

Scientific Documentation

L-Menthol, Crystal, USP

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 L-Menthol, Crystal, USP (ME110)

| | |
|-------------------|--|
| Item Number | ME110 |
| Item | L-Menthol, Crystal, USP |
| CAS Number | 2216-51-5 |
| Molecular Formula | C ₁₀ H ₂₀ O |
| Molecular Weight | 156.27 |
| MDL Number | |
| Synonyms | 3-p-Menthanol ; Natural Menthol ; Levomenthol ; (-)-(1R,3R,4S)-Menthol |

| Test | Specification | |
|--|--|-------------|
| | Min | Max |
| APPEARANCE | | |
| IDENTIFICATION (A) | RETENTION TIME CORRESPONDS TO STANDARD | |
| IDENTIFICATION (B) | -45° to -51° | |
| ASSAY | 98.0 | 102.0 % |
| MELTING RANGE | 41 - 44°C | |
| SPECIFIC ROTATION [α] _D ²⁵ | -45° to -51° | |
| NONVOLATILE RESIDUE | | 0.05 % |
| RELATED COMPOUNDS: | | |
| ISOMENTHOL | | 0.5 % |
| INDIVIDUAL IMPURITIES | | 0.3 % |
| TOTAL IMPURITIES | | 2.0 % |
| ELEMENTAL IMPURITIES | | AS REPORTED |
| CERTIFIED KOSHER | | |
| EXPIRATION DATE | | |
| DATE OF MANUFACTURE | | |
| RESIDUAL SOLVENTS | | AS REPORTED |
| 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 | ME110 | Lot Number | 4ND0018 |
| Item | L-Menthol, Crystal, USP | Manufacturer Lot | H2-008/L/20-21 |
| CAS Number | 2216-51-5 | Manufacturer Code | 35 |
| Molecular Formula | C ₁₀ H ₂₀ O | Molecular Weight | 156.27 |

| TEST | SPECIFICATION | | RESULT |
|---------------------------------------|--|-------------|--|
| | MIN | MAX | |
| APPEARANCE | | | CLEAR COLORLESS CRYSTALS |
| IDENTIFICATION (A) | RETENTION TIME CORRESPONDS TO STANDARD | | RETENTION TIME CORRESPONDS TO STANDARD |
| IDENTIFICATION (B) | -45° to -51° | | -48° |
| ASSAY | 98.0 | 102.0 % | 99.66765 % |
| MELTING RANGE | 41 - 44°C | | 42.8 °C |
| SPECIFIC ROTATION [α] _D 25 | -45° to -51° | | -49.9° |
| NONVOLATILE RESIDUE | | 0.05 % | 0.02 % |
| RELATED COMPOUNDS: | | | . |
| ISOMENTHOL | | 0.5 % | 0.02675 % |
| INDIVIDUAL IMPURITIES | | 0.3 % | <0.3 % |
| TOTAL IMPURITIES | | 2.0 % | 0.74 % |
| ELEMENTAL IMPURITIES | | AS REPORTED | NO ELEMENTAL IMPURITIES |
| CERTIFIED KOSHER | | | CERTIFIED KOSHER |
| EXPIRATION DATE | | | 25-MAY-2025 |
| DATE OF MANUFACTURE | | | 25-MAY-2020 |
| RESIDUAL SOLVENTS | | AS REPORTED | NO RESIDUAL SOLVENTS PRESENT |
| MONOGRAPH EDITION | | | USP 2023 |

Certificate of Analysis Results Entered By:

CACEVEDO
Charmian Acevedo
19-APR-24 08:32:49

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
19-APR-24 08:34:16

Spectrum Chemical Mfg Corp
777 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, repackaging 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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Sharp Mint Limited at C-03, SMA Cooperative Industrial Estate, G.T.Karnal Road, New Delhi, Delhi 110033, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

spectrum®



Revision date 02-November-2022

Revision Number 2

1. Identification

Product identifier

Product Name L-MENTHOL, CRYSTAL, USP

Other means of identification

Product Code(s) ME110

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 corrosion/irritation | Category 2 |
| Serious eye damage/eye irritation | Category 2A |
| Specific target organ toxicity (single exposure) | Category 3 |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



Appearance Crystalline

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear protective gloves/eye protection/face protection

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 occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor if you feel unwell

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed. Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% |
|---------------|-----------|----------|
| L-Menthol | 2216-51-5 | 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. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur. |
| Eye contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area. |
| Skin contact | Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. |
| 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 effects, 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 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 No information available.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide.

Explosion data

Sensitivity to mechanical impact 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 Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment 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. 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.

