



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

## Safety Data Sheet

### 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 (General)** • (484) 539-9800

#### 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**

**OSHA HCS 2012** • Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

**Section 3 - Composition/Information on Ingredients**

**Substances**

• Material does not meet the criteria of a substance.

**Mixtures**

Composition					
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Pitolisant hydrochloride	CAS:903576-44-3	13% TO 18%	No data available	<b>OSHA HCS 2012:</b> Skin Irrit 2; Eye Irrit. 2; STOT SE 3: Resp. Irrit.; Lact.	NDA
Cellulose	CAS:9004-34-6	50% TO 70%	Ingestion/Oral-Rat LD50 • >5 g/kg Inhalation-Rat LC50 • >5800 mg/m <sup>3</sup> 4 Hour(s) Skin-Rabbit LD50 • >2 g/kg	<b>OSHA HCS 2012:</b> Comb. Dust	NDA
Crospovidone Poly(1-vinyl-2-pyrrolidinone) homopolymer	CAS:9003-39-8	6% TO 8%	Ingestion/Oral-Rat LD50 • 100 g/kg	<b>OSHA HCS 2012:</b> Not Classified	NDA

Talc	CAS:14807-96-6	< 10%	No data available	OSHA HCS 2012: STOT RE 1 (Lungs / Inhl)	NDA
Stearic acid, magnesium salt	CAS:557-04-0	1% TO 3%	Ingestion/Oral-Rat LD50 • >10000 mg/kg	OSHA HCS 2012: Comb. Dust	NDA
Silica, amorphous	CAS:7631-86-9	< 1%	Ingestion/Oral-Rat LD50 • >22500 mg/kg	OSHA HCS 2012: Not Classified	NDA
Polyvinyl alcohol	CAS:25213-24-5	1% TO 5%	No data available	OSHA HCS 2012: Not Classified	NDA
Titanium dioxide	CAS:13463-67-7	< 10%	No data available	OSHA HCS 2012: Muta. 2; Carc. 2 (Inhl); STOT RE 2 (Lungs/Inhl)	NDA
Macrogol/PEG	25322-68-3	1% TO 5%	No data available	OSHA HCS 2012: Not Classified	NDA

## 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

- 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, CO<sub>2</sub>, 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**

Exposure Limits/Guidelines				
	Result	ACGIH	NIOSH	OSHA
Stearic acid, magnesium salt (557-04-0)	TWAs	10 mg/m3 TWA (inhalable particulate matter, listed under Stearates); 3 mg/m3 TWA (respirable particulate matter, listed under Stearates)	Not established	Not established
Silica, amorphous (7631-86-9)	TWAs	Not established	6 mg/m3 TWA	Not established
Titanium dioxide (13463-67-7)	TWAs	10 mg/m3 TWA	Not established	15 mg/m3 TWA (total dust)
Talc (14807-96-6)	TWAs	2 mg/m3 TWA (particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter)	2 mg/m3 TWA (containing no Asbestos and <1% Quartz, respirable dust)	Not established
Cellulose (9004-34-6)	TWAs	10 mg/m3 TWA	10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)	15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)

**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**

• 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.

**Measures/Controls**

**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/m<sup>3</sup> = Milligrams per cubic meter

mppcf = Million particles per cubic foot

**Section 9 - Physical and Chemical Properties****Information on Physical and Chemical Properties**

<b>Material Description</b>			
Physical Form	Solid	Appearance/Description	Solid tablet with white coating.
Color	White	Odor	No data available
Odor Threshold	No data available		
<b>General Properties</b>			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	No data available
Viscosity	No data available		
<b>Volatility</b>			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
<b>Flammability</b>			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
<b>Environmental</b>			
Octanol/Water Partition coefficient	No data available		

**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.

**Hazardous decomposition products**

- Not determined.

