

# **Scientific Documentation**

**SO140**, Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP

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, Global Supplier Quality Assurance qualityassurance@spectrumchemical.com

## Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- 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
- Kosher Certificate



## Specification for Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP (SO140)

Item Number	<u>SO140</u>
Item	Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP
CAS Number	7782-85-6
Molecular Formula	Na <sub>2</sub> HPO <sub>4</sub> .7H <sub>2</sub> O
Molecular Weight	268.07
MDL Number	
Synonyms	Dibasic Sodium Phosphate; Disodium Hydrogen Phosphate; Disodium Phosphate

Test	Specif	ïcation
	Min	Max
ASSAY (DRIED BASIS)	98.0 - 100.5 %	
LOSS ON DRYING	43.0 - 50.0 %	
INSOLUBLE MATTER		0.4 %
CHLORIDE (Cl)		0.06 %
SULFATE		0.2 %
ARSENIC (As)		16 ppm
HEAVY METALS (as Pb)		0.002 %
IDENTIFICATION		TO PASS TEST
CERTIFIED KOSHER		
RETEST DATE		
RESIDUAL SOLVENTS		TO PASS TEST

#### 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





## SAFETY DATA SHEET

Preparation Date: 1/5/2015 Revision Date: 1/14/2016 Revision Number: G2

1. IDENTIFICATION

**Product identifier** 

Product code: SO140

Product Name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE, CRYSTAL, USP

Other means of identification

**Synonyms:** Dibasic Sodium Phosphate heptahydrate;

Disodium Hydrogen Phosphate, heptahydrate

CAS #: 7782-85-6

RTECS # WC4600000

CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use:
Uses advised against
No information available.
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 numberChemtrec 1-800-424-9300Contact 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

**Product code:** SO140 **Product name:** DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE,

#### 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 %
Sodium Phosphate, Dibasic, Heptahydrate	7782-85-6	100
7782-85-6		

#### 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 effects, 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

#### 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.

**Product code:** SO140 **Product name:** DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE,

CRYSTAL, USP

2/11

#### 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 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. 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:**

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**

Product code: SO140

#### National occupational exposure limits

U.S Occupational Exposure Limits: Not determined

Product name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE, CRYSTAL, USP

3/11

#### **United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Sodium Phosphate, Dibasic,	None	None	None	None
Heptahydrate				
7782-85-6				

#### Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
Sodium Phosphate, Dibasic,	None	None	None	None
Heptahydrate				
7782-85-6				

#### **Australia and Mexico**

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Sodium Phosphate, Dibasic,	None	None
Heptahydrate		
7782-85-6		

#### 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: SO140

**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: Appearance: Color:

Solid. Granular. Crystals. Crystalline. White.

Odor: Taste Formula:

Na2HPO4.7H2O No information available Odorless.

Molecular/Formula weight: Flammability: Flash point (°C):

No information available No data available 268.07

Flashpoint (°C/°F): **Autoignition Temperature (°C/°F):** Flash Point Tested according to:

No information available. Not applicable No information available

**Upper Explosion Limit (%):** Lower Explosion Limit (%): :Ha

No information available No information available No information available

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

48 °C/119 °F (loses 5 H2O at 48 °C) No information available No information available

Specific gravity: **Bulk density:** Density (g/cm3):

1.679-1.7 @ 25 deg. C No information available No information available

Vapor pressure @ 20°C (kPa): **Evaporation rate:** Vapor density:

No information available No information available No information available

Partition coefficient VOC content (g/L): Odor threshold (ppm): No information available No information available (n-octanol/water):

No information available

Viscosity: Miscibility: Solubility:

No information available No information available Easily soluble in water

Solubility in Water: 104 g/100 ml @ 40 deg. C; 11.8 g/100 g @ 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. Loses 5 H2O @ 48 deg. C. Incompatible materials.

**Incompatible Materials:** Oxidizing agents. Acids. Bases.

Hazardous decomposition products: No information available.

Other Information

Product code: SO140

**Corrosivity:** No information available

Special Remarks on Corrosivity: No information available

#### 11. TOXICOLOGICAL INFORMATION

Product name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE,

5/11

#### 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

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

Ingestion. Inhalation.

#### **Acute Toxicity**

#### **Component Information**

Sodium Phosphate, Dibasic, Heptahydrate - 7782-85-6

LD50/oral/rat = 12930 mg/kg (RTECS)
LD50/oral/mouse = No information available
LD50/dermal/rat = No information available
LD50/dermal/rabbit = No information available
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 = 12930mg/kg

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: SO140

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. Ingestion of large doses may affect behavior/central nervous system (tetany). However, if a significant amount of phosphate is absorbed, hypophosphatemia will occur. Severe hypophosphatemia may result in hypocalcemia and tetany. Cardiovasular, respiratory, neurologic, and musculoskeletal effects may occur

secondary to hypernatremia, hypophosphatemia, and hypcalcemia.

