

Scientific Documentation

Methylparaben Sodium, NF

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





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Specification for Methylparaben Sodium, NF (M1277)

Item Number	M1277
Item	Methylparaben Sodium, NF
CAS Number	5026-62-0
Molecular Formula	C ₈ H ₇ NaO ₃
Molecular Weight	174.14
MDL Number	
Synonyms	Sodium Methyl Hydroxybenzoate ; p-Hydroxybenzoic Acid Methyl Ester Sodium Salt ; Sodium Methylparaben

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	95.0	102.0 %
COMPLETENESS OF SOLUTION	TO PASS TEST	
pH OF A 1 IN 1000 SOLUTION	9.5	10.5
WATER DETERMINATION		5.0 %
CHLORIDE		0.035 %
SULFATE		0.12 %
RELATED COMPOUNDS	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
CERTIFIED KOSHER		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	
CLASS 2 (SOLVENT) / METHANOL		

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.

Spectrum Chemical Mfg Corp

 Corporate Headquarters:
 West Coast Facility:

 New Brunswick, NJ 08901
 Gardena, CA 90248

 732.214.1300
 310.516.8000



Certificate Of Analysis

Item Number	M1277	Lot Number	2LF0370
Item	Methylparaben Sodium, NF	CAS Number	5026-62-0
Molecular Formula	C ₈ H ₇ NaO ₃	Molecular Weight	174.14

TFCT	SPECIFICATION		DECLUIT
TEST	MIN	MAX	RESULT
ASSAY (ANHYDROUS BASIS)	95.0	102.0 %	101.7 %
COMPLETENESS OF SOLUTION	TO PASS TEST		PASSES TEST
pH OF A 1 IN 1000 SOLUTION	9.5	10.5	9.995 %
WATER DETERMINATION		5.0 %	1.9947 %
CHLORIDE		0.035 %	<0.035 %
SULFATE		0.12 %	<0.12 %
RELATED COMPOUNDS	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES
	AS REPORTED		PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-MAR-2025
DATE OF MANUFACTURE			01-APR-2022
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			<3000 PPM

Certificate of Analysis Results Entered By:

TDAO Tiffany DAO 26-AUG-22 13:13:06

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 26-AUG-22 13:55:00

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

Revision date 22-February-2023

1. Identification		
Product identifier		
Product Name	METHYLPARABEN SODIUM, NF	
Other means of identification		
Product Code(s)	M1277	
Synonyms	None	
Recommended use of the chemica	l 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

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2B
Skin sensitization	Category 1A

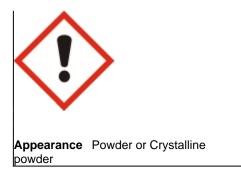
Hazards not otherwise classified (HNOC) Not applicable

Label elements Warning

Hazard statements Harmful if swallowed Causes eye irritation May cause an allergic skin reaction



Revision Number 2



Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product 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 IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water and soap If skin irritation or rash occurs: Get medical advice/attention Wash contaminated clothing before reuse IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth

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-%
Methylparaben Sodium	5026-62-0	100

4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists. Remove contact lenses, if present and easy to do. Continue rinsing.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

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

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	Product is or contains a sensitizer. May cause sensitization by skin contact.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Sodium oxides.
Explosion data Sensitivity to mechanical impac	t none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	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

Personal precautions	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.
Other information	Refer to protective measures listed in Sections 7 and 8.
Methods and material for containm	ent and cleaning up
Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling 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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.

8. Exposure controls/personal protection

Control parameters

Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.	
Appropriate engineering controls		
Engineering controls	Showers Eyewash stations Ventilation systems.	
Individual protection measures, such as personal protective equipment		
Eye/face protection	Wear safety glasses with side shields (or goggles). None required for consumer use.	
Hand protection	Wear suitable gloves.	
Skin and body protection Respiratory protection	Wear suitable protective clothing. No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.	
General hygiene considerations	Avoid contact with skin, eyes or clothing.	

