

# Scientific Documentation

## Propylparaben, NF, BP, EP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://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



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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 <sub>10</sub> H <sub>12</sub> O <sub>3</sub>
Molecular Weight	180.20
MDL Number	
Synonyms	Propyl p-Hydroxybenzoate ; Propyl 4-Hydroxybenzoate ; Propyl Parahydroxybenzoate

Test	Specification	
	Min	Max
ASSAY	98.0	102.0 %
MELTING RANGE	96°	99°C
COLOR OF SOLUTION	CLEAR LESS COLOR THAN STANDARD	
APPEARANCE OF SOLUTION	CLEAR LESS COLOR THAN REFERENCE	
ACIDITY		0.1 ml
RESIDUE ON IGNITION (SULPHATED ASH)		0.1 %
RELATED SUBSTANCES:		
p-HYDROXYBENZOIC ACID		0.5 %
UNSPECIFIED IMPURITIES		0.5 %
TOTAL IMPURITIES		1.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	96°	99°C
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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

## Certificate Of Analysis

Item Number	PR133	Lot Number	2MA0237
Item	Propylparaben, NF, BP, EP	CAS Number	94-13-3
Molecular Formula	C <sub>10</sub> H <sub>12</sub> O <sub>3</sub>	Molecular Weight	180.20

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY	98.0	102.0 %	100.5 %
MELTING RANGE	96°	99°C	98°C
COLOR OF SOLUTION	CLEAR LESS COLOR THAN STANDARD		CLEAR LESS COLOR THAN STANDARD
APPEARANCE OF SOLUTION	CLEAR LESS COLOR THAN REFERENCE		CLEAR LESS COLOR THAN REFERENCE
ACIDITY		0.1 ml	0.01 ml
RESIDUE ON IGNITION (SULPHATED ASH)		0.1 %	0.00 %
RELATED SUBSTANCES:			.
p-HYDROXYBENZOIC ACID		0.5 %	<0.5 %
UNSPECIFIED IMPURITIES		0.5 %	<0.5 %
TOTAL IMPURITIES		1.0 %	<1.0 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	96°	99°C	98°C
EXPIRATION DATE			30-OCT-2026
DATE OF MANUFACTURE			31-OCT-2021
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 3 (solvent) / 1-PROPANOL			<5000 ppm
MONOGRAPH EDITION			(EP) 11, (BP) 2022

TEST	SPECIFICATION		RESULT
	MIN	MAX	
MONOGRAPH EDITION			(USP-NF) 2022

Certificate of Analysis Results Entered By:

HERMUDEZ  
Hernan Bermudez  
05-MAR-24 09:20:35

Certificate of Analysis Results Approved By:

SHANSEN  
Selin Hansen  
05-MAR-24 09:21:56

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



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

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

# SAFETY DATA SHEET

# spectrum®



Revision date 20-May-2022

Revision Number 2

## 1. Identification

### Product identifier

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

### Other means of identification

**Product Code(s)** PR133

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Skin sensitization	Category 1A
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

May cause an allergic skin reaction



**Appearance** Crystals or Crystalline powder

**Physical state** Solid

**Odor** Odorless

**Precautionary Statements - Prevention**

Avoid breathing dust/fume/gas/mist/vapors/spray  
Contaminated work clothing must 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 water and soap  
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

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Propylparaben	94-13-3	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** Itching. Rashes. Hives.

**Indication of any immediate medical attention and special treatment needed**



**Note to physicians**

May cause sensitization in susceptible persons. Treat symptomatically.

## 5. Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	Product is or contains a sensitizer. May cause sensitization by skin contact.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
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### Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## 7. Handling and storage

### Precautions for safe handling

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.
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### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.
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## 8. Exposure controls/personal protection

### Control parameters

<b>Exposure Limits</b>	The following ingredients are the only ingredients of the product above the cut-off level (or
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### Appropriate engineering controls

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available

<b>Molecular weight</b>	180.20
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

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<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	Itching. Rashes. Hives.
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### Acute toxicity

#### Numerical measures of toxicity

No information available

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	May cause sensitization by skin contact.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Propylparaben 94-13-3	-	LC50: =6.4mg/L (96h, Danio rerio)	-	-

**Persistence and degradability**  
**Bioaccumulation**

No information available.  
Inherently biodegradable.

