1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Product Name Rapaflo

Other means of identification
Product Code FG00110
Synonyms Silodosin

Recommended use of the chemical and restrictions on use
Recommended Use BPH

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address SDS@Allergan.com

Emergency telephone number
Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Acute toxicity - Oral</th>
<th>Acute toxicity - Dermal</th>
<th>Acute toxicity - Inhalation (Dusts/Mists)</th>
<th>Skin corrosion/irritation</th>
<th>Serious eye damage/eye irritation</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Category 4</td>
<td>Category 3</td>
<td>Category 4</td>
<td>Category 2</td>
<td>Category 2</td>
<td>Category 2</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Danger

Hazard statements
H311 - Toxic in contact with skin
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child

**Precautionary statements**

P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P361 - Remove/Take off immediately all contaminated clothing
P363 - Wash contaminated clothing before reuse
P322 - Specific measures (see supplemental first aid instructions on this label)
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor if you feel unwell
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see supplemental first aid instructions on this label)
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P281 - Use personal protective equipment as required
P280 - Wear protective gloves/protective clothing/eye protection/face protection

**Other Information**

**Unknown Acute Toxicity**

81% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM LAURYL SULFATE NF</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Silodosin</td>
<td>160970-54-7</td>
<td>N/A</td>
<td>7 - 13*</td>
</tr>
<tr>
<td>MANNITOL USP</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>3 - 7*</td>
</tr>
<tr>
<td>Trosplum Chloride</td>
<td>10405-02-4</td>
<td>233-875-4</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>1317-70-0</td>
<td>215-280-1</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (AVICEL PH102)</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE NF (FAST FLOW) (SPRAY DRIED)</td>
<td>64044-51-5</td>
<td>N/A</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>Povidone USP (PLASDONE K-29-32)</td>
<td>9003-39-8</td>
<td>N/A</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>MAGNESIUM STEARATE NF (VEGETABLE SOURCE)</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>TALC USP (1656)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>Sucrose Palmitate</td>
<td>26446-38-8</td>
<td>247-706-7</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>STEARIC ACID NF</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>PWDRD CELLULOSE BW40 NF</td>
<td>9004-32-4</td>
<td>N/A</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30)</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>CROSCARMELLOSE SODIUM NF (TYPE A, AC-DI-SOL)</td>
<td>74811-65-7</td>
<td>N/A</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>COLOIDAL SILICON DIOXIDE (CAB-O-SIL GRADE M-5P)</td>
<td>112945-52-5</td>
<td>N/A</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL NF 6000</td>
<td>25833-68-3</td>
<td>N/A</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>CORN STARCH NF</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>White Cresin Wax</td>
<td>8002-74-2</td>
<td>232-315-6</td>
<td>&lt;0.1*</td>
</tr>
<tr>
<td>CARNABUA WAX NF</td>
<td>8015-86-9</td>
<td>232-399-4</td>
<td>&lt;0.1*</td>
</tr>
</tbody>
</table>

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

Eye contact
Rinse immediately with plenty of water and seek medical advice.

Skin Contact
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Remove to fresh air.

Ingestion
Consult a physician if necessary.

Chemical Name
Silodosin

Note to physicians
RAPAFLO was evaluated at doses of up to 48 mg/day in healthy male subjects. The dose-limiting adverse event was postural hypotension. Should overdose of RAPAFLO lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by maintaining the patient in the supine position. If this measure is inadequate, administration of intravenous fluid should be considered. If necessary, vasopressors could be used, and renal function should be monitored and supported as needed. Dialysis is unlikely to be of significant benefit since silodosin is highly (97%) protein bound.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

<table>
<thead>
<tr>
<th>Sensitivity to Mechanical Impact</th>
<th>Sensitivity to Static Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not impact sensitive.</td>
<td>Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.</td>
</tr>
</tbody>
</table>

Protective equipment and precautions 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
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
Do not allow into any sewer, on the ground or into any body of water.

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Avoid creating dust.

