

Scientific Documentation

Peppermint Oil, 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 Peppermint Oil, NF (PE105)

| | |
|-------------------|--|
| Item Number | PE105 |
| Item | Peppermint Oil, NF |
| CAS Number | 8006-90-4 |
| Molecular Formula | |
| Molecular Weight | |
| MDL Number | |
| Synonyms | Oil of Peppermint ; Mentha Piperita (Peppermint) Oil |

| Test | Specification | |
|---|---|-------------|
| | Min | Max |
| APPEARANCE | | |
| ASSAY FOR TOTAL ESTERS (AS MENTHYL ACETATE; $C_{12}H_{22}O_2$) | 5.0 % | |
| ASSAY FOR TOTAL MENTHOL (FREE AND AS ESTERS; $C_{10}H_{20}O$) | 50.0 % | |
| SOLUBILITY IN 70% ALCOHOL | ONE VOLUME DISSOLVES IN 3 VOLUMES OF 70% ALCOHOL, NMT SLIGHT OPALESCENCE | |
| SPECIFIC GRAVITY @ 25°C | 0.896 | 0.908 |
| ANGULAR ROTATION | -18° to -32° | |
| REFRACTIVE INDEX @ 20°C | 1.459 | 1.465 |
| ELEMENTAL IMPURITIES | | AS REPORTED |
| DIMETHYL SULFIDE | A WHITE FILM DOES NOT FORM AT THE ZONE OF CONTACT WITHIN 1 MIN. | |
| IDENTIFICATION | DEVELOPS A BLUE COLOR DEEPENS WITH COPPER-COLORED FLUORESCENCE AND THEN FADES WITH GOLDEN-YELLOW SOLUTION | |
| CERTIFIED KOSHER | | |
| EXPIRATION DATE | | |

| Test | Specification | |
|-------------------|---------------|-----|
| | Min | Max |
| MANUFACTURE DATE | | |
| MONOGRAPH EDITION | | |
| RESIDUAL SOLVENTS | AS REPORTED | |

Spectrum Chemical Mfg Corp

| | |
|---------------------------------------|------------------------------------|
| <i>Corporate Headquarters:</i> | <i>West Coast Facility:</i> |
| 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 | PE105 | Lot Number | 2MF0111 |
| Item | Peppermint Oil, NF | CAS Number | 8006-90-4 |

| TEST | SPECIFICATION | | RESULT |
|---|--|-------------|--|
| | MIN | MAX | |
| APPEARANCE | | | CLEAR COLORLESS FREE-FLOWING LIQUID |
| ASSAY FOR TOTAL ESTERS (AS MENTHYL ACETATE; $C_{12}H_{22}O_2$) | 5.0 % | | 5.6 % |
| ASSAY FOR TOTAL MENTHOL (FREE AND AS ESTERS; $C_{10}H_{20}O$) | 50.0 % | | 52.5 % |
| SOLUBILITY IN 70% ALCOHOL | ONE VOLUME DISSOLVES IN 3 VOLUMES OF 70% ALCOHOL, NMT SLIGHT OPALESCENCE | | 1 VOLUME DISSOLVES IN 3 VOLUME 70% ALCOHOL, NMT SLIGHT OPALESCENCE |
| SPECIFIC GRAVITY @ 25°C | 0.896 | 0.908 | 0.900 |
| ANGULAR ROTATION | -18° to -32° | | -24.8° |
| REFRACTIVE INDEX @ 20°C | 1.459 | 1.465 | 1.461 |
| ELEMENTAL IMPURITIES | | AS REPORTED | NO ELEMENTAL IMPURITIES PRESENT |
| DIMETHYL SULFIDE | A WHITE FILM DOES NOT FORM AT THE ZONE OF CONTACT WITHIN 1 MIN. | | A WHITE FILM DOES NOT FORM AT THE ZONE OF CONTACT WITHIN 1 MIN |

| TEST | SPECIFICATION | | RESULT |
|-------------------|---|-----|--|
| | MIN | MAX | |
| IDENTIFICATION | DEVELOPS A BLUE COLOR DEEPENS WITH COPPER-COLORED FLUORESCENCE AND THEN FADES WITH GOLDEN-YELLOW SOLUTION | | DEVELOPS A BLUE COLOR AND MEETS REQUIREMENTS |
| CERTIFIED KOSHER | | | CERTIFIED KOSHER |
| EXPIRATION DATE | | | 01-JUN-2025 |
| MANUFACTURE DATE | | | 01-JUN-2023 |
| MONOGRAPH EDITION | | | NF 2023 |
| RESIDUAL SOLVENTS | AS REPORTED | | NO RESIDUAL SOLVENTS PRESENT |