**Other adverse effects**

No information available.

## 13. Disposal considerations

### Waste treatment methods

**Waste from residues/unused products**

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging**

Do not reuse empty containers.

## 14. Transport information

**DOT**

not regulated

**TDG**

not regulated

**MEX**

not regulated

**ICAO (air)**

not regulated

**IATA**

not regulated

**IMDG**

not regulated

**RID**

not regulated

**ADR**

not regulated

**ADN**

not regulated

## 15. Regulatory information

### International Inventories

**TSCA**

Complies

**DSL/NDSL**  
**EINECS/ELINCS**  
**ENCS**  
**IECSC**  
**KECL**  
**PICCS**  
**AICS**

Complies  
Complies  
This product complies with ENCS:  
This product complies with China:  
Complies  
Complies  
All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information****NFPA**

**Health hazards** 2

**Flammability** 1

**Instability** 0

**Physical and chemical properties** -

**HMIS**

**Health hazards** 2

**Flammability** 1

**Physical hazards** 0

**Personal protection** X

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Legend** Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA Ceiling	TWA (time-weighted average) Maximum limit value	STEL	STEL (Short Term Exposure Limit)
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#### **Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
 U.S. Environmental Protection Agency ChemView Database  
 European Food Safety Authority (EFSA)  
 EPA (Environmental Protection Agency)  
 Acute Exposure Guideline Level(s) (AELG(s))  
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
 U.S. Environmental Protection Agency High Production Volume Chemicals  
 Food Research Journal  
 Hazardous Substance Database  
 International Uniform Chemical Information Database (IUCLID)  
 Japan GHS Classification  
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
 NIOSH (National Institute for Occupational Safety and Health)  
 National Library of Medicine's ChemID Plus (NLM CIP)  
 National Library of Medicine's PubMed database (NLM PUBMED)  
 National Toxicology Program (NTP)  
 New Zealand's Chemical Classification and Information Database (CCID)  
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
 Organization for Economic Co-operation and Development Screening Information Data Set  
 World Health Organization

<b>Revision date</b>	20-May-2022
<b>Revision Note</b>	No information available.

#### **Disclaimer**

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

**End of Safety Data Sheet**



**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
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

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 [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

