



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **PreserVision® With Lutein Softgel**
- Product Code** • AB63210; FCP-4265D
- Product Description** • This product is a high-potency antioxidant vitamin and mineral supplement.
- Relevant identified uses of the substance or mixture and uses advised against**
- Recommended use** • Vitamin and Mineral Supplement
- Restrictions on use** • This product is not intended to diagnose, treat, cure or prevent any disease. If any discomfort develops, immediately discontinue use of this product. If discomfort persists, contact your eye care professional. Use only in accordance with product literature.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com
- Telephone (General)** • 1-800-553-5340

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - Infotrac

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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

- Hazard statements** • Causes eye irritation (with direct contact)

Precautionary statements

- Prevention** • Wash thoroughly after handling.

- Response** • 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.

- Storage/Disposal**
- Keep tightly closed. Store at room temperature 15-25C (59-77F), to maintain product integrity. Use before expiration date marked on carton and tube.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	Identifiers	%
L-Ascorbic acid	CAS:50-81-7 EINECS:200-066-2	< 35%
dI Alpha tocopheryl acetate	CAS:7695-91-2 EINECS:231-710-0	< 30%
Soybean oil	CAS:8001-22-7 EINECS:232-274-4	< 10%
Zinc oxide	CAS:1314-13-2 EINECS:215-222-5	< 10%
Lutein	CAS:127-40-2 EINECS:204-840-0	< 5%
Soybean lecithin	CAS:8030-76-0 EINECS:310-129-7	< 5%
Yellow beeswax	CAS:8012-89-3 EINECS:232-383-7	< 1%
Cupric oxide	CAS:1317-38-0 EINECS:215-269-1	< 1%
Glycerine	CAS:56-81-5 EINECS:200-289-5	< 10%
Gelatins	CAS:9000-70-8 EINECS:232-554-6	< 20%
Silicon dioxide, anhydrous	CAS:7631-86-9 EINECS:231-545-4	< 1%
Titanium dioxide/Glycerin Dispersion		< 1%
Titanium dioxide [N/A]	CAS:13463-67-7 EINECS:236-675-5	N/A
Glycerine [N/A]	CAS:56-81-5 EINECS:200-289-5	N/A
FD&C Red #40	CAS:25956-17-6 EINECS:247-368-0	< 0.1%
FD&C Blue #1	CAS:3844-45-9 EINECS:223-339-8	< 0.01%

Section 4: First-Aid Measures

Description of first aid measures

- | | |
|-------------------|--|
| Inhalation | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop. |
| Skin | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. |
| Eye | <ul style="list-style-type: none"> 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. |
| Ingestion | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not hazardous by ingestion when used in accordance with product literature. If quantities exceeding the recommended intake are accidentally ingested, get medical attention immediately. |

Most important symptoms and effects, both acute and delayed

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

- | | |
|---------------------------------------|--|
| Suitable Extinguishing Media | <ul style="list-style-type: none"> LARGE FIRE: Water spray, fog or regular foam. SMALL FIRES: Dry chemical, CO₂, water spray or regular foam. |
| Unsuitable Extinguishing Media | <ul style="list-style-type: none"> No data available |
| Firefighting Procedures | <ul style="list-style-type: none"> As in any fire, wear self-contained breathing apparatus and full protective gear. |

Special hazards arising from the substance or mixture

- | | |
|---|--|
| Unusual Fire and Explosion Hazards | <ul style="list-style-type: none"> No data available |
| Hazardous Combustion Products | <ul style="list-style-type: none"> No data available. |

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- | | |
|-----------------------------|--|
| Personal Precautions | <ul style="list-style-type: none"> No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8. |
| Emergency Procedures | <ul style="list-style-type: none"> No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended. For bulk material spills, keep unauthorized personnel away. Isolate spill area and stop source of release if safe to do so. Ensure adequate ventilation. |

Environmental precautions

- No data available on the environmental impact of this product. Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- For bulk material spills: Contain spilled product. For small spills, scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Prohibited Materials

- None known.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.

Conditions for safe storage, including any incompatibilities

Storage

- Store at a controlled room temperature: 15-25C (59-77F).