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder or Crystalline powder
Color	White
Odor	Odorless
Odor threshold	No information available
Property	Values

Property	Values	Remarks • Method
рН	9.7-10.3	None known
Melting point / freezing point	125 °C / 257 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.42	None known
Water solubility	Very soluble in water	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
· · ·		

Other information	
Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	174.14
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

STOT - single exposure

Information on likely routes of exposure

Product Information		
Inhalation	Specific test data for the substance or mixture is not available.	
Eye contact	Specific test data for the substance or mixture is not available. Causes eye irritation. May cause redness, itching, and pain.	
Skin contact	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).	
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	Itching. Rashes. Hives. May cause redness and tearing of the eyes.	
Acute toxicity		
Numerical measures of toxicity No information available		
	mg/kg	
Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	May cause skin irritation. Classification based on data available for ingredients. Irritating to eyes. May cause sensitization by skin contact. No information available.	
Reproductive toxicity	No information available.	

No information available.

STOT - repeated exposure Aspiration hazard	No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information		
Ecotoxicity	The environmental impact of this product has not been fully investigated.	
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

Not listed

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Does not Comply
PICCS	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 0 Instability 0 Physical and chemical properties -<u>HMIS</u> Health hazards 2 Flammability 0 Physical hazards 0 Personal protection X

AICS

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

 Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

 TWA
 TWA (time-weighted average)
 STEL
 STEL (Short Term Exposure Limit)

 Ceiling
 Maximum limit value
 STEL
 STEL (Short Term Exposure Limit)

 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) (AEGL(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

Revision date22-February-2023Revision NoteNo information available.DisclaimerNo

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
M1277	Methylparaben Sodium, NF

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

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

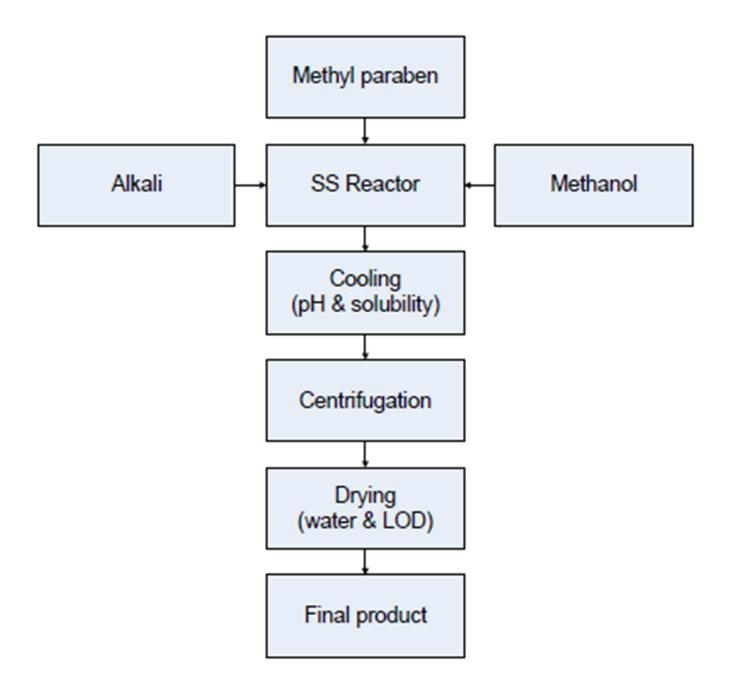
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

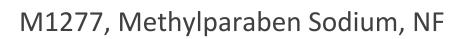
Sincerely, Quality Assurance Spectrum Chemical Mfg. Corp.

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



Manufacturing Process Flowchart - Methylparaben Sodium, NF (Catalog No. M1277)





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

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 the above-mentioned material.

Animal Testing Statement

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

Celery

Cereals containing Gluten

- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm





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 36 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)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



Elemental Impurities - Methylparaben Sodium, NF (Catalog No. M1277)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above 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 the 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.

Sincerely, Technical Services Spectrum Chemical Mfg. Corp.

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



Residual Solvents - Methylparaben Sodium, NF (Catalog No. M1277)

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.

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.



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