**Aspiration hazard** No information available

Delayed and immediate effects as 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, Heptahydrate	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 STOT - repeated exposure

**Target Organs:** 

No information available No information available No information available

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

Product code: SO140

**Ecotoxicity effects:** No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

**Mobility:** No information available

Product name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE, CRYSTAL, USP

#### 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	RCRA - K Series	RCRA - P	RCRA - U Series Wastes
	Wastes	Wastes	Series	
			Wastes	
Sodium Phosphate, Dibasic, Heptahydrate	None	None	None	None

#### 14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

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

Packing Group: None

**ERG No:** No information available

Marine Pollutant

DOT RQ (lbs):

No data available

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

Product code: SO140

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 **IMDG Page:** No information available **Marine Pollutant** No information available MFAG: No information available

Product name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE, CRYSTAL, USP

#### 14. TRANSPORT INFORMATION

Maximum Quantity: 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.
Sodium Phosphate, Dibasic, Heptahydrate	Not Listed	Not present	Present	Not present	Present	Present	Not present

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

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	Male Reproductive Toxicity	Female Reproductive Toxicity:
Sodium Phosphate, Dibasic, Heptahydrate	Not Listed	Not Listed	Not Listed	Not Listed

#### **CERCLA/SARA**

Product code: SO140

Product name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE, CRYSTAL, USP

Substances and their	Hazardous	Section 302 Extremely Hazardous Substances and RQs	Chemical Category	Section 313 - Reporting de minimis
	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
Heptahydrate		

#### 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,	Not Listed	Not Listed
Heptahydrate		

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

#### **EU Classification**

#### R-phrase(s)

none

#### S -phrase(s)

none

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

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

#### Indication of danger:

Product code: SO140

Not dangerous

Product name: DIBASIC SODIUM PHOSPHATE, HEPTAHYDRATE, CRYSTAL, USP

#### 16. OTHER INFORMATION

Preparation Date: 1/5/2015
Revision Date: 1/14/2016
Prepared by: Sonia Owen

Disclaimer:

Product code: SO140

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: SO140, Dibasic Sodium Phosphate, Heptahydrate, Crystal, 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 qualityassurance@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 18, 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 Sodium Phosphate, Heptahydrate, Crystal,	
SO140	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:2020632Spectrum-New Brunswick, NJ:2246824Spectrum-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 20, 2016

Re: Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP-SO140

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, Heptahydrate, Crystal, USP-SO140

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



April 19, 2016

Re: Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP-SO140

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; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO<sub>2</sub>; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP-SO140

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



April 19, 2016

Re: Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP-SO140

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, Heptahydrate, Crystal, USP-SO140

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,

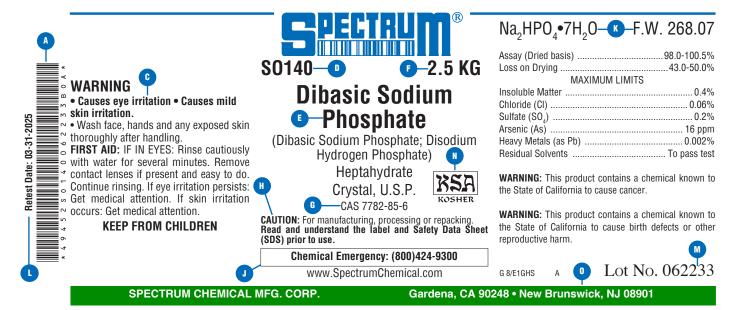
Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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	SO140	Lot Number	1EI0530
Item	Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP		
CAS Number	7782-85-6		
Molecular Formula	Na <sub>2</sub> HPO <sub>4</sub> .7H <sub>2</sub> O	Molecular Weight	268.07

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0 - 100.5 %		99.4 %
LOSS ON DRYING	43.0 - 50.0 %		45.8 %
INSOLUBLE MATTER		0.4 %	0.00 %
CHLORIDE (CI)		0.06 %	<0.06 %
SULFATE		0.2 %	<0.2 %
ARSENIC (As)		16 ppm	<16 ppm
HEAVY METALS (as Pb)		0.002 %	<0.002 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED KOSHER			KOSHER
RETEST DATE			24-MAR-2018
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE CRYSTALS
MANUFACTURE DATE			24-MAR-2015

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

1 36 7 1

Adan Hernandez Quality Control Manager

Spectrum Chemicals & Laboratory Products

Certificate of Analysis Results Certified By:





# **Certificate Of Analysis**

Item Number	SO140	Lot Number	2FA0102
Item	Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP		
CAS Number	7782-85-6		
Molecular Formula	Na <sub>2</sub> HPO <sub>4</sub> .7H <sub>2</sub> O	Molecular Weight	268.07

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0 - 100.5 %		99.4 %
LOSS ON DRYING	43.0 - 50.0 %		46.1 %
INSOLUBLE MATTER		0.4 %	0.0 %
CHLORIDE (CI)		0.06 %	<0.06 %
SULFATE		0.2 %	<0.2 %
ARSENIC (As)		16 ppm	<16 ppm
HEAVY METALS (as Pb)		0.002 %	<0.002 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED KOSHER			KOSHER
RETEST DATE			29-DEC-2018
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE CRYSTALS
DATE OF MANUFACTURE			29-DEC-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: SO140, Dibasic Sodium Phosphate, Heptahydrate, Crystal, USP

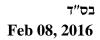
Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, SO140, Dibasic Sodium Phosphate, Heptahydrate, Crystal, 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

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** 

Sodium Phosphate Dibasic, Heptahydrate, Crystal, USP - SO140

**Brand** 

Spectrum

**UKD-ID** 

KSAV3-Q1T1X20

D/P/M

P

**Symbol Required** 

**KSA** 

This certificate expires on Feb 28, 2017

**Special Conditions** 

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.