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines						
	Result	ACGIH	Canada British Columbia	Canada Nova Scotia	Canada Ontario	Canada Quebec
Titanium dioxide (13463-67-7)	TWAs	10 mg/m3 TWA	10 mg/m3 TWA (total dust); 3 mg/m3 TWA (respirable fraction)	10 mg/m3 TWA	10 mg/m3 TWA	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total dust)
Glycerine (56-81-5)	TWAs	Not established	10 mg/m3 TWA (mist); 3 mg/m3 TWA (mist, respirable)	Not established	10 mg/m3 TWA (mist)	10 mg/m3 TWAEV (mist)
Zinc oxide (1314-13-2)	STELs	10 mg/m3 STEL (respirable fraction)	10 mg/m3 STEL (respirable)	10 mg/m3 STEL (respirable fraction)	10 mg/m3 STEL (respirable)	10 mg/m3 STEV (fume)
	TWAs	2 mg/m3 TWA (respirable fraction)	2 mg/m3 TWA (respirable)	2 mg/m3 TWA (respirable fraction)	2 mg/m3 TWA (respirable)	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total dust); 5 mg/m3 TWAEV (fume)
Glycerine (56-81-5)	TWAs	Not established	10 mg/m3 TWA (mist); 3 mg/m3 TWA (mist, respirable)	Not established	10 mg/m3 TWA (mist)	10 mg/m3 TWAEV (mist)
Exposure Limits/Guidelines (Con't.)						
	Result	NIOSH		OSHA		
Titanium dioxide (13463-67-7)	TWAs	Not established		15 mg/m3 TWA (total dust)		
Glycerine (56-81-5)	TWAs	Not established		15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)		

Cupric oxide (1317-38-0)	TWAs	0.1 mg/m3 TWA (fume, as Cu)	Not established
Silicon dioxide, anhydrous (7631-86-9)	TWAs	6 mg/m3 TWA	Not established
Zinc oxide (1314-13-2)	TWAs	5 mg/m3 TWA (dust and fume)	5 mg/m3 TWA (fume); 15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)
	Ceilings	15 mg/m3 Ceiling (dust)	Not established
	STELs	10 mg/m3 STEL (fume)	Not established
Glycerine (56-81-5)	TWAs	Not established	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)

Exposure Control Notations

ACGIH

- Titanium dioxide (13463-67-7): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)

Exposure Limits Supplemental

OSHA

- Silicon dioxide, anhydrous (7631-86-9): **Mineral Dusts:** (20 mppcf TWA; (80)/(% SiO₂) mg/m3 TWA)

ACGIH

- Zinc oxide (1314-13-2): **TLV Basis - Critical Effects:** (metal fume fever)
- Titanium dioxide (13463-67-7): **TLV Basis - Critical Effects:** (lower respiratory tract irritation) | **Notice of Intended Changes (TLVs):** (Withdrawn from notice of intended changes)

Exposure controls

Engineering Measures/Controls

- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Oblong softgel capsule, no markings.

Color	Orange, opaque.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
pH	Not relevant	Specific Gravity/Relative Density	Not relevant
Water Solubility	Soluble	Viscosity	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not flammable.		

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

- No data available.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information

- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
L-Ascorbic acid ($< 35\%$)	50-81-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 11900 mg/kg; <i>Sense Organs and Special Senses:</i> Eye: Lacrimation ; <i>Behavioral:</i> Somnolence (general depressed activity) ; <i>Gastrointestinal:</i> Hypermotility, diarrhea ; Mutagen: DNA damage • Ingestion/Oral-Mouse • 1 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 2500 mg/kg (1-22D preg); <i>Reproductive Effects:</i> Effects on Fertility: Post-implantation mortality ; Tumorigen / Carcinogen: Ingestion/Oral-Rat TDLo • 1802500 mg/kg 103 Week(s)-Continuous; <i>Tumorigenic:</i> Carcinogenic by RTECS criteria ; <i>Blood:</i> Leukemia
dl Alpha tocopheryl acetate ($< 30\%$)	7695- 91-2	Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 2800 mg/kg 7 Week(s)-Intermittent; <i>Liver:</i> Other changes ; <i>Blood:</i> Changes in serum composition (e.g., TP, bilirubin cholesterol) ; <i>Biochemical:</i> Metabolism (intermediary): Lipids, including transport ; Reproductive: Ingestion/Oral-Rat TDLo • 500 mg/kg (1-22D preg); <i>Reproductive Effects:</i> Effects on Fertility: Post-implantation mortality