7. HANDLING AND STORAGE

Advice on safe handling
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silodosin</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>10</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>100 ug/m^3</td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULO(AVICEL PH102)</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>MAGNESIUM STEARATE NF(VEGETABLE SOURCE)</td>
<td>TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter TWA: 10 mg/m² inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Description</td>
<td>TWA: 2 mg/m³ particulate matter containing no asbestos and &lt;1% crystalline silica, respirable particulate matter</td>
<td>(vacated) TWA: 2 mg/m³ respirable dust &lt;1% Crystalline silica, containing no Asbestos</td>
<td>TWA: 20 mppcf if 1% Quartz or more; use Quartz limit</td>
<td>IDLH: 1000 mg/m³ TWA: 2 mg/m³ containing no Asbestos and &lt;1% Quartz respirable dust</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEARIC ACID NF 57-11-4</td>
<td>TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30) 1309-37-1</td>
<td>TWA: 5 mg/m³ respirable particulate matter TWA: 10 mg/m³ fume TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 10 mg/m³ fume and total dust Iron oxide (vacated) TWA: 5 mg/m³ respirable fraction regulated under Rouge</td>
<td>IDLH: 2500 mg/m³ Fe dust and fume TWA: 5 mg/m³ Fe dust and fume</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CORN STARCH NF 9005-25-8</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White Cresin Wax 8002-74-2</td>
<td>TWA: 2 mg/m³ fume (vacated) TWA: 2 mg/m³ fume</td>
<td>TWA: 2 mg/m³ fume</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Appropriate engineering controls**

**Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Skin and body protection**

During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

**Respiratory protection**

Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Color</th>
<th>Odor threshold</th>
<th>Appearance</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

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

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silodosin</td>
<td>See Symptoms for more information.</td>
<td>Irritating to eyes.</td>
<td>Causes skin irritation.</td>
<td>See Symptoms for more information.</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.</td>
<td>Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).</td>
<td>In therapeutic use, this compound has caused swelling of the skin, rash and anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapeutic use of Trospium. Angioedema associated with</td>
<td>If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with</td>
</tr>
</tbody>
</table>
upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50
---|---|---|---
SODIUM LAURYL SULFATE NF | = 1288 mg/kg (Rat) | = 200 mg/kg (Rabbit) | > 3900 mg/m³ (Rat) 1 h
MANNITOL USP | = 13500 mg/kg (Rat) | N/A | N/A
Trospium Chloride | = 1510 mg/kg (Rat) | N/A | N/A
MICROCRYSTALLINE CELLULOSE (AVICEL PH102) | > 5 g/kg (Rat) | > 2 g/kg (Rabbit) | > 5800 mg/m³ (Rat) 4 h
POVIDONE USP (PLASDONE K-29-32) | = 100 g/kg (Rat) | N/A | N/A
STEARIC ACID NF | = 4600 mg/kg (Rat) | > 5 g/kg (Rabbit) | N/A
PводРД CELLULOSE BW40 NF | = 27000 mg/kg (Rat) | > 2 g/kg (Rabbit) | > 5800 mg/m³ (Rat) 4 h
FERRIC OXIDE NF (RED 30) | > 10000 mg/kg (Rat) | N/A | N/A
COLOIDAL SILICON DIOXIDE (CAB-O-SIL GRADE M-5P) | = 3160 mg/kg (Rat) | N/A | N/A
White Cresin Wax | > 5000 mg/kg (Rat) | > 3600 mg/kg (Rabbit) | N/A

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silodosin</td>
<td>Genotoxic in vitro at high concentrations, not genotoxic in vivo.</td>
<td>Carcinogenic in mice and rats but relevance to human health is unclear.</td>
<td>Not teratogenic in rats or rabbits. Studies in female rats did not show fertility impairment, however male rats did show significant sperm count and viability reductions.</td>
<td>No information available</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>Animal studies in mice and rats have not shown carcinogenicity.</td>
<td>Studies in rats and rabbits have not shown statistically significant levels of teratogenicity or harm to the fetus.</td>
<td>Detectable amounts of this compound have been identified in the milk of nursing women receiving this drug. Caution should be exercised when taking this compound is administered to nursing women.</td>
</tr>
<tr>
<td>POVIDONE USP (PLASDONE K-29-32)</td>
<td>No information available.</td>
<td>Not suspected of being a human carcinogen.</td>
<td>No information available.</td>
<td>No information available</td>
</tr>
</tbody>
</table>

