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.
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- GMO Statement
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- General Label Information – Sample Label
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• Halal Certificate
# Specification for Castor Oil, USP (CA208)

<table>
<thead>
<tr>
<th>Item Number</th>
<th>CA208</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Castor Oil, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>8001-79-4</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td></td>
</tr>
<tr>
<td>Molecular Weight</td>
<td></td>
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<tr>
<td>MDL Number</td>
<td></td>
</tr>
<tr>
<td>Synonyms</td>
<td>Ricinus Communis (Castor) Seed Oil ; Ricinus Oil</td>
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</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIFIC GRAVITY @ 25°/25</td>
<td>Min 0.957</td>
</tr>
<tr>
<td>TRIGLYCERIDE COMPOSITION:</td>
<td></td>
</tr>
<tr>
<td>RRR</td>
<td>90.0 %</td>
</tr>
<tr>
<td>RRL</td>
<td>2.0</td>
</tr>
<tr>
<td>RRO</td>
<td>2.5</td>
</tr>
<tr>
<td>RRS</td>
<td>0.2</td>
</tr>
<tr>
<td>HYDROXYL VALUE</td>
<td>160</td>
</tr>
<tr>
<td>FATS AND FIXED OILS, ACID VALUE</td>
<td>2.0</td>
</tr>
<tr>
<td>FATS AND FIXED OILS, PEROXIDE VALUE</td>
<td>10.0</td>
</tr>
<tr>
<td>FATS AND FIXED OILS, UNSAPONIFIABLE VALUE</td>
<td>0.8 %</td>
</tr>
<tr>
<td>WATER DETERMINATION</td>
<td>0.3 %</td>
</tr>
<tr>
<td>ELEMENTAL IMPURITIES</td>
<td>AS REPORTED</td>
</tr>
<tr>
<td>IDENTIFICATION A, FATTY ACID COMPOSITION:</td>
<td>FATTY ACID PROFILE Meet Requirement</td>
</tr>
<tr>
<td>PALMITIC ACID (C16:0)</td>
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</tr>
<tr>
<td>STEARIC ACID (C18:0)</td>
<td>2.5 %</td>
</tr>
<tr>
<td>OLEIC ACID (C18:1)</td>
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</tr>
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<tr>
<td>LINOLENIC ACID (C18:3)</td>
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<tr>
<td>cis-11-EICOSENOIC ACID (C20:1)</td>
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<tr>
<td>RICINOLEIC ACID</td>
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<tr>
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</tr>
<tr>
<td>IDENTIFICATION B: DISTINCTION FROM MOST OTHER FIXED OILS</td>
<td>SLIGHTLY SOLUBLE IN SOLVENT HEXANE</td>
</tr>
<tr>
<td>IDENTIFICATION C: ULTRAVIOLET ABSORPTION @270 nm</td>
<td>0.7</td>
</tr>
<tr>
<td>CERTIFIED HALAL</td>
<td></td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
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</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
</tr>
<tr>
<td>APPEARANCE</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>AS REPORTED</td>
</tr>
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<td>Test</td>
<td>Specification</td>
</tr>
<tr>
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<td>-----------------------</td>
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<tr>
<td>SPECIFIC GRAVITY @ 25°/25</td>
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<td>RRL</td>
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<td>RRO</td>
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<td>RRS</td>
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<tr>
<td>HYDROXYL VALUE</td>
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<tr>
<td>FATS AND FIXED OILS, PEROXIDE VALUE</td>
<td>10.0</td>
</tr>
<tr>
<td>FATS AND FIXED OILS, UNSAPONIFIABLE VALUE</td>
<td>0.8 %</td>
</tr>
<tr>
<td>WATER DETERMINATION</td>
<td>0.3 %</td>
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<tr>
<td>ELEMENTAL IMPURITIES</td>
<td>AS REPORTED</td>
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<tr>
<td>IDENTIFICATION A, FATTY ACID COMPOSITION:</td>
<td>FATTY ACID PROFILE MEET REQUIREMENT</td>
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<tr>
<td>PALMITIC ACID (C16:0)</td>
<td>2.0 %</td>
</tr>
<tr>
<td>STEARIC ACID (C18:0)</td>
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<tr>
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<td>cis-11-OCTADECENOIC ACID OR ANY OTHER UNIDENTIFIED FATTY ACID</td>
<td>1.0 %</td>
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<tr>
<td>IDENTIFICATION B: DISTINCTION FROM MOST OTHER FIXED OILS</td>
<td>SLIGHTLY SOLUBLE IN SOLVENT HEXANE</td>
</tr>
<tr>
<td>IDENTIFICATION C: ULTRAVIOLET ABSORPTION @270 nm</td>
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<td>RESIDUAL SOLVENTS</td>
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</table>
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.
1. IDENTIFICATION

