



# Scientific Documentation

ME163, Methylparaben, NF

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

Ver4.06 31.January.2022

## **ME163, Methylparaben, NF**

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spectrum®

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spectrum®

Item Number	ME163
Item	Methylparaben, NF
CAS Number	99-76-3
Molecular Formula	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>
Molecular Weight	152.15
MDL Number	
Synonyms	Methyl p-Hydroxybenzoate ; Methyl 4-Hydroxybenzoate ; Methyl Hydroxybenzoate

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION A	FTIR MATCHES REFERENCE	
IDENTIFICATION:B	125	128°C
ASSAY	98.0	102.0 %
COLOR OF SOLUTION	CLEAR, LESS COLOR THAN STANDARD	
ACIDITY		0.1 ml
RESIDUE ON IGNITION		0.1 %
RELATED SUBSTANCES:	.	
p-HYDROXYBENZOIC ACID		0.5 %
UNSPECIFIED IMPURITIES		0.5 %
TOTAL IMPURITIES		1.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 2 (SOLVENT) / METHANOL	.	
MONOGRAPH EDITION		

***Spectrum Chemical Mfg Corp***

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

Item Number	ME163	Lot Number	2KJ0219
Item	Methylparaben, NF	CAS Number	99-76-3
Molecular Formula	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>	Molecular Weight	152.15

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE CRYSTALLINE POWDER
IDENTIFICATION A	FTIR MATCHES REFERENCE		FTIR MATCHES REFERENCE
IDENTIFICATION:B	125	128°C	125.1°C-127.3°C
ASSAY	98.0	102.0 %	100.8%
COLOR OF SOLUTION	CLEAR, LESS COLOR THAN STANDARD		CLEAR
ACIDITY		0.1 ml	0.1ML
RESIDUE ON IGNITION		0.1 %	0.01%
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		COMPLIES WITH STANDARD
EXPIRATION DATE			11-MAY-2026
DATE OF MANUFACTURE			12-MAY-2021
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL	.		<3000PPM
MONOGRAPH EDITION			USPNF 2021

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

*Jigisha Patel*

Jigisha Patel  
VP Regulatory Compliance & Technical Services,  
Regulatory

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

Preparation Date: 7/29/2014

Revision date 5/17/2018

Revision Number: G3

### 1. Identification

#### Product identifier

**Product code:** ME163  
**Product Name:** METHYLPARABEN, NF

#### Other means of identification

**Synonyms:** Methyl-p-hydroxybenzoate;  
 Methyl-p-oxybenzoate;  
 p-Hydroxybenzoic acid methyl ester;  
 methyl parahydroxybenzoate;  
 Methyl ester of p-hydroxy benzoic acid;  
 Benzoic acid, p-hydroxy, methyl ester;  
 Aliol, Aseptofom, Maseptol, Metaben, Methyl Chemosept, Metoxyde, Moldex,  
 Nipagin, Paridol,  
 Preserval M, Spetos, Solbrol, Solbrol M, Tegosept M

**CAS #:** 99-76-3  
**RTECS #** DH2450000  
**CI#:** Not available

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

**Recommended use:** Antimicrobial. Preservative.  
**Uses advised against** No information available

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

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

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

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Skin sensitization	Category 1B
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#### Label elements

**Warning**

**Hazard statements**

**Product code:** ME163

**Product name:** METHYLPARABEN,  
NF

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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 must not be allowed out of the workplace  
Wear protective gloves

**Precautionary Statements - Response**

IF ON SKIN: Wash with plenty of 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**

Component	CAS No	Weight-%
Methylparaben	99-76-3	100

**4. FIRST AID MEASURES**

**First aid measures**

**General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

**Inhalation:** Move to fresh air. If 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.

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

**Symptoms** May cause eye/skin irritation  
May cause an 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.

**Safe Handling Advice**

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

**United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Methylparaben	99-76-3	None	None	None	None

**Canada**

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Methylparaben	99-76-3	None	None	None	None

**Australia and Mexico**

Component	CAS No	Australia	Mexico
Methylparaben	99-76-3	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:** Goggles or Safety glasses with side-shields.

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

**Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified

respirator or equivalent.

**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**

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystals. Crystalline powder.	<b>Color:</b> White.
<b>Odor:</b> Odorless.	<b>Taste:</b> Slight. Burning.	<b>Formula:</b> C8-H8-O3
<b>Molecular/Formula weight (g/mole):</b> 152.15	<b>Flammability (solid, gas):</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 125-131 °C/257-267.8 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> 270-280 °C/518-536 °F (decomposes)	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> 1.96	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Very slightly soluble in water Solubility in Water: 62g/100mL @ 25°C and 78g/100mL @ 75°C Slightly soluble in Carbon Tetrachloride Soluble in Benzene 1 gram dissolves in about 40 ml of warm oil. 1 gram dissolves in about 70 ml of warm glycerol.	