**Target Organ Effects**

Prostate.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity**

81% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

- ATEmix (oral) 1690 mg/kg
- ATEmix (dermal) 787 mg/kg
- ATEmix (inhalation-dust/mist) 1.3 mg/l

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**
Toxic to aquatic life with long lasting effects

86% of the mixture consists of components(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM LAURYL SULFATE NF 151-21-3</td>
<td>53: 72 h Desmodesmus subspicatus mg/L EC50 30 - 100: 96 h Desmodesmus subspicatus mg/L EC50 117: 96 h Pseudokirchneriella subcapitata mg/L EC50 3.59 - 15.6: 96 h Pseudokirchneriella subcapitata mg/L EC50 5.99 - 28.5: 96 h</td>
<td>4.06 - 5.75: 96 h Lepomis macrochirus mg/L LC50 static 10.8 - 16.6: 96 h Poecilia reticulata mg/L LC50 static 4.3 - 8.5: 96 h Oncorhynchus mykiss mg/L LC50 static 22.1 - 22.8: 96 h Pimephales promelas mg/L LC50 static 4.2 - 4.8: 96 h Lepomis macrochirus mg/L LC50 flow-through 4.5: 96 h Lepomis macrochirus mg/L LC50 13.5 - 18.3: 96 h Poecilia reticulata mg/L LC50 semi-static 7.97: 96 h Brachydanio rerio mg/L LC50 flow-through 6.2 - 9.6: 96 h Pimephales promelas mg/L LC50 1.31: 96 h Cyprinus carpio mg/L LC50 semi-static 4.62: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 8 - 12.5: 96 h Pimephales promelas mg/L LC50 static 4.2: 96 h Oncorhynchus mykiss mg/L LC50 9.9 - 20.1: 96 h Brachydanio rerio mg/L LC50 semi-static 10.2 - 22.5: 96 h Pimephales promelas mg/L LC50 semi-static 15 - 18.9: 96 h Pimephales promelas mg/L LC50 static 5.8 - 7.5: 96 h Pimephales promelas mg/L LC50 static 1.8: 48 h Daphnia magna mg/L EC50</td>
<td>N/A</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM LAURYL SULFATE NF 151-21-3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>1.6</td>
</tr>
<tr>
<td>Trospium Chloride 10405-02-4</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>Log P = 0.70</td>
</tr>
</tbody>
</table>

Other adverse effects

No information available

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Disposal of wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging**

Do not reuse container. Dispose of contents/containers in accordance with local regulations.

### 14. TRANSPORT INFORMATION

**DOT**

Not regulated

**TDG**

Not regulated

**ICAO (air)**

Not regulated
**IATA**  
Not regulated

**IMDG**  
Not regulated

**ADR**  
Not regulated

**ADN**  
Not regulated

---

**15. REGULATORY INFORMATION**

**International Inventories**

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
</tr>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**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

**US Federal Regulations**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (AVICEL PH102) 9004-34-6</td>
<td>-</td>
<td>Group 1</td>
<td>Known</td>
<td>X</td>
</tr>
<tr>
<td>Povidone USP (PLASDONE K-29-32) 9003-39-8</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Talc USP (1656) 14807-96-6</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>Ferric Oxide NF (RED 30) 1309-37-1</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Colloidal Silicon Dioxide (CAB-O-SIL GRADE M-5P) 112945-52-5</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**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**

- Acute health hazard: No
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No

**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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO(AVICEL PH102) - 9004-34-6</td>
<td>Carcinogen</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Revision Date** 29-Sep-2018  
**Revision Note** No information available  
**Disclaimer** The information provided in this Material 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*