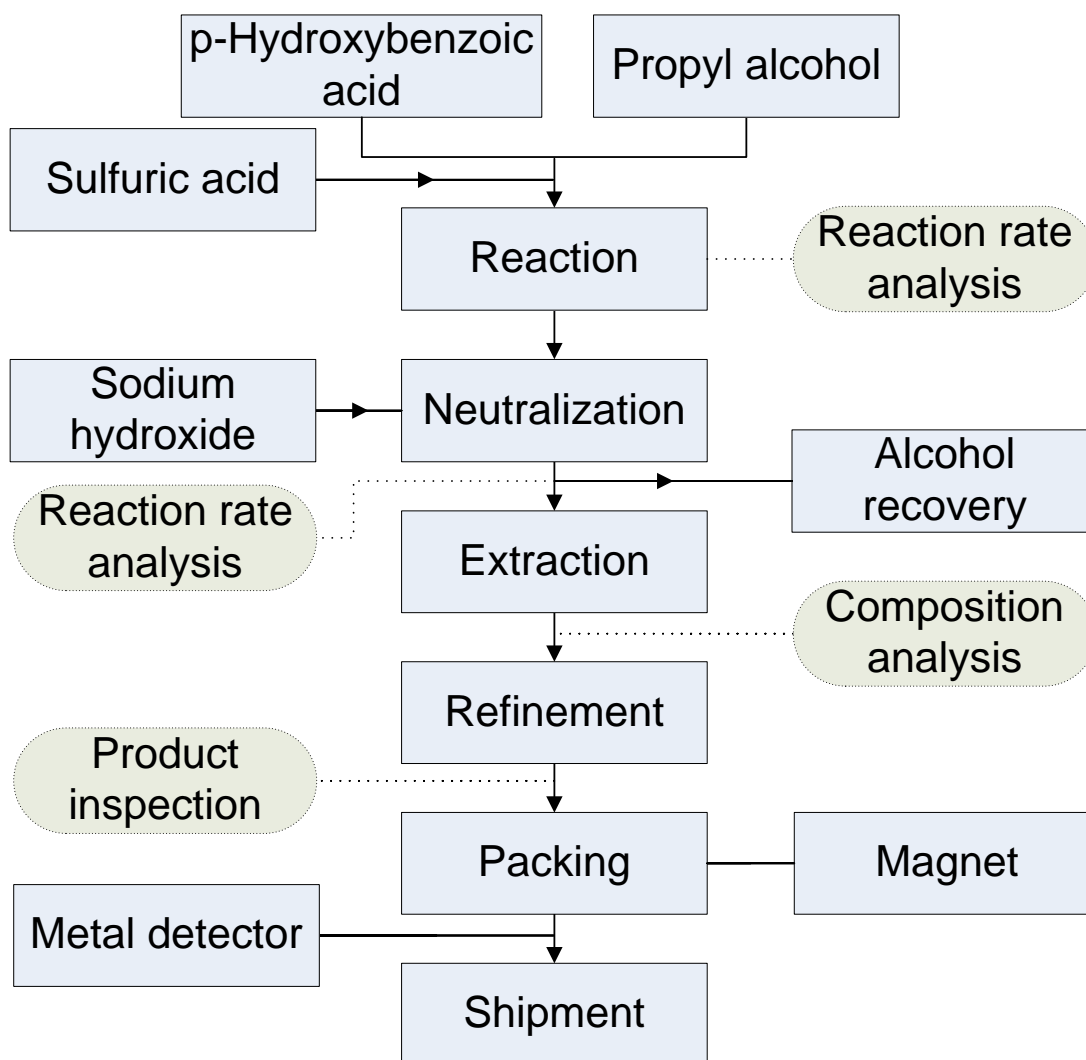
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Propylparaben, NF, BP, EP - PR133



#### ***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



## PR133, Propylparaben, NF, BP, EP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                  |
|---------------------|------------------|
| • Aflatoxins        | • CMR Substances |
| • Antibiotics       | • Pesticides     |
| • Bisphenol A (BPA) | • Phthalates     |



**RE: Elemental Impurities - Propylparaben, NF, BP, EP (Cat# PR133)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**RE: Residual Solvents - Propylparaben, NF, BP, EP (Cat# PR133)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
1-Propanol	3	< 5000 ppm

No Class 1, Class 2, or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

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## 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. Below you will find a typical label example for this catalog item.




**WARNING**

- May cause an allergic skin reaction.
- Wear protective gloves • Avoid breathing dust • Contaminated work clothing must not be allowed out of the workplace.

**FIRST AID:** IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention.

**KEEP FROM CHILDREN**



**PR133                      SIZ SY**

**Propylparaben**

(Propyl *p*-Hydroxybenzoate)

N.F., B.P., E.P.

CAS 94-13-3

**CAUTION:** For manufacturing, processing or repacking.  
Read and understand the label and Safety Data Sheet (SDS) prior to use.

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{10}H_{12}O_3$                       F.W. 180.20

Assay ..... 98.0-102.0%

Melting Range ..... 96°-99°C

Color of Solution ..... To pass test

Appearance of Solution ..... To pass test

MAXIMUM LIMITS

Acidity ..... To pass test

Residue on Ignition (Sulfated Ash) ..... 0.1%

Related Substances ..... To pass test

Elemental Impurities ..... As reported

Residual Solvents ..... To pass test

G 14/G10GHS    ?    Lot No. XQ####

### Spectrum Chemical Mfg Corp

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