Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Ocuvite® PreserVision™ Vitamin and Mineral Supplement**

Product Code • AB43262N; AB43272N; FCP-4255F; HS43270N

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

Manufacturer • +1 352-323-3500 - International - 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 Revision 3

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

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	< 15%
Zinc oxide	**CAS:**1314-13-2 **EINECS:**215-222-5	< 5%
Cupric oxide	**CAS:**1317-38-0 **EINECS:**215-269-1	< 0.1%
Silicon dioxide, anhydrous	**CAS:**7631-86-9 **EINECS:**231-545-4	< 1%
Microcrystalline cellulose	**CAS:**9004-34-6 **EINECS:**232-674-9	< 20%
Lactose monohydrate	**CAS:**64044-51-5	< 35%
Magnesium stearate	**CAS:**557-04-0 **EINECS:**209-150-3	< 1%
Crospovidone	**CAS:**9003-39-8	< 10%
Stearic acid	**CAS:**57-11-4 **EINECS:**200-313-4	< 1%
dl Alpha tocopheryl acetate	**CAS:**7695-91-2 **EINECS:**231-710-0	< 25%
Triethyl citrate	**CAS:**77-93-0 **EINECS:**201-070-7	< 1%
Polysorbate 80	**CAS:**9005-65-6	< 0.1%
Opadry orange		< 5%
..... Hypromellose *[N/A]*	**CAS:**9004-65-3	*< 1%*
..... Titanium dioxide *[N/A]*	**CAS:**13463-67-7 **EINECS:**236-675-5	*< 1%*
..... Polyethylene glycol *[N/A]*	**CAS:**25322-68-3	*< 1%*
..... FD&C Yellow #6 *[N/A]*	**CAS:**2783-94-0 **EINECS:**220-491-7	*< 1%*
..... FD&C Red #40 *[N/A]*	**CAS:**25956-17-6 **EINECS:**247-368-0	*< 1%*

Beta carotene	**CAS:**7235-40-7 **EINECS:**230-636-6	< 5%

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation
- 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
- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye
- 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
- 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
- LARGE FIRE: Water spray, fog or regular foam.
  SMALL FIRES: Dry chemical, CO2, water spray or regular foam.

Unsuitable Extinguishing Media
- No data available

Firefighting Procedures
- 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
- No data available

Hazardous Combustion Products
- No data available.

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
- 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
- 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 Ontario	Canada Quebec	NIOSH	OSHA
Cupric oxide (1317-38-0)	TWAs	Not established	Not established	Not established	0.1 mg/m3 TWA (fume, as Cu)	Not established
Silicon dioxide, anhydrous (7631-86-9)	TWAs	Not established	Not established	Not established	6 mg/m3 TWA	Not established
Zinc oxide (1314-13-2)	STELs	10 mg/m3 STEL (respirable fraction)	10 mg/m3 STEL (respirable)	10 mg/m3 STEV (fume)	10 mg/m3 STEL (fume)	Not established
	TWAs	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)	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	Not established	Not established	Not established	15 mg/m3 Ceiling (dust)	Not established
Microcrystalline cellulose (9004-34-6)	TWAs	10 mg/m3 TWA	10 mg/m3 TWA	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total dust)	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

•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)

•Microcrystalline cellulose (9004-34-6): **TLV Basis - Critical Effects:** (upper respiratory tract irritation)