Product identifier

Product code: CA208
Product name: CASTOR OIL, USP

Other means of identification

Synonyms:
- Cosmetol
- Ricinus oil
- Ricinus

CAS #: 8001-79-4

RTECS #: FI410000

CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use:
Medication; in the preparation of coatings, urethanes, surfactants and dispersants, cosmetics (e.g. lipstick), lubricants; chief raw material for the production of sebacic acid, a basic ingredient in the production of synthetic resins and fibers; as a lubricant in metal drawing, machine lubrication and 2-cycle engine fuels, in hydraulic fluids, rubber preservative and mold lubricants; constituent of embalming fluids; in soap manufacturing; to impart emollient and lubricant properties to cosmetic preparations; as Turkey-red oil (sulfated castor oil) for dyeing and finishing textiles; as dehydrated castor oil in alkyds, resinous copolymers, varnishes oil-based paints, enamels, caulks and putties; as blown oil (oxidized oil) for plasticizing oilcloth, artificial leather, coated fabrics, lacquers, to plasticize rosin in the manufacture of sticky fly-paper, for nitrocellulose and similar coating systems, hot melts, duplicating and stencil inks, adhesives, and laminates; as a release and anti-sticking agent in hard candy manufacture; in the production of elastomers, fatty acids, electrical insulating compounds; in the manufacture of fungicides; used in the production of transparent soap, textile processing aids, toiletries.

Uses advised against
No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com

Emergency telephone number
Chemetrec 1-800-424-9300
Contact Person:
Tom Tyner (USA - West Coast)
Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)
Label elements

Not classified

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms
May cause eye/skin irritation
Ingestion may cause nausea, vomiting, and diarrhea
Abdominal pain
Thirst
Dehydration

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Product code: CA208
Product name: CASTOR OIL, USP
Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide.

Specific hazards May be combustible at high temperatures. May be ignited by heat, sparks or flames. Container explosion may occur under fire conditions or when heated.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth).

Methods for cleaning up Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions: Provide sufficient air exchange and/or exhaust in work rooms. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice: Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe vapors or spray mist. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions: Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Store under nitrogen.

Incompatible Materials:
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WEEL</th>
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<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
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<td>None</td>
<td>None</td>
<td>None</td>
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Canada

<table>
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<tr>
<th>Component</th>
<th>CAS No</th>
<th>Canada - Alberta</th>
<th>Canada - British Columbia</th>
<th>Canada - Ontario</th>
<th>Canada - Quebec</th>
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Australia and Mexico

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<th>Mexico</th>
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<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields.

Skin and body protection: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient. Use a vapor respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentrations of mist or vapor, inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
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</thead>
<tbody>
<tr>
<td>Liquid</td>
<td>Oily</td>
<td>Colorless. Light yellow.</td>
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</table>

<table>
<thead>
<tr>
<th>Odor:</th>
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<tbody>
<tr>
<td>Characteristic. Mild.</td>
<td>Acid. Nauseating.</td>
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Product code: CA208
Product name: CASTOR OIL, USP
10. STABILITY AND REACTIVITY

