Section 1: Identification

Product identifier

Product Name: Wakix® (pitolisant) 4.45 mg and 17.8 mg Tablets

Synonyms: Ciproxidine; Pitolisant Hydrochloride; Tiprolisant

Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceutical for human use in treatment of excessive daytime sleepiness in adult patients with narcolepsy

Restrictions on use: Any use not directed by prescribing physician

Details of the supplier of the safety data sheet

Manufacturer: Harmony Biosciences, LLC
630 W. Germantown Pike
Plymouth Meeting, PA 19462
United States

Telephone: (484) 539-9800
(General)

Emergency telephone number

Manufacturer: 1-800-424-9300 - CHEMTREC NORTH AMERICA

Section 2: Hazard Identification

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012: Skin Irritation 2
Eye Irritation 2
Effects on or via Lactation

Label elements

OSHA HCS 2012

WARNING
Hazard statements • Causes skin irritation
Causes serious eye irritation

Precautionary statements
Prevention • Obtain special instructions before use.
Do not breathe dust.
Avoid direct contact during pregnancy/while nursing.
Wash thoroughly after handling.
Do not eat, drink or smoke when handling this product.
Wear protective gloves/protective clothing/eye protection/face protection.

Response • If on skin: Wash with plenty of water.
Take off contaminated clothing and wash before reuse.
Specific treatment, see supplemental first aid information.
If skin irritation occurs: Get medical advice/attention.
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 exposed or concerned: Get medical advice/attention.

Other hazards

Section 3 - Composition/Information on Ingredients

Substances

• Material does not meet the criteria of a substance.

Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
<th>LD50/LC50</th>
<th>Classifications According to Regulation/Directive</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitolisant hydrochloride</td>
<td>CAS:903576-44-3</td>
<td>13%</td>
<td>No data available</td>
<td>OSHA HCS 2012: Skin Irrit 2; Eye Irrit. 2; STOT SE 3: Resp. Irrit.; Lact.</td>
<td>NDA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>CAS:9004-34-6</td>
<td>50%</td>
<td>Ingestion/Oral-Rat LD50 •</td>
<td>OSHA HCS 2012: Comb. Dust</td>
<td>NDA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TO 70%</td>
<td>&gt;5 g/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation-Rat LC50 •</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt;5800 mg/m³ 4 Hour(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin-Rabbit LD50 • &gt;2 g/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crospovidone Poly(1-vinyl-2-pyrrolidinone) homopolymer</td>
<td>CAS:9003-39-8</td>
<td>6% TO 8%</td>
<td>Ingestion/Oral-Rat LD50 •</td>
<td>OSHA HCS 2012: Not Classified</td>
<td>NDA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 g/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Section 4: First-Aid Measures

Description of first aid measures

Inhalation
• Move victim to fresh air. Administer oxygen if breathing is difficult. Give artificial respiration if victim is not breathing.

Skin
• In case of contact with substance, immediately flush skin with running water for at least 20 minutes.

Eye
• In case of contact with substance, immediately flush eyes with running water for at least 20 minutes.

Ingestion
• If large quantities are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed
• Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed
• All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Notes to Physician
• All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
• LARGE FIRE: Water spray, fog or regular foam.
  SMALL FIRES: Dry chemical, CO2, water spray or regular foam.

Unsuitable Extinguishing Media
• No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
• Some may burn but none ignite readily.

Hazardous Combustion Products
• No data available

Advice for firefighters
• Structural firefighters’ protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
• Do not walk through spilled material.
Emergency Procedures
• Use normal clean up procedures.

Environmental precautions
• Avoid release to the environment.

Methods and material for containment and cleaning up
Containment/Clean-up Measures
• Carefully shovel or sweep up spilled material and place in suitable container.

Section 7 - Handling and Storage

Precautions for safe handling
Handling
• Use good safety and industrial hygiene practices. Avoid contact with skin, eyes, and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Conditions for safe storage, including any incompatibilities
Storage
• Protect from moisture. Keep bottle tightly closed. Store at 20-25°C (68-77°F).