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	Oval shape tablet embossed with "BL01" on one side, bisected on the other side.
Color	Plain white to off-white, with yellow to reddish brown mottling.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point/Freezing 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 (< 15%)	50-81-7	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 11900 mg/kg; *Sense Organs and Special Senses:Eye*:**Lacrimation**; *Behavioral*:**Somnolence (general depressed activity)**; *Gastrointestinal*:**Hypermotility, diarrhea**; **Mutagen:** DNA damage • Ingestion/Oral-Mouse • 1 mg/kg; **Reproductive:** Ingestion/Oral-Rat TDLo • 2500 mg/kg (1-22D preg); *Reproductive Effects:Effects on Fertility*:**Post-implantation mortality**; **Tumorigen / Carcinogen:** Ingestion/Oral-Rat TDLo • 1802500 mg/kg 103 Week(s)-Continuous; *Tumorigenic*:**Carcinogenic by RTECS criteria**; *Blood*:**Leukemia**
Zinc oxide (< 5%)	1314-13-2	**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); *Reproductive Effects:Specific Developmental Abnormalities*:**Homeostasis**; *Reproductive Effects:Effects on Newborn*:**Stillbirth**; *Reproductive Effects:Effects on Newborn*:**Growth statistics (e.g., reduced weight gain)**
Cupric oxide (< 0.1%)	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; *Gastrointestinal*:**Hypermotility, diarrhea**; *Gastrointestinal*:**Nausea or vomiting**; *Gastrointestinal*:**Other changes**
Silicon dioxide, anhydrous (< 1%)	7631-86-9	**Acute Toxicity:** Ingestion/Oral-Rat LDLo • 5 g/kg; *Nutritional and Gross Metabolic:Changes in Chemistry or Temperature*:**Other changes**; **Irritation:** Eye-Rabbit • 25 mg 24 Hour(s) • Mild irritation
Microcrystalline cellulose (< 20%)	9004-34-6	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • >5 g/kg
Magnesium stearate (< 1%)	557-04-0	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • >10000 mg/kg
Crospovidone (< 10%)	9003-39-8	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 100 g/kg; *Gastrointestinal*:**Hypermotility, diarrhea**; **Tumorigen / Carcinogen:** Intraperitoneal-Rat TDLo • 2500 mg/kg; *Tumorigenic*:**Carcinogenic by RTECS criteria**; *Endocrine*:**Tumors**; *Reproductive Effects:Tumorigenic Effects*:**Ovarian tumors**
Stearic acid (< 1%)	57-11-4	**Irritation:** Skin-Human • 75 mg 3 Day(s)-Intermittent • Mild irritation; **Tumorigen / Carcinogen:** Implant-Mouse TDLo • 400 mg/kg; *Tumorigenic*:**Equivocal tumorigenic agent by RTECS criteria**; *Kidney, Ureter, and Bladder*:**Tumors**
dl Alpha tocopheryl acetate (< 25%)	7695-91-2	**Reproductive:** Ingestion/Oral-Rat TDLo • 500 mg/kg (1-22D preg); *Reproductive Effects:Effects on Fertility*:**Post-implantation mortality**
Triethyl citrate (< 1%)	77-93-0	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 5900 mg/kg; *Behavioral*:**Altered sleep time (including change in righting reflex)**; *Lungs, Thorax, or Respiration*:**Respiratory depression**; *Nutritional and Gross Metabolic:Changes in Chemistry or Temperature*:**Body temperature decrease**

Polysorbate 80 (< 0.1%)	9005-65-6	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 34500 µL/kg; **Irritation:** Eye-Rabbit • 150 mg • Mild irritation; **Reproductive:** Ingestion/Oral-Rat TDLo • 635 g/kg (multigenerations); *Reproductive Effects:Effects on Newborn*:**Viability index (e.g., # alive at day 4 per # born alive)**; *Reproductive Effects:Effects on Newborn*:**Weaning or lactation index**; **Tumorigen / Carcinogen:** Ingestion/Oral-Rat TDLo • 2163 g/kg 2 Year(s)-Continuous; *Tumorigenic*:**Equivocal tumorigenic agent by RTECS criteria**; *Endocrine*:**Adrenal cortex tumors**
Hypromellose (< 1%)	9004-65-3	**Acute Toxicity:** Intraperitoneal-Rat LD50 • 5200 mg/kg
Titanium dioxide (< 1%)	13463-67-7	**Acute Toxicity:** Ingestion/Oral-Rat TDLo • 60 g/kg; *Gastrointestinal*:**Hypermotility, diarrhea**; *Gastrointestinal*:**Other changes**; **Irritation:** Skin-Human • 300 µg 3 Day(s)-Intermittent • Mild irritation; **Mutagen:** 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; **Tumorigen / Carcinogen:** Inhalation-Rat • 10 mg/m³ 18 Hour(s) 2 Year(s)-Intermittent; *Tumorigenic*:**Carcinogenic by RTECS criteria**; *Lungs, Thorax, or Respiration*:**Tumors**
Polyethylene glycol (< 1%)	25322-68-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 1054 mg/kg; Skin-Rabbit LD50 • >20 g/kg; **Irritation:** Eye-Rabbit • 500 mg • Mild irritation; Skin-Rabbit • 500 mg-Open • Mild irritation; **Mutagen:** Cytogenetic analysis • Hamster • Liver (Somatic cell) • 3 mmol/L 16 Hour(s); **Reproductive:** Ingestion/Oral-Rabbit TDLo • 130 mg/kg (6-18D preg); *Reproductive Effects:Maternal Effects*:**Other effects**; **Tumorigen / Carcinogen:** Intravaginal-Mouse TDLo • 416 mg/kg 1 Year(s)-Intermittent; *Tumorigenic*:**Equivocal tumorigenic agent by RTECS criteria**; *Reproductive Effects:Tumorigenic Effects*:**Other reproductive system tumors**
FD&C Yellow #6 (< 1%)	2783-94-0	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • >2000 mg/kg; **Mutagen:** DNA damage • Ingestion/Oral-Mouse • 4.55 mg/kg 2 Week(s)-Intermittent; **Reproductive:** Ingestion/Oral-Rat TDLo • 3000 mg/kg (6-15D preg); *Reproductive Effects:Effects on Embryo or Fetus*:**Fetotoxicity (except death, e.g., stunted fetus)**; *Reproductive Effects:Effects on Newborn*:**Growth statistics (e.g., reduced weight gain)**
FD&C Red #40 (< 1%)	25956-17-6	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • >10000 mg/kg; **Mutagen:** DNA damage • Ingestion/Oral-Mouse • 10 mg/kg; **Reproductive:** Ingestion/Oral-Rat TDLo • 38500 mg/kg (14D male/14D pre); *Reproductive Effects:Effects on Fertility*:**Mating performance**
Beta carotene (< 5%)	7235-40-7	**Acute Toxicity:** Intraperitoneal-Mouse TDLo • 5 ng/kg; *Immunological Including Allergic*:**Increase in humoral immune response**

