

Scientific Documentation

PR133, Propylparaben, NF, BP, EP

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp

769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300



Dear Customer,

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

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

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

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

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

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

Sincerely,

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

16.May.2016

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Specification for Propylparaben, NF, BP, EP (PR133)

Item Number	PR133
Item	Propylparaben, NF, BP, EP
CAS Number	94-13-3
Molecular Formula	$C_{I0}H_{I2}O_3$
Molecular Weight	180.20
MDL Number	
Synonyms	Propyl 4-Hydroxybenzoate; Propyl p-Hydroxybenzoate; Propyl Parahydroxybenzoate

Test	Specif	ïcation
	Min	Max
ASSAY	98.0 - 102.0 %	
MELTING RANGE	96° - 99°C	
COLOR OF SOLUTION		TO PASS TEST
APPEARANCE OF SOLUTION		TO PASS TEST
ACIDITY		TO PASS TEST
RESIDUE ON IGNITION (SULPHATED ASH)		0.10%
RELATED SUBSTANCES		TO PASS TEST
IDENTIFICATION		TO PASS TEST
RETEST DATE		
RESIDUAL SOLVENTS		TO PASS TEST

Spectrum Chemical Mfg Corp

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

732.214.1300

14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

West Coast Facility:





SAFETY DATA SHEET

Preparation Date: 7/29/2014 Revision Date: 7/29/2014 Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: PR133

Product Name: PROPYLPARABEN, NF, EP, BP, JP

Other means of identification

Synonyms: Aseptoform P; Betacide P; Bonomold P; Nipasol; Parben; Parasept; Paseptol;

Preserval P; Propyl aseptoform; Propyl chemosept; Propyl parasept; Protaben P;

Tegosept P;

Propyl-p-hydroxybenzoate; n-Propyl-p-hydroxybenzoate;

Benzoic acid, 4-hydroxy-, propyl ester; p-Hydroxybenzoic acid propyl ester;

p-Hydroxypropyl benzoate

Benzoic Acid, p-hydroxy-, propyl ester

CAS #: 94-13-3
RTECS # DH2800000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use:Uses advised against
Antibacterial. Preservative.
No information available

Supplier: Spectrum Chemicals and Laboratory Products, Inc.

14422 South San Pedro St. Gardena, CA 90248

(310) 516-8000

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

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

2. HAZARDS IDENTIFICATION

Classification

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

Skin sensitization Category 1B

Label elements

Product code: PR133 Product name: PROPYLPARABEN, 1/11

Warning

Hazard statements

May cause an allergic skin reaction



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

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 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 94-13-3	94-13-3	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 irritation occurs. If symptoms

persist, call a physician.

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

Get medical attention.

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

unconscious person. Consult a physician if necessary.

Product code: PR133 Product name: PROPYLPARABEN, 2 / 11

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation. May cause allergic skin reaction.

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: 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

Special Protective Actions for Firefighters

Specific Methods: No information available.

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

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

and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

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

and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage. Prevent entry into waterways, sewers.

Methods and material for containment and cleaning up

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

Methods for cleaning up

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

surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

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

Product code: PR133 Product name: PROPYLPARABEN, 3 / 11

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 - 94-13-3				

Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
	None	None	None	None
Propylparaben - 94-13-3				

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Propylparaben 94-13-3	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: Safety glasses. Safety glasses with side-shields.

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

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

Product code: PR133 Product name: PROPYLPARABEN, 4/11

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: Appearance: Color:

Solid. Crystals. Crystalline powder. White.

Odor:TasteFormula:Odorless.No information availableC10-H12-O3

Molecular/Formula weight:Flash point (°C):Flashpoint (°C/°F):180.20No data availableNo information available.