Section 8 - Exposure Controls/Personal Protection

Control parameters

<table>
<thead>
<tr>
<th></th>
<th>Exposure Limits/Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result</td>
</tr>
<tr>
<td>Stearic acid,</td>
<td>TWAs</td>
</tr>
<tr>
<td>magnesium salt</td>
<td></td>
</tr>
<tr>
<td>(557-04-0)</td>
<td></td>
</tr>
<tr>
<td>Silica, amorphous</td>
<td>TWAs</td>
</tr>
<tr>
<td>(7631-86-9)</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>TWAs</td>
</tr>
<tr>
<td>(13463-67-7)</td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>TWAs</td>
</tr>
<tr>
<td>(14807-96-6)</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>TWAs</td>
</tr>
<tr>
<td>(9004-34-6)</td>
<td></td>
</tr>
</tbody>
</table>

Exposure Limits Supplemental
OSHA
• Talc (14807-96-6): Mineral Dusts: (20 mppcf TWA (if 1% Quartz or more; use Quartz limit))
• Silica, amorphous (7631-86-9): Mineral Dusts: (20 mppcf TWA; (80)/(% SiO2) mg/m3 TWA)

Exposure controls

Engineering Measures/Controls
• 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 to an acceptable level.

Personal Protective Equipment

Respiratory
• In case of insufficient ventilation, wear suitable respiratory equipment.

Eye/ Face
• Wear safety glasses.

Skin/Body
• Wear appropriate gloves.
Environmental Exposure Controls

- Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways. Follow best practice for site management and disposal of waste.

Key to abbreviations
- ACGIH = American Conference of Governmental Industrial Hygiene
- NIOSH = National Institute of Occupational Safety and Health
- OSHA = Occupational Safety and Health Administration
- TWAs = Time-Weighted Averages are based on 8h/day, 40h/week exposures
- mg/m³ = Milligrams per cubic meter
- mppcf = Million particles per cubic foot

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>Solid tablet with white coating.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Form</td>
<td>Solid</td>
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</tr>
<tr>
<td>Color</td>
<td>White</td>
<td>Odor</td>
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<tr>
<td>Odor Threshold</td>
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<table>
<thead>
<tr>
<th>General Properties</th>
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<tr>
<td>Boiling Point</td>
<td>No data available</td>
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<tr>
<td>Decomposition Temperature</td>
<td>No data available</td>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity/Relative Density</td>
<td>No data available</td>
<td>Water Solubility</td>
<td>No data available</td>
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<tr>
<td>Viscosity</td>
<td>No data available</td>
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<table>
<thead>
<tr>
<th>Volatility</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Vapor Pressure</td>
<td>No data available</td>
<td>Vapor Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>No data available</td>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>Flammability</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash Point</td>
<td>No data available</td>
<td>UEL</td>
<td>No data available</td>
</tr>
<tr>
<td>LEL</td>
<td>No data available</td>
<td>Autoignition</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Octanol/Water Partition coefficient</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- Hazardous polymerization will not occur.

Conditions to avoid

- Excess heat.

Incompatible materials

- None identified.
## Section 11 - Toxicological Information

### Information on toxicological effects

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute Toxicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose (50% TO 70%)</td>
<td>Ingestion/Oral-Rat LD50 • &gt;5 g/kg; Inhalation-Rat LC50 • &gt;5800 mg/m³ 4 Hour(s); Skin-Rabbit LD50 • &gt;2 g/kg</td>
</tr>
<tr>
<td>Polyvinyl alcohol (6% TO 8%)</td>
<td>Ingestion/Oral-Rat LD50 • 100 g/kg; Gastrointestinal/ Hypermotility, diarrhea</td>
</tr>
<tr>
<td>Talc (&lt; 10%)</td>
<td>Skin-Human • 300 µg 3 Day(s)-Intermittent • Mild irritation; Inhalation-Rat TCLo • 18 mg/m³ 6 Hour(s) 2 Year(s)-Intermittent; Tumorigenic; Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration: Tumors; Inhalation-Rat TCLo • 18 mg/m³ 6 Hour(s) 2 Year(s)-Intermittent; Tumorigenic: Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration: Bronchiogenic carcinoma; Endocrine: Tumors</td>
</tr>
<tr>
<td>Stearic acid, magnesium salt (1% TO 3%)</td>
<td>Ingestion/Oral-Rat LD50 • &gt;10000 mg/kg</td>
</tr>
<tr>
<td>Silica, amorphous (&lt; 1%)</td>
<td>Lungs, Thorax, or Respiration</td>
</tr>
<tr>
<td>Titanium dioxide (&lt; 10%)</td>
<td>Skin-Human • 300 µg 3 Day(s)-Intermittent • Mild irritation; Inhalation-Rat TCLo • 10 mg/m³ 6 Hour(s) 13 Week(s)-Intermittent; Eye-Rabbit • 25 mg 24 Hour(s) • Mild irritation; Ingestion/Oral-Mouse • 280 mg/kg 7 Day(s)-Intermittent; DNA damage; Ingestion/Oral-Mouse • 280 mg/kg 7 Day(s)-Intermittent; Cytogenetic analysis; Ingestion/Oral-Mouse • 280 mg/kg 7 Day(s)-Intermittent; Skin: Cytotoxic; Ingestion/Oral-Mouse • 280 mg/kg 7 Day(s)-Intermittent; Lungs, Thorax, or Respiration: Chronic pulmonary edema; Lungs, Thorax, or Respiration: Other changes; Tumorigen / Carcinogen: Inhalation-Rat • 10 mg/m³ 18 Hour(s) 2 Year(s)-Intermittent; Tumorigenic: Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration: Tumors</td>
</tr>
</tbody>
</table>