GHS Properties	Classification
Acute toxicity	**UN GHS 3** • Classification criteria not met
Skin corrosion/Irritation	**UN GHS 3** • Classification criteria not met
Serious eye damage/Irritation	**UN GHS 3** • Eye Mild Irritation 2B
Skin sensitization	**UN GHS 3** • Classification criteria not met
Respiratory sensitization	**UN GHS 3** • Classification criteria not met
Aspiration Hazard	**UN GHS 3** • Classification criteria not met
Carcinogenicity	**UN GHS 3** • Classification criteria not met
Germ Cell Mutagenicity	**UN GHS 3** • Classification criteria not met
Toxicity for Reproduction	**UN GHS 3** • Classification criteria not met
STOT-SE	**UN GHS 3** • Classification criteria not met
STOT-RE	**UN GHS 3** • Classification criteria not met

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
FD&C Yellow #6	2783-94-0	Group 3-Not Classifiable	Evidence of Carcinogenicity
Titanium dioxide	13463-67-7	Group 2B-Possible Carcinogen	Evidence of Carcinogenicity
Polysorbate 80	9005-65-6	Not Listed	Evidence of Carcinogenicity
Silicon dioxide, anhydrous	7631-86-9	Group 3-Not Classifiable	Not Listed
L-Ascorbic acid	50-81-7	Not Listed	Evidence of Carcinogenicity
Crospovidone	9003-39-8	Group 3-Not Classifiable	Not Listed

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
FD&C Yellow #6	2783-94-0	Yes	Yes	Yes
dl Alpha tocopheryl acetate	7695-91-2	Yes	Yes	Yes
Beta carotene	7235-40-7	Yes	Yes	Yes
Microcrystalline cellulose	9004-34-6	Yes	Yes	Yes
Triethyl citrate	77-93-0	Yes	Yes	Yes
Cupric oxide	1317-38-0	Yes	Yes	Yes
Lactose monohydrate	64044-51-5	No	No	No
Hypromellose	9004-65-3	Yes	No	Yes
L-Ascorbic acid	50-81-7	Yes	Yes	Yes
Polyethylene glycol	25322-68-3	Yes	No	Yes
Crospovidone	9003-39-8	Yes	No	Yes
Silicon dioxide, anhydrous	7631-86-9	Yes	Yes	Yes
Polysorbate 80	9005-65-6	Yes	No	Yes
Stearic acid	57-11-4	Yes	Yes	Yes
Magnesium stearate	557-04-0	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

• Crospovidone	9003-39-8	Uncontrolled product according to WHMIS classification criteria (listed under Providone)
• Stearic acid	57-11-4	Uncontrolled product according to WHMIS classification criteria
• 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
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Uncontrolled product according to WHMIS classification criteria (including microcrystalline and paper fibers)
• Zinc oxide	1314-13-2	Uncontrolled product according to WHMIS classification criteria
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Uncontrolled product according to WHMIS classification criteria
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Uncontrolled product according to WHMIS classification criteria
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	D2B
• Polyethylene glycol	25322-68-3	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

Canada - WHMIS - Ingredient Disclosure List

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	1 %
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed

• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	1 %
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	1 %
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

Europe

Other

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	N; R50-53
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	N R:50/53 S:60-61
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed

• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	S:60-61
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

United States

Environment

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		1.0 % de minimis concentration (listed under Chemical Category N982)
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed

• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

United States - California

Environment

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	carcinogen, 9/2/2011 (airborne, unbound particles of respirable size)
• Titanium dioxide as Titanium compounds		Not Listed

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed

• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

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

• Crospovidone	9003-39-8	Not Listed
• Stearic acid	57-11-4	Not Listed
• L-Ascorbic acid	50-81-7	Not Listed
• Cupric oxide	1317-38-0	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	Not Listed
• Zinc oxide as Zinc compounds		Not Listed
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Beta carotene	7235-40-7	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hypromellose	9004-65-3	Not Listed
• FD&C Red #40	25956-17-6	Not Listed
• FD&C Yellow #6	2783-94-0	Not Listed
• Polyethylene glycol	25322-68-3	Not Listed
• Titanium dioxide	13463-67-7	Not Listed
• Titanium dioxide as Titanium compounds		Not Listed

Section 16 - Other Information

Revision Date
- 15/June/2016

Last Revision Date
- 31/May/2016

Preparation Date
- 28/February/2002

Disclaimer/Statement of Liability
- To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution.

Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.