**Section 11 - Toxicological Information**

**Information on toxicological effects**

Components		
Cellulose (50% TO 70%)	9004-34-6	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >5 g/kg; Inhalation-Rat LC50 • >5800 mg/m <sup>3</sup> 4 Hour(s); Skin-Rabbit LD50 • >2 g/kg
Polyvinyl alcohol (6% TO 8%)	9003-39-8	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 100 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea</i>
Talc (< 10%)	14807-96-6	<b>Irritation:</b> Skin-Human • 300 µg 3 Day(s)-Intermittent • Mild irritation; <b>Tumorigen / Carcinogen:</b> Inhalation-Rat • 11 mg/m <sup>3</sup> 1 Year(s)-Intermittent; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Lungs, Thorax, or Respiration:Tumors</i> ; Inhalation-Rat TClO • 18 mg/m <sup>3</sup> 6 Hour(s) 2 Year(s)-Intermittent; <i>Tumorigenic:Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration:Bronchiogenic carcinoma; Endocrine:Tumors</i>
Stearic acid, magnesium salt (1% TO 3%)	557-04-0	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >10000 mg/kg
Silica, amorphous (< 1%)	7631-86-9	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >22500 mg/kg; <b>Irritation:</b> Eye-Rabbit • 25 mg 24 Hour(s) • Mild irritation; <b>Multi-dose Toxicity:</b> Inhalation-Rat TClO • 30 mg/m <sup>3</sup> 6 Hour(s) 6 Week(s)-Intermittent; <i>Sense Organs and Special Senses:Eye:Lacrimation; Lungs, Thorax, or Respiration:Pulmonary emboli; Gastrointestinal:Changes in structure or function of salivary glands</i>
Titanium dioxide (< 10%)	13463-67-7	<b>Irritation:</b> Skin-Human • 300 µg 3 Day(s)-Intermittent • Mild irritation; <b>Multi-dose Toxicity:</b> Inhalation-Rat TClO • 10 mg/m <sup>3</sup> 6 Hour(s) 13 Week(s)-Intermittent; <i>Lungs, Thorax, or Respiration:Fibrosis (interstitial); Lungs, Thorax, or Respiration:Other changes; Biochemical:Metabolism (intermediary):Effect on inflammation or mediation of inflammation</i> ; Inhalation-Rat TClO • 250 mg/m <sup>3</sup> 6 Hour(s) 4 Week(s)-Intermittent; <i>Lungs, Thorax, or Respiration:Chronic pulmonary edema; Lungs, Thorax, or Respiration:Other changes</i> ; <b>Mutagen:</b> Micronucleus test • 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; <b>Tumorigen / Carcinogen:</b> Inhalation-Rat • 10 mg/m <sup>3</sup> 18 Hour(s) 2 Year(s)-Intermittent; <i>Tumorigenic:Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration:Tumors</i>

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012•No data available
Skin corrosion/Irritation	OSHA HCS 2012•Skin Irritation 2
Serious eye damage/Irritation	OSHA HCS 2012•Eye Irritation 2
Skin sensitization	OSHA HCS 2012•No data available
Respiratory sensitization	OSHA HCS 2012•No data available
Aspiration Hazard	OSHA HCS 2012•No data available
Carcinogenicity	OSHA HCS 2012•No data available
Germ Cell Mutagenicity	OSHA HCS 2012•No data available
Toxicity for Reproduction	OSHA HCS 2012•Additional category for effects on or via lactation
STOT-SE	OSHA HCS 2012•No data available

STOT-RE	OSHA HCS 2012•No data available
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**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.

Carcinogenic Effects		
	CAS	IARC
Titanium dioxide	13463-67-7	Group 2B-Possible Carcinogen

**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**

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA

**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**

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

**United States****Labor**

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

- Stearic acid, magnesium salt
- Cellulose

557-04-0 Not Listed  
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. - OSHA - Specifically Regulated Chemicals**

•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

**Environment**

**U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants**

•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. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

•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. - CERCLA/SARA - Radionuclides and Their Reportable Quantities**

•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. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**

•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. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs**

•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. - CERCLA/SARA - Section 313 - Emission Reporting**

•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. - CERCLA/SARA - Section 313 - PBT Chemical Listing**

•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

**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	carcinogen, 9/2/2011 (airborne, unbound particles of respirable size)
•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 - 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-pyrrolidinone) 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-pyrrolidinone) 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.

**Section 16 - Other Information**

<b>Revision Date</b>	• 03/October/2019
<b>Last Revision Date</b>	• 03/October/2019
<b>Preparation Date</b>	• 25/July/2018
<b>Disclaimer/Statement of Liability</b>	• The information herein is given in good faith but no warranty, expressed or implied, is made.