

# **Scientific Documentation**

# **Spearmint Oil, Natural, 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





# **Table of Contents**

Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Technical Statements General Label Information – Sample Label



# **Specification for Spearmint Oil, Natural, FCC** (SP306)

Item Number	SP306
Item	Spearmint Oil, Natural, FCC
CAS Number	8008-79-5
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Oleum Menthae Viridis ; Oleum Menthae Crispae ; Mentha Spicata (Spearmint) Leaf Oil

Test	Specification		
	Min	Max	
ASSAY (KETONES ; v/v)	55.0 %		
ANGULAR ROTATION	-48° to -59°		
REACTIVITY	TO PASS TEST		
REFRACTIVE INDEX @ 20°C	1.484	1.491	
SOLUBILITY IN ALCOHOL	TO PASS TEST		
SPECIFIC GRAVITY @ 25°C	0.917	0.934	
IDENTIFICATION	TO PASS TEST		
APPEARANCE			
EXPIRATION DATE			
DATE OF MANUFACTURE			

#### 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	SP306	Lot Number	1NB0101
Item	Spearmint Oil, Natural, FCC	CAS Number	8008-79-5

TECT	SPECIFICATION		
TEST	MIN	MAX	RESULT
ASSAY (KETONES ; v/v)	55.0 %		66.77 %
ANGULAR ROTATION	-48° to -59°		-55.96°
REACTIVITY	TO PASS TEST		PASSES TEST
REFRACTIVE INDEX @ 20 <sup>0</sup> C	1.484	1.491	1.4902
SOLUBILITY IN ALCOHOL	TO PASS TEST		PASSES TEST
SPECIFIC GRAVITY @ 25 <sup>0</sup> C	0.917	0.934	0.929
IDENTIFICATION	TO PASS TEST		PASSES TEST
APPEARANCE			CLEAR, COLORLESS LIQUID
EXPIRATION DATE			18-JAN-2026
DATE OF MANUFACTURE			18-JAN-2024

Certificate of Analysis Results Entered By:

SHANSEN Selin Hansen 08-MAR-24 15:15:15

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



Ana Mendez

Certificate of Analysis Results Approved By:

08-MAR-24 15:18:04

AMENDEZ

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

Revision date 24-October-2022

1. Identification	
Product identifier	
Product Name	SPEARMINT OIL, FCC
Other means of identification	
Product Code(s)	SP306
UN/ID no	UN1197
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 2B
Flammable liquids	Category 3

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

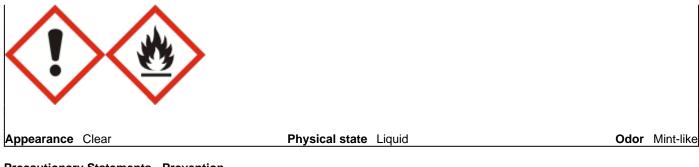
Warning

Hazard statements

Causes skin irritation Causes eye irritation Flammable liquid and vapor



Revision Number 2



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

Wash face, hands and any exposed skin thoroughly after handling Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking Keep container tightly closed Ground/bond container and receiving equipment Use explosion-proof electrical/ ventilating / lighting/ .? / equipment Use only non-sparking tools Take precautionary measures against static discharge 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 skin irritation occurs: Get medical advice/attention IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower 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-%
Spearmint Oil	8008-79-5	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. 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. 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. Get medical attention if irritation develops and persists.
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. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.
Most important symptoms and effect	cts, both acute and delayed
Symptoms	No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

#### 5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam. 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	risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Hazardous combustion products	Carbon monoxide. 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. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.
Other information	Ventilate the area. Refer to protective measures listed in Sections 7 and 8.
Methods and material for containm	ent and cleaning up
Methods for containment	Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers 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.

#### Precautions for safe handling

Advice on safe handling	Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. 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. 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. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Protect from light.

# 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. Impervious gloves.	
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.	
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. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or clothing.	