Flash Point Tested according to: Lower Explosion Limit (%): Upper Explosion Limit (%): No information available No information available

Autoignition Temperature (°C/°F): pH: Melting point/range(°C/°F): No information available 96-97 °C/204.8-206.6 °F

Boiling point/range(°C/°F): Decomposition temperature(°C/°F): Specific gravity: No information available 1.0630 @ 102 °C

Density (g/cm3):Bulk density:Vapor pressure @ 20°C (kPa):No information availableNo information available

Evaporation rate: Vapor density: VOC content (g/L):

No information available

No information available

No information available

No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available 3.04

ğ

Miscibility: Solubility:

No information available

Very slightly soluble in water
Soluble in Acetone

Soluble in Ether

Freely soluble in alcohol

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. Incompatible materials.

Incompatible Materials: Strong oxidizing agents. Bases.

Hazardous decomposition products: Carbon monoxide. Carbon dioxide.

Other Information

Corrosivity: No information available

Product code: PR133 Product name: PROPYLPARABEN, 5 / 11

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

Propylparaben - 94-13-3

LD50/oral/rat = No information available

LD50/oral/mouse = 6332 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 = 6332mg/kg

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.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May cause digestive (gastointestinal) tract irritation. It may affect behavior/central

nervous system/nervous system(CNS depression, ataxia, paralysis).

Product code: PR133 Product name: PROPYLPARABEN, 6/11

Aspiration hazardNo information available

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 kidneys, and endocrine system (adrenal gland, thyroid (thyroid hypofunction)

Sensitization: May cause sensitization by skin contact

Mutagenic Effects: May affect genetic material

Carcinogenic effects: Not considered carcinogenic.

Components	ACGIH -	IARC	NTP	OSHA HCS -	Australia - Prohibited	Australia - Notifiable
-	Carcinogens			Carcinogens	Carcinogenic	Carcinogenic
				_	Substances	Substances
Propylparaben	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
No information available

Specific Target Organ Toxicity

STOT - single exposure
STOT - repeated exposure
Target Organs:

No information available
No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

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

Product code: PR133 Product name: PROPYLPARABEN, 7/11

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	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not regulated

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

Subsidiary Risk: Not applicable

Packing Group: None

Marine Pollutant

ERG No:

DOT RQ (lbs):

No data available
No information 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

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 **Maximum Quantity:** No information available

RID

UN-No: Not Regulated

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

Product code: PR133 Product name: PROPYLPARABEN, 8 / 11

14. TRANSPORT INFORMATION

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.
Propylparaben	Present	Present KE- 20396	Present	Present (3)- 1585	Present	Present	Present 202-307-7

U.S. Regulations

Propylparaben

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1670

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	Female Reproductive
			Toxicity	Toxicity:
Propylparaben	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

	CERCLA - Hazardous Substances and their		Section 302 Extremely Hazardous	Section 313 - Chemical Category	Section 313 - Reporting de minimis
	Reportable Quantities	Substances and TPQs	Substances and RQs		
Propylparaben	None	None	None	None	None

U.S. TSCA

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

Product code: PR133 Product name: PROPYLPARABEN, 9/11

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	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory	
		Reporting	
Propylparaben	Not listed	Not listed	

EU Classification

R-phrase(s)

not determined none

Components	Classification	Concentration Limits:	Safety Phrases
Propylparaben		No information	

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

Indication of danger:

Not dangerous

16. OTHER INFORMATION

Product code: PR133 Product name: PROPYLPARABEN, 10 / 11

16. OTHER INFORMATION		
NFPA	HMIS	Personal Protective Equipment



Health Hazard	1
Fire Hazard	1
Reactivity	0



See Section 8.

