

# **Scientific Documentation**

# Methyl Salicylate, 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 Methyl Salicylate, NF (ME170)**

Item Number	ME170
Item	Methyl Salicylate, NF
CAS Number	119-36-8
Molecular Formula	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>
Molecular Weight	152.15
MDL Number	
Synonyms	Methyl 2-Hydroxybenzoate ; Wintergreen Oil, Synthetic ; Teaberry Oil ; Gaultheria Oil

Test	Specificat	Specification	
	Min	Max	
ASSAY	98.0	102.0 %	
SOLUBILITY IN 70% ALCOHOL	TO PASS TEST		
SPECIFIC GRAVITY @ 25º/25°C	1.180	1.185	
DIMETHYL 4-HYDROXYISOPHTHALATE		0.5 %	
SALICYLIC ACID		0.1 %	
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION	TO PASS TEST		
APPEARANCE			
EXPIRATION DATE			
MANUFACTURE DATE			
RESIDUAL SOLVENTS	AS REPORTED		
CLASS 2 (SOLVENT) / METHANOL			
MONOGRAPH EDITION			

#### Spectrum Chemical Mfg Corp

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



## **Certificate Of Analysis**

Item Number	ME170	Lot Number	1NC0009
Item	Methyl Salicylate, NF	CAS Number	119-36-8
Molecular Formula	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>	Molecular Weight	152.15

TFCT	SPECIFICATION		
TEST	MIN	MAX	RESULT
ASSAY	98.0	102.0 %	99.84 %
SOLUBILITY IN 70% ALCOHOL	TO PASS TEST		PASSES TEST
SPECIFIC GRAVITY @ 25 <sup>0</sup> /25 <sup>0</sup> C	1.180	1.185	1.182
DIMETHYL 4-HYDROXYISOPHTHALATE		0.5 %	0.025 %
SALICYLIC ACID		0.1 %	0.037 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
APPEARANCE			CLEAR COLORLESS LIQUID
EXPIRATION DATE			01-JUN-2028
MANUFACTURE DATE			01-JUL-2023
RESIDUAL SOLVENTS	AS REPORTED		
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 15-MAR-24 08:16:46

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 15-MAR-24 09:26:11

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 11-June-2020

1. Identification	
Product identifier	
Product Name	METHYL SALICYLATE, NF
Other means of identification	
Product Code(s)	ME170
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**

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2A

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

Hazard statements

Harmful if swallowed Causes serious eye irritation



Revision Number 2



Physical state Liquid

Odor Wintergreen

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Wear eye protection/ face protection

#### **Precautionary Statements - Response**

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 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-%	Trade secret
Methyl Salicylate	119-36-8	100	*

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

#### 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. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Wash skin with soap and water.
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.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).
Most important symptoms and effe	ects, both acute and delayed
Symptoms	May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures	
Suitable Extinguishing Media Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. 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	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.
Explosion data Sensitivity to mechanical impac	et 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 meas	

#### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Personal precautions Other information	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. 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. Do not eat, drink or smoke when using this product.
Conditions for safe storage, includ	ing any incompatibilities
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

#### 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	If splashes are likely to occur, wear safety glasses with side-shields.		
Hand protection	Wear suitable gloves.		
Skin and body protection	Wear suitable protective clothing.		
Respiratory protection	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. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.		

#### 9. Physical and chemical properties

Information on basic physical and o Physical state Appearance Color Odor Odor	<u>Ehemical properties</u> Liquid Oily Yellow; red; colorless Wintergreen No information available	
Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	-8.6 °C / 16.5 °F	None known
Boiling point / boiling range	220 - 224 °C / 428 - 435.2 °F	None known
Flash point	96 °C / 204.8 °F	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	5.25	None known
Relative density	1.18 - 1.185	None known
Water solubility	Very slightly soluble in cold water	None known
Solubility(ies)	Soluble in Chloroform	None known
	Soluble in diethyl ether	
	Soluble in most organic solvents	
Partition coefficient	2.5 454 °C / 849.2 °F	None known
Autoignition temperature	454 °C / 849.2 °F	None known
Decomposition temperature	na data available	None known
Kinematic viscosity	no data available No data available	None known None known
Dynamic viscosity	NO Udla avaliable	NOTE KTOWIT
Other information Explosive properties Oxidizing properties Softening point	No information available No information available No information available	

152.15 No information available No information available 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

Information on likely routes of exposure

Product Information		
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.	
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.	
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation.	
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).	
Symptoms related to the physical, chemical and toxicological characteristics		

Symptoms May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methyl Salicylate	= 887 mg/kg (Rat)	> 5000 mg/kg (Rabbit)	-
119-36-8			

#### 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. Causes serious eye irritation. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure	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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Methyl Salicylate 119-36-8	-	-	-	EC50: =50mg/L (24h, Daphnia magna)

Persistence and degradability
Bioaccumulation

No information available. Inherently biodegradable.

#### Component Information

Chemical name	Partition coefficient
Methyl Salicylate	2.55
119-36-8	

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
<u>MEX</u>	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

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	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 TWA (time-weighted average) STEL (Short Term Exposure Limit) STEL Ceiling Maximum limit value 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 date11-June-2020Revision NoteNo 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

# spectrum

#### 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
ME170	Methyl Salicylate, NF

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

Spectrum-Gardena, CA: Spectrum-New Brunswick, NJ: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

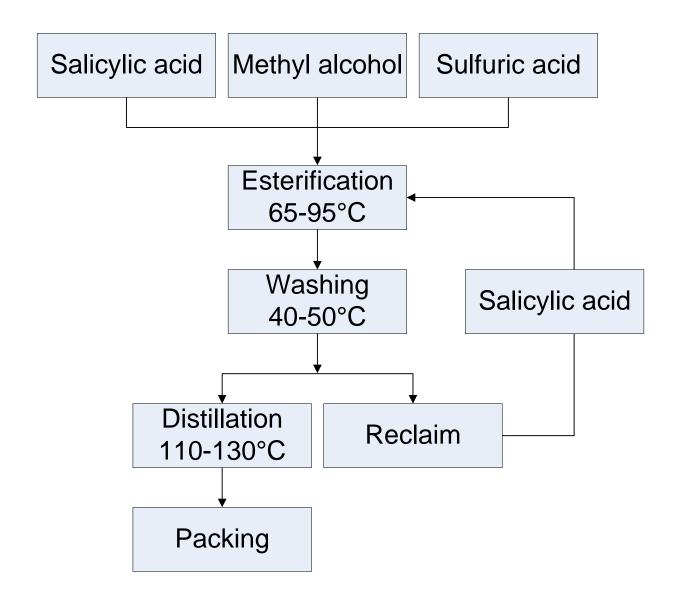
Oulu Umy

Oralia Chavez Quality Assurance Specialist



### **Manufacturing Process Flowchart**

### Methyl Salicylate, NF - ME170



#### 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

# spectrum

### ME170, Methyl Salicylate, 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 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

# spectrum®

#### RE: Elemental Impurities - Methyl Salicylate, NF (Cat# ME170)

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 <u>TechServices@spectrumchemical.com.</u>

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

AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

# spectrum

#### RE: Residual Solvents - Methyl Salicylate, NF (Cat# ME170)

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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

#### CORPORATE HEADQUARTERS

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AN ISO 9001:2015 REGISTERED COMPANY

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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.

#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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