Soybean oil (< 10%)	8001-22-7	Multi-dose Toxicity: Ingestion/Oral-Mouse TDLo • 168 g/kg 20 Week(s)-Continuous; <i>Skin and Appendages:Other:Hair</i> ; Mutagen: Specific locus test • Ingestion/Oral-Drosophila melanogaster • 12 pph 48 Hour(s)-Continuous
Zinc oxide (< 10%)	1314-13-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 7950 mg/kg; Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Mutagen: Cytogenetic analysis • Inhalation-Rat • 100 µg/m³; Reproductive: Ingestion/Oral-Rat TDLo • 6846 mg/kg (1-22D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Homeostasis</i> ; <i>Reproductive Effects:Effects on Newborn:Stillbirth</i> ; <i>Reproductive Effects:Effects on Newborn:Growth statistics (e.g., reduced weight gain)</i>
Lutein (< 5%)	127-40-2	Multi-dose Toxicity: Ingestion/Oral-Monkey TDLo • 40 mg/kg 2 Day(s)-Intermittent; <i>Gastrointestinal:Other changes</i> ; <i>Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol)</i>
Cupric oxide (< 1%)	1317-38-0	Acute Toxicity: Ingestion/Oral-Rat LD50 • 470 mg/kg; Multi-dose Toxicity: Ingestion/Oral-Woman TDLo • 0.7 mg/kg 7 Day(s)-Continuous; <i>Gastrointestinal:Hypermotility, diarrhea</i> ; <i>Gastrointestinal:Nausea or vomiting</i> ; <i>Gastrointestinal:Other changes</i>
Glycerine (< 10%)	56-81-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 12600 mg/kg; Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Mutagen: Cytogenetic analysis • Ingestion/Oral-Rat • 1 g/kg; Reproductive: Ingestion/Oral-Rat TDLo • 100 mg/kg (1D male); <i>Reproductive Effects:Effects on Fertility:Post-implantation mortality</i> ; Tumorigen / Carcinogen: Ingestion/Oral-Mouse TDLo • 87.5 g/kg 25 Week(s)-Intermittent; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria</i> ; <i>Lungs, Thorax, or Respiration:Tumors</i> ; <i>Tumorigenic:Facilitates action of known carcinogen</i>
Gelatins (< 20%)	9000-70-8	Reproductive: Intraperitoneal-Mouse TDLo • 700 mg/kg (7-13D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Urogenital system</i> ; <i>Reproductive Effects:Effects on Newborn:Growth statistics (e.g., reduced weight gain)</i>
Silicon dioxide, anhydrous (< 1%)	7631-86-9	Acute Toxicity: Ingestion/Oral-Rat LDLo • 5 g/kg; <i>Nutritional and Gross Metabolic:Changes in Chemistry or Temperature:Other changes</i> ; Irritation: Eye-Rabbit • 25 mg 24 Hour(s) • Mild irritation
Titanium dioxide (N/A)	13463-67-7	Acute Toxicity: Ingestion/Oral-Rat TDLo • 60 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea</i> ; <i>Gastrointestinal:Other changes</i> ; Irritation: Skin-Human • 300 µg 3 Day(s)-Intermittent • Mild irritation; Tumorigen / Carcinogen: Inhalation-Rat • 10 mg/m³ 18 Hour(s) 2 Year(s)-Intermittent; <i>Tumorigenic:Carcinogenic by RTECS criteria</i> ; <i>Lungs, Thorax, or Respiration:Tumors</i> ; Inhalation-Rat TCLo • 250 mg/m³ 6 Hour(s) 2 Year(s)-Intermittent; <i>Tumorigenic:Carcinogenic by RTECS criteria</i> ; <i>Lungs, Thorax, or Respiration:Tumors</i>
Glycerine (N/A)	56-81-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 12600 mg/kg; <i>Behavioral:General anesthetic</i> ; <i>Behavioral:Muscle weakness</i> ; <i>Liver:Other changes</i> ; Irritation: Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Reproductive: Ingestion/Oral-Rat TDLo • 100 mg/kg (1D male); <i>Reproductive Effects:Effects on Fertility:Post-implantation mortality</i> ; Tumorigen / Carcinogen: Ingestion/Oral-Mouse TDLo • 87.5 g/kg 25 Week(s)-Intermittent; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria</i> ; <i>Lungs, Thorax, or Respiration:Tumors</i> ; <i>Tumorigenic:Facilitates action of known carcinogen</i>
FD&C Red #40 (< 0.1%)	25956-17-6	Acute Toxicity: Ingestion/Oral-Dog LD50 • >5 g/kg; Mutagen: DNA damage • Ingestion/Oral-Mouse • 10 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 38500 mg/kg (14D male/14D pre); <i>Reproductive Effects:Effects on Fertility:Mating performance</i>
FD&C Blue #1 (< 0.01%)	3844-45-9	Acute Toxicity: Subcutaneous-Mouse LD50 • 4600 mg/kg; <i>Behavioral:Convulsions or effect on seizure threshold</i> ; Tumorigen / Carcinogen: Subcutaneous-Rat TDLo • 5500 mg/kg 97 Week(s)-Intermittent; <i>Tumorigenic:Neoplastic by RTECS criteria</i> ; <i>Tumorigenic:Tumors at site of application</i>