Preparation Date: 7/29/2014
Revision Date: 7/29/2014
Prepared by: Sonia Owen

Disclaimer:

Product code: PR133

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

Product name: PROPYLPARABEN, 11 / 11



Manufacturer

Product Covered: PR133, Propylparaben, NF, BP, EP

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

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

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

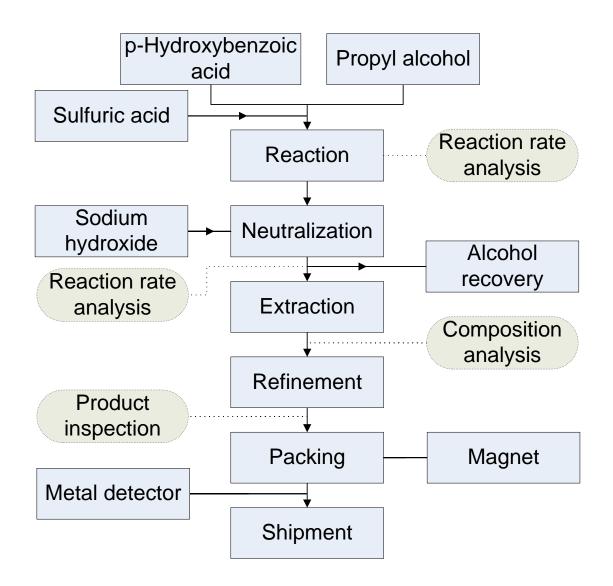
Sincerely,

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



Manufacturing Process Flowchart

Propylparaben, NF, BP, EP - PR133



Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.

New Brunswick, NJ 08901

732.214.1300

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 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: 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 certificate.com or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn 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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston

Quality Assurance Specialist

Michelle Weston



May 9, 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	
PR133	Propylparaben, NF, BP, EP	

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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston

Quality Assurance Specialist

Michelle Wester



May 6, 2016

Re: Propylparaben, NF, BP, EP-PR133

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, NF, BP, EP-PR133

is BSE/TSE free.

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

Sincerely,

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

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



May 6, 2016

Re: Propylparaben, NF, BP, EP-PR133

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 SO₂; Tree nuts; Wheat; Peanuts; Soy; Cereals containing Gluten).

Propylparaben, NF, BP, EP-PR133

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

Sincerely,

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

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



May 12, 2016

Re: Propylparaben, NF, BP, EP- PR133

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, NF, BP, EP- PR133

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

Sincerely,

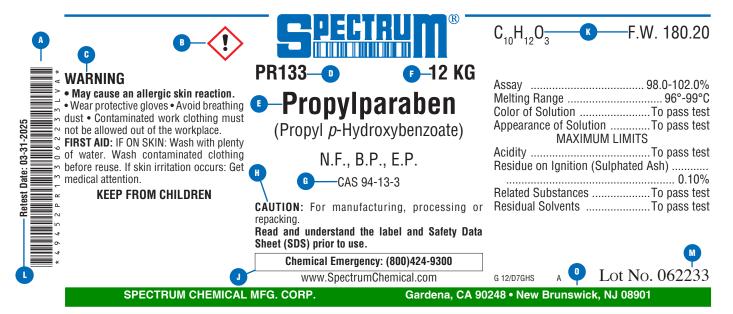
Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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	PR133	Lot Number	2EI0201
Item	Propylparaben, NF, BP, EP		
CAS Number	94-13-3		
Molecular Formula	$C_{10}H_{12}O_3$	Molecular Weight	180.20

Test	Specification		Result
	min	max	
ASSAY	98.0 - 102.0 %		100.0 %
MELTING RANGE	96° - 99°C		96 - 98 C
COLOR OF SOLUTION		TO PASS TEST	PASSES TEST
APPEARANCE OF SOLUTION		TO PASS TEST	PASSES TEST
ACIDITY		TO PASS TEST	PASSES TEST
RESIDUE ON IGNITION (SULPHATED ASH)		0.10%	0.01 %
RELATED SUBSTANCES		TO PASS TEST	PASSES TEST
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			16-NOV-2019
RESIDUAL SOLVENTS		TO PASS TEST	
CLASS 3 (solvent) / 1-PROPANOL			<5000 ppm
APPEARANCE			WHITE POWDER
DATE OF MANUFACTURE			17-NOV-2014

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 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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michael Dang

Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: PR133, Propylparaben, NF, BP, EP

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

The product, PR133, Propylparaben, NF, BP, EP, 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