

Scientific Documentation

Mineral Oil, Low Viscosity, FCC

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 Mineral Oil, Low Viscosity, FCC (M1193)

Item Number	M1193
Item	Mineral Oil, Low Viscosity, FCC
CAS Number	8042-47-5
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	White Mineral Oil, Light

Test	Specification		
	Min	Max	
CARBON NUMBER AT 5% DISTILLATION POINT	17	25	
VISCOSITY RANGE @ 40°C	10.8	13.6 cSt	
SPECIFIC GRAVITY @ 25°C	0.829	0.859	
ULTRAVIOLET ABSORBANCE (POLYNUCLEAR HYDROCABONS)	TO PASS TEST		
VISCOSITY @ 100° C	3 - 11 cSt		
LEAD (Pb)		1 mg/kg	
READILY CARBONIZABLE SUBSTANCES	TO PASS TEST		
IDENTIFICATION	TO PASS TEST		
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	M1193	Lot Number	2LL0166
Item	Mineral Oil, Low Viscosity, FCC	CAS Number	8042-47-5

TECT	SPECIFICATION		DECLU T
TEST	MIN	MAX	RESULT
CARBON NUMBER AT 5% DISTILLATION POINT	17	25	21.9
VISCOSITY RANGE @ 40°C	10.8	13.6 cSt	11.84 cSt
SPECIFIC GRAVITY @ 25°C	0.829	0.859	0.8451
ULTRAVIOLET ABSORBANCE (POLYNUCLEAR HYDROCABONS)	TO PASS TEST		PASSES TEST
VISCOSITY @ 100° C	3 - 11 cSt		3 cSt
LEAD (Pb)		1 mg/kg	0.08 mg/kg
READILY CARBONIZABLE SUBSTANCES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			03-NOV-2024
DATE OF MANUFACTURE			03-NOV-2021
APPEARANCE			COLORLESS LIQUID

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 29-DEC-22 13:46:09

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 30-DEC-22 05:20:25

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.

SAFETY DATA SHEET SPECTRUM®



Revision date 14-September-2020 Revision Number 2

1. Identification

Product identifier

Product Name MINERAL OIL, WHITE, LIGHT, FCC

Other means of identification

Product Code(s) M1193

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

Aspiration hazard Category 1

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

May be fatal if swallowed and enters airways



Appearance Oily and viscous Physical state Liquid Odor Odorless

Precautionary Statements - Response

IF SWALLOWED: Immediately call a POISON CENTER or doctor Do NOT induce vomiting

Precautionary Statements - Storage

Store locked up.

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
Mineral Oil, light, white	8042-47-5	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 Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance.

Inhalation Aspiration into lungs can produce severe lung damage. If breathing has stopped, give

artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. If breathing is difficult, (trained personnel should) give oxygen. Get immediate medical advice/attention. Delayed

pulmonary edema may occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Wash skin with soap and water.

Ingestion ASPIRATION HAZARD IF SWALLOWED - CAN ENTER LUNGS AND CAUSE DAMAGE.

Do NOT induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use

barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as

required.

Most important symptoms and effects, both acute and delayed

Symptoms Difficulty in breathing. Coughing and/ or wheezing. Dizziness.

Indication of any immediate medical attention and special treatment needed

Note to physiciansBecause of the danger of aspiration, emesis or gastric lavage should not be employed

unless the risk is justified by the presence of additional toxic substances.

5. Fire-fighting measures

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.

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.

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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Sensitive to light. Store in light-resistant containers. Keep containers tightly closed in a dry,

cool and well-ventilated place. Store locked up. Keep out of the reach of children. Store

away from other materials.

8. Exposure controls/personal protection

Control parameters

The following ingredients are the only ingredients of the product above the cut-off level (or **Exposure Limits**

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.

Skin and body protection No special protective equipment required.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid

Appearance Oily and viscous Color colorless Odor Odorless

No information available **Odor threshold**

Remarks • Method Property Values

no data available None known Melting point / freezing point no data available None known > 230 °C / 446 °F None known **Boiling point / boiling range** 93.3 °C / 199.9 °F Flash point None known no data available None known **Evaporation rate** 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 <0.1 @ 20°C (kPa) None known no data available Vapor density None known 0.83 - 0.86 Relative density None known Insoluble in water None known Water solubility None known Solubility(ies) Soluble in most organic solvents None known **Partition coefficient** >6 None known

Autoignition temperature no data available

Decomposition temperature None known no data available Kinematic viscosity None known **Dynamic viscosity** No data available None known

Other information

No information available **Explosive properties Oxidizing properties** No information available No information available Softening point No information available Molecular weight

VOC Content (%)
Liquid Density
No information available
No information available
No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under recommended storage 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

Inhalation Specific test data for the substance or mixture is not available. Aspiration into lungs can

produce severe lung damage. May cause pulmonary edema. Pulmonary edema can be

fatal. May cause irritation of respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. May cause irritation.

Skin contact Repeated exposure may cause skin dryness or cracking.

Ingestion Specific test data for the substance or mixture is not available. Potential for aspiration if

swallowed. May cause lung damage if swallowed. Aspiration may cause pulmonary edema

and pneumonitis. May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Difficulty in breathing. Coughing and/ or wheezing. Dizziness.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Mineral Oil, light, white 8042-47-5	> 5000 mg/kg (Rat)	-	-

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

No information available.
No information available.
No information available.

Reproductive toxicityNo information available.

STOT - single exposure
STOT - repeated exposure
No information available.
No information available.

Aspiration hazard May be fatal if swallowed and enters airways.

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
		1.000		
Mineral Oil, light, white	-	LC50: >10000mg/L (96h,	-	-
8042-47-5		Lepomis macrochirus)		

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Mineral Oil, light, white	>6
8042-47-5	

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

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

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

ENCS IECSCThis product complies with ENCS:
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 14-September-2020 Revision Note 14-September-2020 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
M1193	Mineral Oil, Low Viscosity, FCC

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,

Oralia Chavez

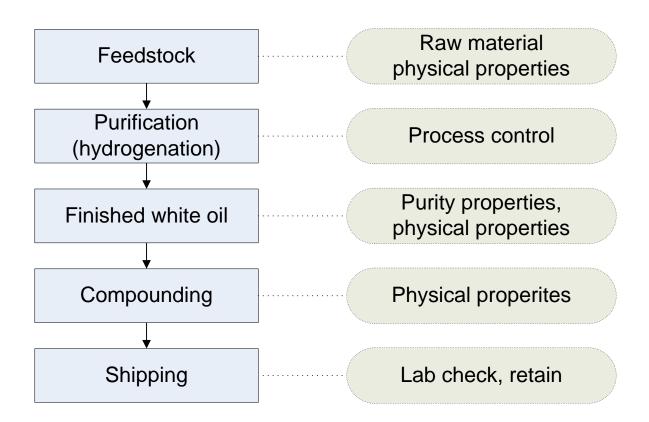
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Mineral Oil, Low Viscosity, FCC - M1193



Spectrum Chemical Mfg Corp

West Coast Facility:



M1193, Mineral Oil, Low Viscosity, FCC

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 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



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.





M1193

Mineral Oil, Low Viscosity

SIZ SY

(White Mineral Oil, Light) FCC

CAS 8042-47-5

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

Stabilized with DL- α -Tocopherol (Vitamin E).

FLUSHED WITH NITROGEN

resistant containers.

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 9/I5GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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

732.214.1300 310.516.8000