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
15-DEC-23 12:49:04

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
15-DEC-23 13:04:15

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

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

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

SAFETY DATA SHEET

spectrum®



Revision date 25-April-2022

Revision Number 2

1. Identification

Product identifier

Product Name PEPPERMINT OIL, NF

Other means of identification

Product Code(s) PE105

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

| | |
|-----------------------------------|-------------|
| Serious eye damage/eye irritation | Category 2A |
| Skin sensitization | Category 1A |
| Flammable liquids | Category 4 |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes serious eye irritation
May cause an allergic skin reaction
Combustible liquid



Appearance Clear and Oily

Physical state Liquid

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
Contaminated work clothing must not be allowed out of the workplace
Keep away from flames and hot surfaces. - No smoking
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 or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse
In case of fire: Use CO₂, dry chemical, or foam to extinguish

Precautionary Statements - Storage

Store in a well-ventilated place. Keep cool

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% | Trade secret |
|----------------|-----------|----------|--------------|
| Peppermint Oil | 8006-90-4 | 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. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Skin contact

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation.

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 Dry chemical. Carbon dioxide (CO₂). water spray. Alcohol resistant foam.
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 Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Product is or contains a sensitizer. May cause sensitization by skin contact.

Hazardous combustion products Carbon dioxide (CO₂).

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

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 Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Take precautionary measures against static discharges. Do not touch or walk through spilled material. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. 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 containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Use personal protection equipment. Do not breathe vapor or mist. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take

precautionary measures against static discharges. Use with local exhaust ventilation. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. 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 away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. 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 | Tight sealing safety goggles. |
|----------------------------|-------------------------------|

| | |
|------------------------|-----------------------|
| 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 | Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. |
|---------------------------------------|--|

9. Physical and chemical properties

Information on basic physical and chemical properties

| | |
|-----------------------|-----------------------------|
| Physical state | Liquid |
| Appearance | Clear and Oily |
| Color | Colorless; or; light yellow |
| 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 | no data available | None known |
| Boiling point / boiling range | no data available | None known |

| | | |
|--|-------------------------------|-----------------|
| Flash point | 67 - 71 °C / 152.6 - 159.8 °F | CC (closed cup) |
| 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 | 0.896 - 0.908 | None known |
| Water solubility | Insoluble in water | None known |
| Solubility(ies) | Soluble in Alcohol | 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 | Heat, flames and sparks. |
| 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 | 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). 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. May be harmful if swallowed. |

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

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------------------|----------------------|-------------|-----------------|
| Peppermint Oil 8006-90-4 | = 2426 mg/kg (Rat) | - | - |

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

| | |
|--|--|
| Skin corrosion/irritation | May cause skin irritation. |
| Serious eye damage/eye irritation | Classification based on data available for ingredients. Causes serious eye irritation. |
| Respiratory or skin sensitization | May cause sensitization by skin contact. |
| 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 | The environmental impact of this product has not been fully investigated. |
| 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 | Does not Comply |
| 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 2

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 2

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 25-April-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 |
|----------------|--------------------|
| PE105 | Peppermint Oil, 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,

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

Oralia Chavez
Quality Assurance Specialist

PE105, Peppermint Oil, NF

Source Statement

The above mentioned catalog item is derived from plant source (*Mentha piperita*). 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.

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 24 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
- Bisphenol A (BPA)
- CMR Substances
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Peppermint Oil, NF (Cat# PE105)

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 - Peppermint Oil, NF (Cat# PE105)

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

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

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 • May cause an allergic skin reaction • Combustible liquid • May be harmful if swallowed.
 • Keep away from flame and hot surfaces • No smoking • Wear protective gloves, eye protection, face protection • Avoid breathing mist or vapors • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.
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. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO₂ to extinguish.

KEEP FROM CHILDREN

PE105 **SIZ SY**
Peppermint Oil
 NF
 CAS 8006-90-4

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

The volatile oil obtained by steam distillation from the fresh overground parts of the flowering plant of *Mentha piperita* L. (Fam. Labiatae).

| | |
|--|--------------|
| Assay For Total Esters (as Menthyl Acetate; C ₁₂ H ₂₂ O ₂) | Min. 5.0% |
| Assay For Total Menthyl (Free and as Esters; C ₁₀ H ₁₈ O) | Min. 50.0% |
| Solubility in 70% Alcohol | To pass test |
| Specific Gravity | 0.896-0.908 |
| Angular Rotation | -18° to -32° |
| Refractive Index @ 20°C | 1.459-1.465 |

MAXIMUM LIMITS

| | |
|----------------------------|--------------|
| Elemental Impurities | As reported |
| Dimethyl Sulfide | To pass test |
| Residual Solvents | To pass test |

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.
 FLUSHED WITH NITROGEN

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

R 11/J7GHS ? Lot No. XQ####

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 20, 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 PE105, Peppermint Oil, NF

Brand Spectrum

UKD-ID KSAV3-Y5U3M58

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.