

Scientific Documentation

P1457, Propylparaben Sodium, NF

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

Ver4.04 28.March.2018



Dear Customer,

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

Spectrum has been proudly serving the 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, CQA Director, Global Supplier Quality Assurance awang@spectrumchemical.com

P1457, Propylparaben Sodium, NF

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Item Number	<u>P1457</u>
Item	Propylparaben Sodium, NF
CAS Number	35285-69-9
Molecular Formula	$C_{10}H_{11}NaO_3$
Molecular Weight	202.00
MDL Number	
Synonyms	Propyl p-Hydroxybenzoate Sodium Salt ; Sodium Propylparaben ; Sodium Propyl

Test	Specification		
	Min	Max	
ASSAY (ANHYDROUS BASIS)	94.0	102.0 %	
COMPLETENESS OF SOLUTION	TO PASS TEST		
pH OF A 1 IN 1000 SOLUTION	9.5 - 10.5		
WATER DETERMINATION		5.0 %	
CHLORIDE		0.035 %	
SULFATE		0.12 %	
RELATED COMPOUNDS	TO PASS TEST		
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION	TO PASS TEST		
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS:	TO PASS TEST		

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000





SAFETY DATA SHEET

Preparation Date: 12/19/2014	Revision Date: 12/19/2014	Revision Number: G1		
1. IDENTIFICATION				
Product identifier				
Product code:	P1457			
Product Name:	PROPYLPARABEN SODIUM, NF			
Other means of identification				
Synonyms:	Propyl-p-hydroxybenzoate, sodium salt			
	Benzoic acid, p-hydroxy-, propyl ester, sodium salt			
CAS #:	35285-69-9			
RTECS #	DH2850000			
CI#:	Not available			
Recommended use of the chem	lical and restrictions on use			
Recommended use:	No information available.			
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 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)

	Cotogon (2D
Serious eye damage/eye irritation	Category 2B
Skin sensitization	Category 1

Label elements

Warning

Hazard statements Causes eye irritation

May cause an allergic skin reaction



Hazards not otherwise classified (HNOC) Not Applicable

Other hazards Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Avoid breathing dust/fume/gas/mist/vapors/spray Contaminated work clothing should not be allowed out of the workplace Wear protective gloves

Precautionary Statements - Response

Specific treatment (see .? on this label) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN: Wash with plenty of soap and water If skin irritation or rash occurs: Get medical advice/attention Wash contaminated clothing before reuse

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Propylparaben Sodium 35285-69-9	35285-69-9	100	*

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 symptoms persist, call a physician.

Inhalation:	Move to fresh air. If n Get medical attention	not breathing, give artificial respiration. If breathing is difficult, give oxygen.	
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 effe		layed . May cause skin irritation. May cause allergic skin reaction.	
Indication of any immediate medica Notes to Physician:	al attention and special treatment needed Treat symptomatically		
Protection of first-aiders First-Aid Providers: Avoid exposure to contaminated clothing and equipment		Vear gloves and other necessary protective clothing. Dispose of	
	5. FIRE-FIC	GHTING MEASURES	
Extinguishing Media			
Suitable Extinguishing Media:		Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.	
Unsuitable Extinguishing Media:		No information available.	
Specific hazards arising from	the chemical		
Hazardous Combustion Products:		Carbon monoxide; Carbon dioxide	
Specific hazards:		May be combustible at high temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.	
Special Protective Actions for	r Firefighters		
Specific Methods:		No information available.	
Special Protective Equipment fo	or Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear	
	6. ACCIDENTA	L RELEASE MEASURES	
Personal precautions, protective	e equipment and em	ergency procedures	
Personal Precautions:	Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.		
Environmental precautions	Prevent further leal	kage or spillage. Prevent entry into waterways, sewers.	

Methods and material for containment and cleaning up

- Methods for containmentStop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.
- Methods for cleaning upSweep up and shovel into suitable containers for disposal. Clean contaminated
surface thoroughly.

7. HANDLING AND STORAGE

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. 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:

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:

Strong oxidizing agents. 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
	None	None	None	None
Propylparaben Sodium - 35285-69-9				

Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
	None	None	None	None
Propylparaben Sodium - 35285-69-9				

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Propylparaben Sodium 35285-69-9	None	None

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:	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

Physical state: Solid.

Odor: Odorless.

Molecular/Formula weight: 202.00

Flash Point Tested according to: Not available

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

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

Density (g/cm3): No information available

Evaporation rate: No information available

Odor threshold (ppm): No information available

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

Taste No information available

Flash point (°C): No data available

Lower Explosion Limit (%): No information available

pH: No information available

Decomposition temperature(°C/°F): No information available

Bulk density: No information available

Vapor density: No information available

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

Solubility: Soluble in Water Color: White.