GHS Properties

Classification

Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Skin

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

Acute (Immediate)

- Exposure to dust may cause irritation. Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Ingestion

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Carcinogenic Effects			
	CAS	IARC	NTP
Titanium dioxide	13463-67-7	Group 2B-Possible Carcinogen	Evidence of Carcinogenicity
FD&C Blue #1	3844-45-9	Group 3-Not Classifiable	Not Listed
Silicon dioxide, anhydrous	7631-86-9	Group 3-Not Classifiable	Not Listed
L-Ascorbic acid	50-81-7	Not Listed	Evidence of Carcinogenicity

Reproductive Effects

- No data available for the product.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available.

Mobility in Soil

- No data available.

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

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	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

- No special precautions.

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****SARA Hazard Classifications**

- Acute

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
FD&C Red #40	25956-17-6	Yes	Yes	Yes
dl Alpha tocopheryl acetate	7695-91-2	Yes	Yes	Yes
FD&C Blue #1	3844-45-9	Yes	Yes	Yes
Lutein	127-40-2	No	Yes	Yes
Cupric oxide	1317-38-0	Yes	Yes	Yes
Yellow beeswax	8012-89-3	Yes	Yes	Yes
Gelatins	9000-70-8	Yes	Yes	Yes
Glycerine	56-81-5	Yes	Yes	Yes
Glycerine	56-81-5	Yes	Yes	Yes
L-Ascorbic acid	50-81-7	Yes	Yes	Yes

Silicon dioxide, anhydrous	7631-86-9	Yes	Yes	Yes
Soybean lecithin	8030-76-0	Yes	Yes	Yes
Soybean oil	8001-22-7	Yes	Yes	Yes
Titanium dioxide	13463-67-7	Yes	Yes	Yes
Zinc oxide	1314-13-2	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• L-Ascorbic acid	50-81-7	Uncontrolled product according to WHMIS classification criteria
• Cupric oxide	1317-38-0	Uncontrolled product according to WHMIS classification criteria
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Uncontrolled product according to WHMIS classification criteria
• Zinc oxide	1314-13-2	Uncontrolled product according to WHMIS classification criteria
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Uncontrolled product according to WHMIS classification criteria
• Silicon dioxide, anhydrous	7631-86-9	Uncontrolled product according to WHMIS classification criteria
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	D2A (In certain cases, this classification does not apply. For more information, consult the section Substance Specific Issues - Titanium dioxide, mixture containing on Health Canada's WHMIS Division website.)
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed

• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	1 %
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	1 %
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	N; R50-53
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	N R:50/53 S:60-61
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	S:60-61
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		1.0 % de minimis concentration (listed under Chemical Category N982)
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	Not Listed

• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	carcinogen, initial date 9/2/11 (airborne, unbound particles of respirable size)
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

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

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

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

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

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

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• FD&C Red #40	25956-17-6	Not Listed

• Gelatins	9000-70-8	Not Listed
• Yellow beeswax	8012-89-3	Not Listed
• FD&C Blue #1	3844-45-9	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Glycerine	56-81-5	Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Soybean lecithin	8030-76-0	Not Listed
• Lutein	127-40-2	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed
• Glycerine	56-81-5	Not Listed

Section 16 - Other Information

Last Revision Date

- 21/April/2015

Preparation Date

- 21/April/2015

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