**10. STABILITY AND REACTIVITY**

**Reactivity:**

Reactive with oxidizing agents  
Reacts with strong bases

**Chemical stability:**

**Stability:**

Stable under recommended storage 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

**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

Methylparaben	
CAS No	99-76-3

**LD50/oral/rat** = 2100 mg/kg (RTECS)  
>5600 mg/kg (Hazardous Substance Data Bank)  
**LD50/oral/mouse** = >8000 mg/kg (RTECS)  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = 6000 mg/kg Oral LD50 Rabbit  
3000 mg/kg Oral LD50 Guinea pig

### Product Information

**LD50/oral/rat** =  
**Value - Acute Tox Dermal** = 2100 mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = >8000 mg/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

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NF

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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 (gastrointestinal) tract irritation. It may affect behavior/central nervous system/nervous system/peripheral nervous system (CNS depression, somnolence, ataxia, peripheral nerve and sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage).

**Aspiration hazard** No 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 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.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Methylparaben	99-76-3	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available  
**Developmental Effects:** No information available  
**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** No information available.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility in soil** No information available  
**Other adverse effects** 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.

#### **Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Methylparaben	99-76-3	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

### TDG (Canada)

**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  
**Marine Pollutant** No Information available  
**Description:** No information available

### ADR

**UN Number** -  
**Proper Shipping Name:** No information available

**Product code:** ME163

**Product name:** METHYLPARABEN,  
NF

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**Transport hazard class(es)** No information available  
**Packing group** No information available  
**Subsidiary Risk:** No information available

**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  
**Marine Pollutant** No information available

**RID**

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available

**ICAO (air)**

**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

**IATA**

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** IF exposed or concerned  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
<i>Methylparaben</i>	99-76-3	PresentACTIVE	Present KE-20379	Present	Present (3)-1585	Present	Present	Present 202-785-7

**U.S. Regulations**

*Methylparaben*

**FDA - Food Additives Generally Recognized as Safe (GRAS):** 21 CFR 184.1490  
**FDA - Direct Food Additives** 21 CFR 172.515  
**FDA - 21 CFR - Total Food Additives** 150.141, 150.161, 172.515, 181.23, 184.1490  
**- List Sourced from EAFUS**

**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:**

**Product code:** ME163

**Product name:** METHYLPARABEN,  
NF

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This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Methylparaben	99-76-3	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Methylparaben	99-76-3	None	None	None	None	None

#### U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Methylparaben	99-76-3	Not Applicable	Not Applicable

#### Canada

##### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Methylparaben	99-76-3	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Methylparaben	99-76-3	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Methylparaben	99-76-3	Not listed

#### EU Classification

##### EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Methylparaben	99-76-3	No information

##### EU - CLP (1272/2008)

##### R-phrases(s)

Not determined



**S -phrase(s)**

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Methylparaben	99-76-3		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC****Indication of danger:**

not determined

**16. OTHER INFORMATION**

**Preparation Date:** 7/29/2014  
**Revision date** 5/17/2018  
**Prepared by:** Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



**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
ME163	Methylparaben, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