Formula: C10-H11-NaO3

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

Upper Explosion Limit (%): No information available

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

Specific gravity: No information available

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

VOC content (g/L): No information available

Viscosity: No information available

10. STABILITY AND REACTIVITY

Reactivity Reactive with oxidizing agents Reacts with bases

Chemical stability Stability:	Stable at normal conditions
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur
Conditions to avoid:	Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.
Incompatible Materials:	Strong oxidizing agents. Bases.
Hazardous decomposition products:	Carbon monoxide. Carbon dioxide.

Product code: P1457

Other Information

Corrosivity:

No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure: Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

Propylparaben Sodium - 35285-69-9

LD50/oral/rat = No information available LD50/oral/mouse = = 3700 mg/kg Oral LD50 Mouse 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 = 3700

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

Symptoms

Skin Contact:

May cause skin irritation. May cause sensitization by skin contact. May cause allergic skin reaction.

Product code: P1457

Eye Contact:	Causes eye irritation. Mild to moderate eye irritation.			
Inhalation Ingestion	May cause irritation of respiratory tract. May cause digestive (gastointestinal) tract irritation It may affect behavior/central nervous system/nervous system(CNS depression, ataxia, paralysis)			
Aspiration hazard	No information available			
Delayed and immediate effects a	Delayed and immediate effects as well as chronic effects from short and long-term exposure			
Chronic Toxicity	Skin: Prolonged or repeated skin contact may cause allergic contact dermatitis (allergic skin reaction). Ingestion: Prolonged or repeated ingestion may cause weight loss, and may affect the endocrine system (adrenal gland, thyroid (thyroid hypofunction)			
Sensitization:	May cause sensitization by skin contact			
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
Propylparaben Sodium	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity	No data is available
Reproductive Effects: Developmental Effects:	No information available No information available
Teratogenic Effects:	No information available
Specific Terret Organ Terrisity	

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:	No data available.			
Persistence and degradability:	No information available			
Bioaccumulative potential:	No information available			
Mobility:	No information available			

13. DISPOSAL CONSIDERATIONS

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
Propylparaben Sodium	None	None	None	None

14. TRANSPORT INFORMATION

DOT

DOT	UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant ERG No: DOT RQ (lbs):	Not Regulated No information available No information available Not applicable None No data available No information available No information available
TDG	(Canada)	
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available No information available
	Subsidiary Risk: Packing Group:	No information available
	Description:	No information available
	Beeenplien	
ADR		
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Packing Group:	No information available
	Subsidiary Risk:	No information available
	Classification Code:	No information available
	Description:	No information available No information available
	CEFIC Tremcard No:	No information available
IMO	/ IMDG	
	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:

Maximum Quantity:

No information available

No information available

RID

Not Regulated
No information available

ICAO

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.
Propylparaben Sodium	Not Listed	Not present	Present	Present (3)- 1613	Present	Present	Present 252-488-1

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:
Propylparaben Sodium	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

	Substances and their		Hazardous	Chemical Category	Section 313 - Reporting de minimis
	Reportable Quantities	Substances and TPQs	Substances and RQS		
Propylparaben Sodium	None	None	None	None	None

•	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Propylparaben Sodium	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

D2B Toxic materials

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)
Propylparaben Sodium	Present	Not Listed

Components		CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Propylparaben Sodium	Not listed	Not listed

EU Classification

R-phrase(s)

R36 - Irritating to eyes.

S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Components	Classification	Concentration Limits:	Safety Phrases
Propylparaben Sodium		No information	

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

Indication of danger:

Xi - Irritant.



16. OTHER INFORMATION

16. OTHER INFORMATION		
NFPA	HMIS	Personal Protective Equipment
1 0	Health Hazard1Fire Hazard1Reactivity0	

12/19/2014

12/19/2014 Sonia Owen

Preparation Date: Revision Date: Prepared by:

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: P1457, Propylparaben Sodium, NF

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, CQA Director, Global Supplier Quality Assurance <u>awang@spectrumchemical.com</u>



CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

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

Additional sites:13915 South Main Street, Los Angeles, California, 90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

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

ISO 9001:2015

The quality management system is applicable to:

Main Site: 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. **Certificate Number:** 94-316m-03

Initial Certification Date: 27 December 1994

Certificate Issue Date: 31 July 2017

Certificate Expiry Date: 28 January 2019



Authorized Signature Calin Moldovean President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek 900 Chelmsford Street, Lowell, MA, USA





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



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: 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.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: 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.