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. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved 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 Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline
Color Colorless to White
Odor No information available
Odor threshold No information available

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|---|--|-------------------------|
| pH | no data available | None known |
| Melting point / freezing point | 41 - 44 °C / 105.8 - 111.2 °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 limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| Vapor pressure | No data available | None known |
| Vapor density | no data available | None known |
| Relative density | 0.9 | None known |
| Water solubility | Slightly soluble in water | None known |
| Solubility(ies) | Slightly soluble in Methanol Slightly soluble in chloroform | 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 | No information available |
| 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 | Strong acids. Strong bases. Strong oxidizing agents. |
| 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. Irritating to eyes. (based on components). Causes serious eye irritation. |
| Skin contact | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). |
| Ingestion | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------|---|
| Symptoms | Redness. May cause redness and tearing of the eyes. |
|----------|---|

Acute toxicity

Numerical measures of toxicity

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|------------------------|--------------------|-------------------|-----------------|
| L-Menthol 2216-51-5 | 3300 mg/kg (Rat) | 5 g/kg (Rabbit) | - |

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

| | |
|---------------------------|---|
| Skin corrosion/irritation | Classification based on data available for ingredients. Irritating to skin. |
|---------------------------|---|

| | |
|--|--|
| Serious eye damage/eye irritation | Classification based on data available for ingredients. Causes serious eye irritation. |
| Respiratory or skin sensitization | No information available. |
| Germ cell mutagenicity | No information available. |
| Reproductive toxicity | No information available. |
| STOT - single exposure | No information available. |
| STOT - repeated exposure | No information available. |
| Aspiration hazard | No information available. |
| Other adverse effects | No information available. |
| Interactive effects | No information available. |

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|------------------------|----------------------|---|----------------------------|-----------|
| L-Menthol 2216-51-5 | - | LC50: =18.9mg/L (96h, Pimephales promelas) | - | - |

Persistence and degradability No information available.
Bioaccumulation 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

| | |
|-------------------|---------------|
| <u>DOT</u> | not regulated |
| <u>TDG</u> | not regulated |
| <u>MEX</u> | not regulated |
| <u>ICAO (air)</u> | not regulated |
| <u>IATA</u> | not regulated |
| <u>IMDG</u> | not regulated |
| <u>RID</u> | not regulated |
| <u>ADR</u> | not regulated |
| <u>ADN</u> | not regulated |

15. Regulatory information

International Inventories

TSCA 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** 0**Instability** 0**Physical and chemical properties** -**HMIS****Health hazards** 2**Flammability** 0**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 | STEL (Short Term Exposure Limit) |
| 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 date

02-November-2022

Revision Note

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 |
|----------------|-------------------------|
| ME110 | L-Menthol, Crystal, USP |

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

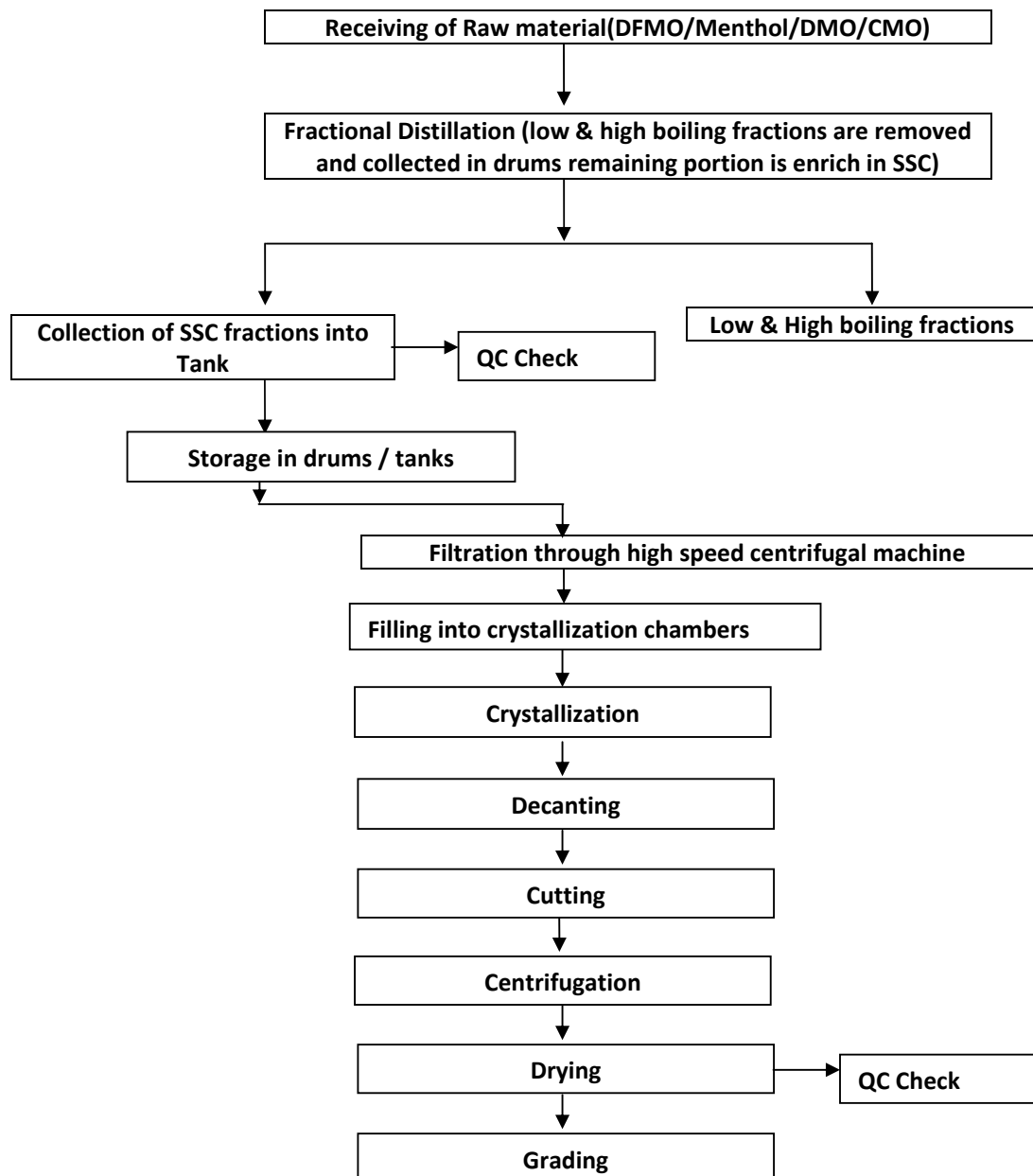
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart L-Menthol, Crystal, USP Catalog ME110

