS Number	7558-79-4		
Molecular Formula	Na <sub>2</sub> HPO <sub>4</sub>	Molecular Weight	141.96

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0 - 100.5 %		100.1 %
LOSS ON DRYING		5.0 %	0.2 %
INSOLUBLE SUBSTANCES		0.4 %	<0.1 %
CHLORIDE (Cl)		0.06 %	0.02
SULFATES $(SO_4)$		0.2 %	0.05 %
ARSENIC (As)		16 ppm	1 ppm
HEAVY METALS (as Pb)		0.002 %	0.001 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			22-JAN-2018
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE POWDER
MANUFACTURE DATE			23-JAN-2015

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.

# Spectrum®

# **Certificate Of Analysis**

Item Number	SO138	Lot Number	2EJ0285
Item	Dibasic Sodium Phosphate, Dried, USP		
CAS Number	7558-79-4		
Molecular Formula	Na <sub>2</sub> HPO <sub>4</sub>	Molecular Weight	141.96

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0 - 100.5 %		100.1 %
LOSS ON DRYING		5.0 %	0.2 %
INSOLUBLE SUBSTANCES		0.4 %	<0.10 %
CHLORIDE (Cl)		0.06 %	<0.02 %
SULFATES $(SO_4)$		0.2 %	0.05 %
ARSENIC (As)		16 ppm	1 ppm
HEAVY METALS (as Pb)		0.002 %	0.001 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			22-JAN-2018
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			FINE WHITE POWDER
DATE OF MANUFACTURE			23-JAN-2015

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



man

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**: 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

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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



#### **Stability – Shelf Life Guidance**

#### Product Covered: SO138, Dibasic Sodium Phosphate, Dried, USP

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

The product, SO138, Dibasic Sodium Phosphate, Dried, USP, 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

fan & //and

Corporate Headquarters 769 Jersey Avenue New Brunswick, NJ 08901-3605