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.

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



管理体系认证 注册证书

兹证明,以下组织:

斯百全化学(上海)

有限公司

上海市松江区申港路3802弄A20

的管理体系,符合以下标准要求并予以注册:

ISO 9001:2015

此管理体系适用于:

药用辅料销售,化学品销售

统一社会信用代码: 91310000777627048K

证书编号: 111310001

首次认证日期: 2015年11月17日

认证决定日期: 2017年12月26日

签发日期: 2017年12月26日

有效期至: 2018年11月10日



Calin Moldovean President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited 是 UKAS 认可的认证机构 , 注册号为 014



对于此证书的签署,Intertek仅对获证组织承担认证协议所规定的义务,而不对其他组织承担任何义务。此证书的有效性基于获证组织能够依照Intertek的体系认证要求使其体系得 到保持。可通过电子邮件certificate.validation@intertek.com或用智能手机扫描该代码对证书有效性进行确认。此证书的所有权归属为Intertek,在必要时证书持有者应按要求归还 证书。



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Spectrum China Ltd.

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

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals

Unified Social Credit Identifier: 91310000777627048K

Certificate Number: 111310001

Initial Certification Date: 17 November 2015

Date of Certification Decision: 26 December 2017

Issuing Date: 26 December 2017

Valid Until: 10 November 2018



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

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.



July 13, 2017

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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 in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

Oula Clany

Oralia Chavez Quality Assurance Specialist



March 28, 2018

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name	
P1457	Propylparaben Sodium, NF	

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 03006174778

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clony

Oralia Chavez Quality Assurance Specialist



June 13, 2016

Re: Propylparaben Sodium, NF-P1457

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

Propylparaben Sodium, NF-P1457

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



June 13, 2016

Re: Propylparaben Sodium, NF-P1457

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.

Propylparaben Sodium, NF-P1457

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

Spectrum®

Certificate Of Analysis

Item Number	P1457	Lot Number	2GF0109
Item	Propylparaben Sodium, NF		
CAS Number	35285-69-9		
Molecular Formula	$C_{I0}H_{II}NaO_3$	Molecular Weight	202.00

Test	Specif	ïcation	Result
	min	max	
ASSAY (ANHYDROUS BASIS)	94.0 - 102.0 %		99.39 %
COMPLETENESS OF SOLUTION	TO PASS TEST		PASSES TEST
pH OF A 1 IN 1000 SOLUTION	9.5 - 10.5		9.6
WATER		5.0 %	2.09 %
CHLORIDE		0.035 %	<0.035 %
SULFATE		0.12 %	<0.03 %
RELATED COMPOUNDS	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-JAN-2020
RESIDUAL SOLVENTS:	TO PASS TEST		PASSES TEST
CLASS 2 (solvent) TOLUENE			<890 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm
APPEARANCE			WHITE POWDER
DATE OF MANUFACTURE			01-FEB-2017

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

Ibad Tirmizi Director of Quality Spectrum Chemical Mfg. Corp.

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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.

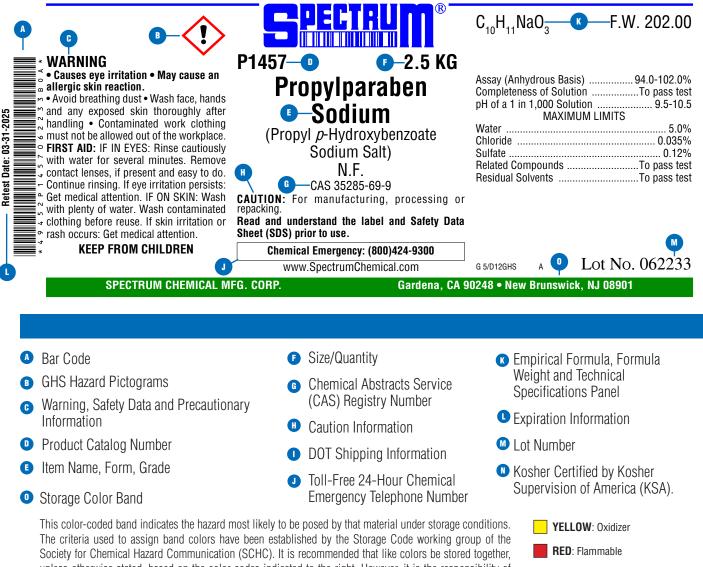


GREEN: General Storage

BLUE: Health Hazard WHITE: Corrosive

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.



unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000



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 928th 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 706th 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: P1457, Propylparaben Sodium, NF

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

The product, P1457, Propylparaben Sodium, NF, is assigned a 60 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