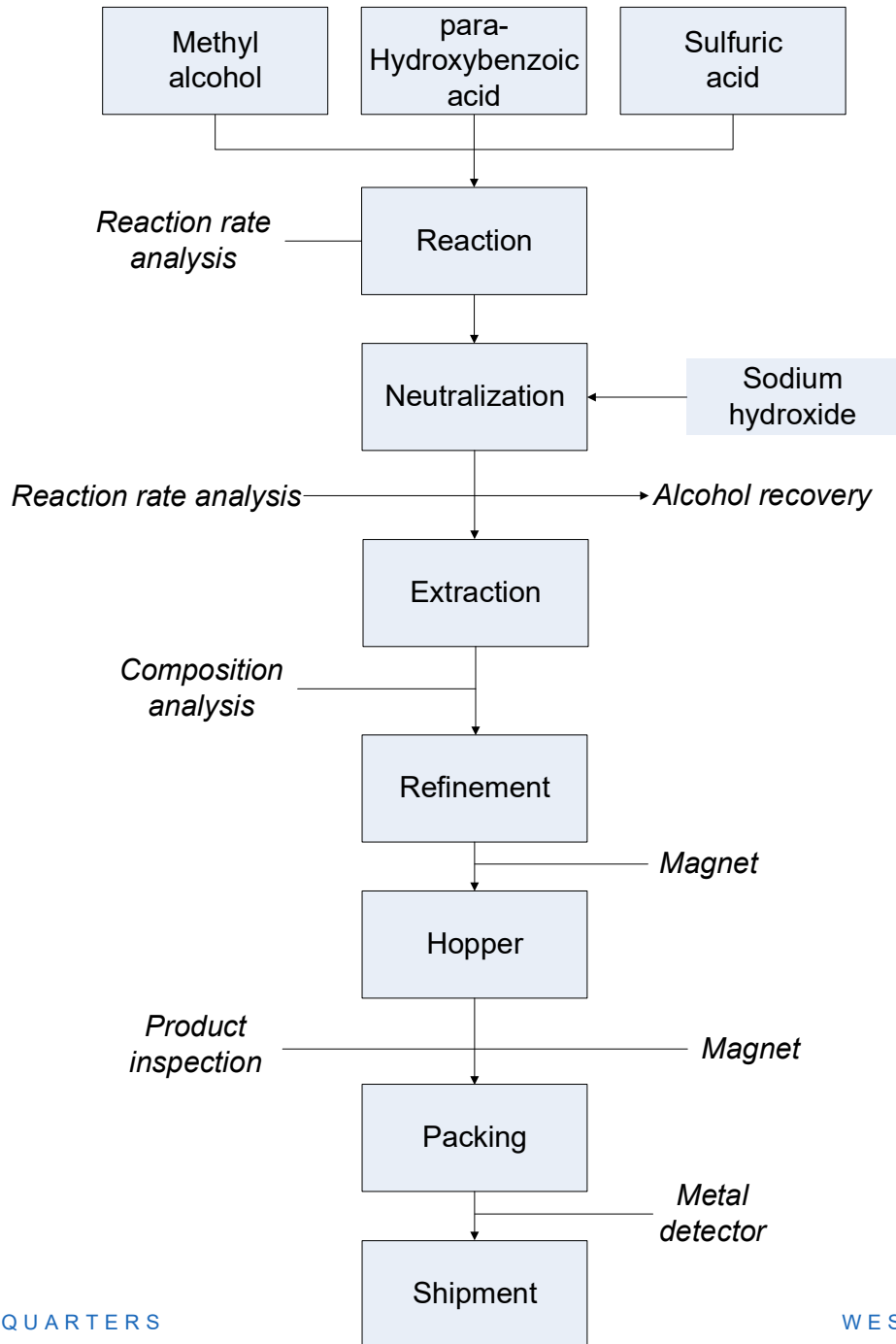
Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

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,

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Methylparaben, NF – ME163



### 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

## ME163, Methylparaben, NF

### 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 manufacturing process 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
- Antibiotics
- Bisphenol A (BPA)
- Pesticides
- Phthalates
- CMR Substances



**RE: Elemental Impurities - Methylparaben, NF (Cat# ME163)**

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 - Methylparaben, NF (Cat# ME163)**

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
Methanol	2	< 3000 ppm

No Class 1, Class 3, 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,

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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.

**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**

**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

**WARNING:** Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

**SPECTRUM CHEMICAL MFG. CORP.** Gardena, CA 90248 • New Brunswick, NJ 08901

- |   |  |   |
|---|--|---|
| <b>A</b> Bar Code   | <b>F</b> Size/Quantity   | <b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel |
| <b>B</b> GHS Hazard Pictograms                              | <b>G</b> Chemical Abstracts Service (CAS) Registry Number      | <b>L</b> Expiration Information   |
| <b>C</b> Warning, Safety Data and Precautionary Information | <b>H</b> Caution Information                                   | <b>M</b> Lot Number   |
| <b>D</b> Product Catalog Number                             | <b>I</b> DOT Shipping Information                              | <b>N</b> Kosher Certified by Kosher Supervision of America (KSA).             |
| <b>E</b> Item Name, Form, Grade                             | <b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number |   |
| <b>O</b> Storage Color Band                                 |  |   |

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

732.214.1300

**West Coast Facility:**

14422 S. San Pedro St.  
 Gardena, CA 90248

310.516.8000





**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example:** ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example:** 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at [quality\\_assurance@spectrumchemical.com](mailto:quality_assurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

Oralia Chavez,  
Quality Assurance Specialist

CORPORATE HEADQUARTERS

769 Jersey Avenue  
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WEST COAST FACILITY

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Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



KOSHER SUPERVISION OF AMERICA

בס"ד  
Jan 20, 2022

The following product(s) prepared by the named company are certified kosher with the stated requirements:

**Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street  
Gardena CA 90248  
USA

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**Product Name** ME163, Methylparaben, NF

**Brand** Spectrum

**UKD-ID** KSAV3-T3X2L60

**D/P/M** P

**Symbol Required** KSA

**Special Conditions**

This certificate expires on  
**Feb 01, 2023**

Rabbi Binyomin Lisbon  
Kashrus Administrator

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Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.