### GHS Properties

<table>
<thead>
<tr>
<th>GHS Properties</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
<td>OSHA HCS 2012*Skin Irritation 2</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
<td>OSHA HCS 2012*Eye Irritation 2</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
<td>OSHA HCS 2012*Additional category for effects on or via lactation</td>
</tr>
<tr>
<td>STOT-SE</td>
<td>OSHA HCS 2012*No data available</td>
</tr>
</tbody>
</table>
Potential Health Effects

Inhalation
Acute (Immediate) • No data available
Chronic (Delayed) • No data available

Skin
Acute (Immediate) • Causes skin irritation.
Chronic (Delayed) • No data available

Eye
Acute (Immediate) • Causes serious eye irritation.
Chronic (Delayed) • No data available

Ingestion
Acute (Immediate) • No data available
Chronic (Delayed) • No data available

Carcinogenic Effects
• Due to the form of the product, exposure to the potentially carcinogenic components is not expected.

<table>
<thead>
<tr>
<th>Carcinogenic Effects</th>
<th>CAS</th>
<th>IARC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>Group 2B-Possible Carcinogen</td>
</tr>
</tbody>
</table>

Reproductive Effects
• There are no or limited amount of data from the use of pitolisant in pregnant women. Studies in animals have shown reproductive toxicity including teratogenicity (in rats at doses > 30 mg/kg and in rabbits at dose > 8 mg/kg). In rats, pitolisant was shown to cross the placenta and pitolisant was measured in breast milk in nursing rats. In rats, pitolisant demonstrated effects on semen parameters, but without a significant impact on reproductive performance in males and reduction in the percentage of live fetuses in treated females.

Key to abbreviations
LC = Lethal Concentration
LD = Lethal Dose
TC = Toxic Concentration

Section 12 - Ecological Information

Toxicity
• Non-mandatory section - information about this substance not compiled for this reason.

Persistence and degradability
• Non-mandatory section - information about this substance not compiled for this reason.

Bioaccumulative potential
• Non-mandatory section - information about this substance not compiled for this reason.

Mobility in Soil
• Non-mandatory section - information about this substance not compiled for this reason.

Other adverse effects
• Non-mandatory section - information about this substance not compiled for this reason.
Section 13 - Disposal Considerations

Waste treatment methods

Product waste • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>NDA</td>
</tr>
</tbody>
</table>

Special precautions for user • None specified.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Inventory</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl alcohol</td>
<td>25213-24-5</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Pitolisant hydrochloride</td>
<td>903576-44-3</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Crospovidone (Poly(1-vinyl-2-pyrrolidinone) homopolymer)</td>
<td>9003-39-8</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Silica, amorphous</td>
<td>7631-86-9</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Stearic acid, magnesium salt</td>
<td>557-04-0</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

• Stearic acid, magnesium salt 557-04-0 Not Listed
• Cellulose 9004-34-6 Not Listed
<table>
<thead>
<tr>
<th>Product Name: Wakix® (pitolisant) tablets, for oral use</th>
</tr>
</thead>
</table>

- **Talc**
- **Titanium dioxide**
- **Silica, amorphous**
- **Acetic acid ethenyl ester - Ethenol polymer**
- **Poly(1-vinyl-2-pyrrolidinone) homopolymer**
- **Pitolisant hydrochloride**

**U.S. - OSHA - Specifically Regulated Chemicals**
- **Stearic acid, magnesium salt**
- **Cellulose**
- **Talc**
- **Titanium dioxide**
- **Silica, amorphous**
- **Acetic acid ethenyl ester - Ethenol polymer**
- **Poly(1-vinyl-2-pyrrolidinone) homopolymer**
- **Pitolisant hydrochloride**

**Environment**

**U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants**
- **Stearic acid, magnesium salt**
- **Cellulose**
- **Talc**
- **Titanium dioxide**
- **Silica, amorphous**
- **Acetic acid ethenyl ester - Ethenol polymer**
- **Poly(1-vinyl-2-pyrrolidinone) homopolymer**
- **Pitolisant hydrochloride**