<table>
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<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Molecular/Formula weight (g/mole):</td>
<td>Flammability (solid, gas)</td>
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<tr>
<td>Flashpoint (°C/°F):</td>
<td>229 °C/445 °F</td>
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<td>Flash Point Tested according to:</td>
<td>Closed cup</td>
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<td>Upper Explosion Limit (%):</td>
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<td>Decomposition temperature(°C/°F):</td>
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<td>Density (g/cm³):</td>
<td>0.945-0.965 @ 25 deg. C.</td>
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<td>Vapor pressure @ 20°C (kPa):</td>
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<td>VOC content (g/L):</td>
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<td>Viscosity:</td>
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<td>Chemical stability</td>
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<tr>
<td>Stability:</td>
<td>Stable under recommended storage conditions.</td>
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<tr>
<td>Possibility of Hazardous Reactions:</td>
<td>Hazardous polymerization does not occur</td>
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<td>Incompatible Materials:</td>
<td>Strong oxidizing agents</td>
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<td>Hazardous decomposition products:</td>
<td>Carbon monoxide. Carbon dioxide.</td>
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<td>Other Information</td>
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<tr>
<td>Special Remarks on Corrosivity:</td>
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</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Principal Routes of Exposure:
Ingestion. Skin.

**Acute Toxicity**

Component Information

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
</tr>
</tbody>
</table>

LD50/oral/rat = No information available
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
Value - Acute Toxicity = No information available

LD50/oral/mouse =
Value - Acute Tox = No information available

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

**Skin Contact:** Causes skin irritation. Mild skin irritation.

**Eye Contact:** Causes eye irritation. Mild eye irritation. May cause slight temporary eye irritation.

**Inhalation**
May cause irritation of respiratory tract.

**Ingestion**
Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause abdominal pain. It is a purgative. May have a strong laxative effect. May cause dehydration. May cause thirst. May affect electrolytes.

**Aspiration hazard**
No information available.

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

Prolonged or repeated ingestion may affect the liver.

Sensitization:

No information available.

Mutagenic Effects:

No information available

Carcinogenic effects:

Not considered carcinogenic.

Reproductive toxicity

No data is available

Reproductive Effects:

Castor oil has been uses to speed the onset of labor. There are no outcome data on use early in pregnancy

Developmental Effects:

No information available

Teratogenic Effects:

No information available

Specific Target Organ Toxicity

STOT - single exposure

No information available.

STOT - repeated exposure

No information available.

Target Organs:

No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:

No data available.

Persistence and degradability:

No information available

Bioaccumulative potential:

No information available.

Mobility in soil

No information available

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**14. TRANSPORT INFORMATION**

**DOT**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Class:** No information available
- **Packing group:** No information available
- **Emergency Response Guide Number:** No information available
- **Marine Pollutant:** No data available
- **DOT RQ (lbs):** No information available
- **Special Provisions:** No Information available
- **Symbol(s):** No information available
- **Description:** No information available

**TDG (Canada)**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Marine Pollutant:** No Information available
- **Description:** No information available

**ADR**
- **UN Number** Not regulated
- **Proper Shipping Name:** No information available
- **Transport hazard class(es):** No information available
- **Packing group:** No information available
- **Subsidiary Risk:** No information available

**IMDG**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Marine Pollutant:** No information available

**RID**
- **UN Number** Not Regulated
- **Proper Shipping Name:** No information available
- **Transport hazard class(es):** No information available
- **Subsidiary Risk:** No information available
- **Packing group:** No information available

**ICAO (air)**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available

**Product code:** CA208  **Product name:** CASTOR OIL, USP  **Page:** 8 / 11
Packing Group: No information available

IATA
UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

<table>
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<tr>
<th>Component</th>
<th>CAS No</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
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<th>Japan ENCS</th>
<th>China IECSC</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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<td>Present</td>
<td>Present</td>
<td>Present 232-293-8</td>
</tr>
</tbody>
</table>

U.S. Regulations

Castor Oil
FDA - Direct Food Additives 21 CFR 172.510 21 CFR 172.876
FDA - 21 CFR - Total Food Additives 172.510 172.876 175.105 175.300 176.210 177.2600 177.2800 178.3520 178.3910
- List Sourced from EAFUS 73.1


Chemicals Known to the State of California to Cause Cancer:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

CERCLA/SARA

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPOs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

U.S. TSCA

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) -Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Canada

WHIMIS 2015 - GHS Classifications

Product code: CA208  Product name: CASTOR OIL, USP  Page 9 / 11
WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Component Castor Oil 8001-79-4 (100)

WHMIS 2015 Hazard Classification
Self-heating substances and mixtures - Undefined: (hazard class was established from consulted scientific literature but did not allow to specify hazard category)

Canada Hazardous Products Regulation
This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