PROCESS FLOW DIAGRAM FOR MENTHOL CRYSTAL



CORPORATE HEADQUARTERS

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

Fine Crystal

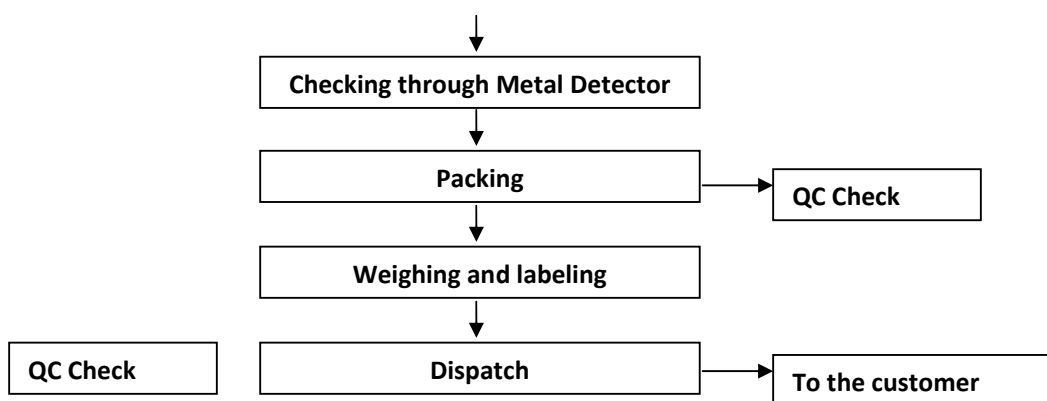
WEST COAST FACILITY

Crystal BP/USP

Sorting

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

Manufacturing Process Flowchart L-Menthol, Crystal, USP Catalog ME110



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

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WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

ME110, L-Menthol, Crystal, USP

Source Statement

The above mentioned catalog item is manufactured by plant derived material (Mentha Arvensis). No animal 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - L-Menthol, Crystal, USP (Cat# ME110)

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.

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 - L-Menthol, Crystal, USP (Cat# ME110)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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.

CORPORATE HEADQUARTERS

769 Jersey Avenue
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FAX 732.246.7132

WEST COAST FACILITY

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

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

- Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation • May be harmful if swallowed.
- Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: 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 attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

KEEP FROM CHILDREN



ME110

SIZ SY

L-Menthol
(Levomenthol; 3-*p*-Menthanol)

Crystal
USP
CAS 2216-51-5

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

$C_{10}H_{20}O$ F.W. 156.27

Manufacturer/Supplier Code ?
Manufacturer Lot Number..... ?

Assay 98.0-102.0%
Melting Range 41-44°C
Specific Rotation, $[\alpha]_D^{25}$ -45° to -51°

MAXIMUM LIMITS

Nonvolatile Residue 0.05%
Related Compounds To pass test
Elemental Impurities As reported
Residual Solvents To pass test

Repackaged by Spectrum as:
Lot No. XQ####

Exp. Date: 00-00-0000



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



KOSHER SUPERVISION OF AMERICA

בס"ד
Jan 19, 2024

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
755-769 Jersey Ave.
New Brunswick NJ 08901
USA

Product Name ME110, L-Menthol, Crystal, USP

Brand Spectrum

UKD-ID KSAV3-A8B6O45

D/P/M P

Symbol Required KSA

Special Conditions

This certificate expires on
Feb 01, 2025

Rabbi Binyomin Lisbon
Kashrus Administrator

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