# 9. Physical and chemical properties

Information on basic physical and chemical properties		
Physical state	Liquid	
Appearance	Clear	
Color	Colorless to Yellow or Greenish-Yellow	

Odor	Mint-like	
Odor threshold	No information available	
Property_	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	no data available	None known
Boiling point / boiling range	228 °C / 442.4 °F	None known
Flash point	60 °C / 140 °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	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	0.92	None known
Water solubility	Very slightly soluble in water	None known
Solubility(ies)	Very 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	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 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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Spearmint Oil	= 5 g/kg (Rat)	-	-
8008-79-5			

#### 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	Classification based on data available for ingredients. Irritating to skin. Classification based on data available for ingredients. Irritating to eyes. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

#### 12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	No information available. Inherently biodegradable.
Other adverse effects	No information available.

#### 13. Disposal considerations

Waste treatment methods	
Waste from residues/unused products	Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Empty containers pose a potential fire and explosion hazard. Do not cut, puncture of weld containers.

#### 14. Transport information

Extracts, flavoring, liquid **Proper Shipping Name:** Hazard class 3 Packing group: Ш Special Provisions B1, IB3, T2, TP1 Marine Pollutant Severe Marine Pollutant UN1197, Extracts, flavoring, liquid, 3, III **Description: Emergency Response Guide** 127 Number TDG UN-No: UN1197 **Proper Shipping Name:** Extracts, flavouring, liquid **Hazard class** 3 Packing Group: Ш **Description:** UN1197, Extracts, flavouring, liquid, 3, III MEX UN-No UN1197 **Proper Shipping Name** Extracts, flavouring, liquid Hazard class 3 **Special Provisions** 223 Packing Group III Description UN1197, Extracts, flavouring, liquid, 3, III ICAO (air) UN1197 UN-No: Extracts, flavouring, liquid **Proper Shipping Name:** Hazard class 3 Ш Packing Group: Special Provisions A3 Description: UN1197, Extracts, flavouring, liquid, 3, III ΙΑΤΑ **UN number** UN1197 **Proper Shipping Name:** Extracts, flavouring, liquid Transport hazard class(es) 3 Ш Packing group 3L **ERG Code Special Provisions** A3 **Description:** UN1197, Extracts, flavouring, liquid, 3, III IMDG **UN number** UN1197 Proper shipping name Extracts, flavouring, liquid Transport hazard class(es) 3 Packing group III F-E, S-D EmS-No **Special Provisions** 223, 955 Marine pollutant NP1 Description UN1197, Extracts, flavouring, liquid, 3, III, (60°C c.c.) RID UN1197 **UN number** EXTRACTS, FLAVOURING, LIQUID **Proper Shipping Name:** Transport hazard class(es) 3 Packing group Ш **Classification code** F1 **Special Provisions** 601 **Description:** UN1197, EXTRACTS, FLAVOURING, LIQUID, 3, III Labels 3 ADR **UN number** UN1197 **Proper Shipping Name:** Extracts, flavouring, liquid Transport hazard class(es) 3 Ш Packing group

Classification code Tunnel restriction code Special Provisions Description: Labels	F1 (D/E) 601 UN1197, Extracts, flavouring, liquid, 3, III, (D/E) 3
ADN	
UN/ID No	UN1197
Proper shipping name	Extracts, flavouring, liquid
Transport hazard class(es)	3
Packing Group	III
Classification code	F1
Special Provisions	601
Description	UN1197, Extracts, flavouring, liquid, 3, III
Hazard label(s)	3
Limited quantity (LQ)	5 L
ventilation	VE01
Equipment Requirements	PP, EX, A

Complies

#### 15. Regulatory information

International Inventories

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

**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 24-October-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

# 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
SP306	Spearmint Oil, Natural, 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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist

# spectrum®

# SP306, Spearmint Oil, Natural, FCC

### **Source Statement**

The above mentioned catalog item is plant derived products. 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

# **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 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
- Antibiotics
- Bisphenol A (BPA)
- Parabens
- CMR Substances
- Preservatives

# spectrum®

# **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.



**KEEP FROM CHILDREN** 

www.SpectrumChemical.com

LIGHT SENSITIVE: Keep tightly closed in lightresistant containers.

R 9/H12GHS ? Lot No. XQ####

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

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

732.214.1300

0000-00-00

Date:

Exp.