CEPA Schedule I - Toxic Substances

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>Not listed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>Not listed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EU Classification

EU GHS - SV - CLP 1272/2008

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>EU GHS - SV - CLP (1272/2008)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil</td>
<td>8001-79-4</td>
<td>EU CLP (1272/2008)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

R-phrase(s)
not determined (not applicable)

S-phrase(s)
none

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
Not dangerous

16. OTHER INFORMATION

Preparation Date: 4/14/2014
Revision date 7/25/2018
Prepared by: Sonia Owen

Disclaimer:
All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may

Product code: CA208
Product name: CASTOR OIL, USP
pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user’s responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

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.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA208</td>
<td>Castor Oil, USP</td>
</tr>
</tbody>
</table>

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
Manufacturing Process Flowchart

Castor Oil, USP - CA208

Castor seeds harvested by growers

Screw press / expeller to extract oil → Cake

Centrifuge

Pale pressed castor oil

Filtering – finished oil – bulk storage

Additional filtering 25 μm

Drumming / packaging / USP testing
CA208, Castor Oil, USP

Source Statement
The above mentioned catalog item is derived from plant material- Ricinus communis- seed. 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 12 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
- Preservatives
- Phthalates
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.
RE: Residual Solvents - Castor Oil, USP (Cat# CA208)

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.
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.

CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Castor Oil
(Ricinus Oil)
USP
CAS 8001-79-4

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs, seek medical attention. KEEP FROM CHILDREN

Spectrum Chemical Mfg Corp

Bar Code
GHS Hazard Pictograms
Warning, Safety Data and Precautionary Information
Product Catalog Number
Item Name, Form, Grade
Size/Quantity

Chemical Abstracts Service (CAS) Registry Number
Caution Information
DOT Shipping Information
Toll-Free 24-Hour Chemical Emergency Telephone Number

Empirical Formula, Formula Weight and Technical Specifications Panel
Expiration Information
Lot Number
Kosher Certified by Kosher Supervision of America (KSA)
Storage Color Band
Halal Certified by IFANCA
bioCertified

Not intended for use in the manufacture of injectable dosage forms.

Identification A, Fatty Acid Composition:

- Palmitic Acid (C16:0) .................................................. Max. 9.0%
- Stearic Acid (C18:0) .................................................. Max. 2.0%
- Oleic Acid (C18:1) .................................................. Max. 10.0%
- Linoleic Acid (C18:2) .................................................. Max. 7.0%
- Linolenic Acid (C18:3) .............................................. Max. 1.0%
- cis-9-11-Octadecadienoic Acid (C18:2) ................. Max. 2.0%
- cis-11-Octadecenoic Acid or Any Other Unidentified Fatty Acid ........................................ Max. 1.0%

Identification B: Distinction From Most Other Fixed Oils ................................. To pass test
Identification C: Ultraviolet Absorption @ 270 nm ........................................... To pass test
Identification D: Specific Gravity @ 20°/20°C .................................................. 0.957-0.961

Total Carbon (%) .......................................................... 91-92

Hydroxyl Value .......................................................... 160-168

Fats and Fixed Oils, Unsaponifiable Value ...................................................... 0.8%
Fats and Fixed Oils, Peroxide Value .............................................................. 10.0
Fats and Fixed Oils, Acid Value .................................................................... 2.0
Water Determination ................................................................................. 0.3%
Elemental Impurities .............................................................................. As reported
Residual Solvents ................................................................................... To pass test

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

Use CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs, seek medical attention. KEEP FROM CHILDREN

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

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
RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products’ Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of six characters, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum’s Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of seven characters. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility
4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist
This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America (IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: July 16, 2020  
Document #: 11205.11209.II201234

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Code</th>
<th>Halal-ID</th>
<th>Product Certificate #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castor Oil, USP</td>
<td>CA208</td>
<td>B94131</td>
<td>HC-20SPZ602</td>
</tr>
</tbody>
</table>

Company Name & Address: Spectrum Laboratory Products, Inc. 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA

Plant Name & Address: Spectrum Laboratory Products, Inc. 14422 South San Pedro Street Gardena, California 90248 USA

Muhammad Munir Chaudry, Ph.D.  
President

This Certificate is valid until August 31, 2021 and subject to renewal at that time.