**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**
- **Stearic acid, magnesium salt**
- **Cellulose**
- **Talc**
- **Titanium dioxide**
- **Silica, amorphous**
- **Acetic acid ethenyl ester - Ethenol polymer**
- **Poly(1-vinyl-2-pyrrolidinone) homopolymer**
- **Pitolisant hydrochloride**

**U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities**
- **Stearic acid, magnesium salt**
- **Cellulose**
- **Talc**
- **Titanium dioxide**
- **Silica, amorphous**
- **Acetic acid ethenyl ester - Ethenol polymer**
- **Poly(1-vinyl-2-pyrrolidinone) homopolymer**
- **Pitolisant hydrochloride**

**U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**
- **Stearic acid, magnesium salt**
- **Cellulose**
- **Talc**
- **Titanium dioxide**
- **Silica, amorphous**
- **Acetic acid ethenyl ester - Ethenol polymer**
- **Poly(1-vinyl-2-pyrrolidinone) homopolymer**
- **Pitolisant hydrochloride**

**U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs**
- **Stearic acid, magnesium salt**
- **Cellulose**
United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

- Stearic acid, magnesium salt 557-04-0 Not Listed
- Cellulose 9004-34-6 Not Listed
- Talc 14807-96-6 Not Listed
titanium dioxide 13463-67-7 Not Listed
- Silica, amorphous 7631-86-9 Not Listed
- Acetic acid ethenyl ester - Ethenol polymer 25213-24-5 Not Listed
- Poly(1-vinyl-2-pyridinolone) homopolymer 9003-39-8 Not Listed
- Pitolisant hydrochloride 903576-44-3 Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

- Stearic acid, magnesium salt 557-04-0 Not Listed
- Cellulose 9004-34-6 Not Listed
- Talc 14807-96-6 Not Listed
titanium dioxide 13463-67-7 Not Listed
- Silica, amorphous 7631-86-9 Not Listed
- Acetic acid ethenyl ester - Ethenol polymer 25213-24-5 Not Listed
- Poly(1-vinyl-2-pyridinolone) homopolymer 9003-39-8 Not Listed
- Pitolisant hydrochloride 903576-44-3 Not Listed

U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)

- Stearic acid, magnesium salt 557-04-0 Not Listed
- Cellulose 9004-34-6 Not Listed
- Talc 14807-96-6 Not Listed
titanium dioxide 13463-67-7 Not Listed
- Silica, amorphous 7631-86-9 Not Listed
- Acetic acid ethenyl ester - Ethenol polymer 25213-24-5 Not Listed
- Poly(1-vinyl-2-pyridinolone) homopolymer 9003-39-8 Not Listed
- Pitolisant hydrochloride 903576-44-3 Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)

- Stearic acid, magnesium salt  557-04-0  Not Listed
- Cellulose  9004-34-6  Not Listed
- Talc  14807-96-6  Not Listed
- Titanium dioxide  13463-67-7  Not Listed
- Silica, amorphous  7631-86-9  Not Listed
- Acetic acid ethenyl ester - Ethenol polymer  25213-24-5  Not Listed
- Poly(1-vinyl-2-pyrrolidinone) homopolymer  9003-39-8  Not Listed
- Pitolisant hydrochloride  903576-44-3  Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

- Stearic acid, magnesium salt  557-04-0  Not Listed
- Cellulose  9004-34-6  Not Listed
- Talc  14807-96-6  Not Listed
- Titanium dioxide  13463-67-7  Not Listed
- Silica, amorphous  7631-86-9  Not Listed
- Acetic acid ethenyl ester - Ethenol polymer  25213-24-5  Not Listed
- Poly(1-vinyl-2-pyrrolidinone) homopolymer  9003-39-8  Not Listed
- Pitolisant hydrochloride  903576-44-3  Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

- Stearic acid, magnesium salt  557-04-0  Not Listed
- Cellulose  9004-34-6  Not Listed
- Talc  14807-96-6  Not Listed
- Titanium dioxide  13463-67-7  Not Listed
- Silica, amorphous  7631-86-9  Not Listed
- Acetic acid ethenyl ester - Ethenol polymer  25213-24-5  Not Listed
- Poly(1-vinyl-2-pyrrolidinone) homopolymer  9003-39-8  Not Listed
- Pitolisant hydrochloride  903576-44-3  Not Listed

Other Information

- **WARNING:** This product contains a chemical known to the State of California to cause cancer.