



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name

- **Ocuvite® Lutein**

Product Code

- AB40319; AB47320; FCP-4269B

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	%	Classifications According to Regulation/Directive
L-Ascorbic acid	CAS:50-81-7 EINECS:200-066-2	< 15%	UN GHS: Skin Corr. 1; Skin Irrit. 2; Eye Dam. 1; Eye Irrit. 2A
Zinc oxide	CAS:1314-13-2 EINECS:215-222-5	< 5%	UN GHS: Classification criteria not met
Cupric oxide	CAS:1317-38-0 EINECS:215-269-1	< 1%	UN GHS: Classification criteria not met
Silicon dioxide, anhydrous	CAS:7631-86-9 EINECS:231-545-4	< 1%	UN GHS: Eye Irrit. 2A
Microcrystalline cellulose	CAS:9004-34-6 EINECS:232-674-9	< 20%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Magnesium stearate	CAS:557-04-0 EINECS:209-150-3	< 1%	UN GHS: Classification criteria not met
Crospovidone	CAS:9003-39-8	< 10%	UN GHS: Classification criteria not met
Stearic acid	CAS:57-11-4 EINECS:200-313-4	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1; Carc. 1A; Repr. 1
dl Alpha tocopheryl acetate	CAS:7695-91-2 EINECS:231-710-0	< 15%	UN GHS: Classification criteria not met
Dibasic calcium phosphate	CAS:7789-77-7	< 30%	UN GHS: Classification criteria not met
Lutein	CAS:127-40-2 EINECS:204-840-0	< 25%	UN GHS: Classification criteria not met
Opadry® II orange coating	NDA	< 5%	UN GHS: Classification criteria not met

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 British Columbia	Canada Nova Scotia	Canada Ontario	Canada Quebec
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)
Microcrystalline cellulose (9004-34-6)	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)
Exposure Limits/Guidelines (Con't.)						
	Result	NIOSH		OSHA		
Silicon dioxide, anhydrous (7631-86-9)	TWAs	6 mg/m3 TWA		Not established		
Cupric oxide (1317-38-0)	TWAs	0.1 mg/m3 TWA (fume, as Cu)		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		
Microcrystalline cellulose (9004-34-6)	TWAs	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	Smooth, modified oval shape tablet engraved with "BL" on one side, engraved with "04" on the other side.
Color	Speckled, red white.	Odor	No odor.
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point	No data available
pH	No data available	Specific Gravity/Relative Density	No data available
Water Solubility	Soluble	Viscosity	No data available
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
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; <i>Sense Organs and Special Senses:Eye:Lacrimation; Behavioral:Somnolence (general depressed activity); Gastrointestinal:Hypermotility, diarrhea;</i> Mutagen: DNA damage • Ingestion/Oral-Mouse • 1 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 2500 mg/kg (1-22D preg); <i>Reproductive Effects:Effects on Fertility:Post-implantation mortality;</i> Tumorigen / Carcinogen: Ingestion/Oral-Rat TDLo • 1802500 mg/kg 103 Week(s)-Continuous; <i>Tumorigenic:Carcinogenic by RTECS criteria; Blood:Leukemia</i>
Zinc oxide (< 5%)	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; Reproductive Effects:Effects on Newborn:Stillbirth; Reproductive Effects:Effects on Newborn:Growth statistics (e.g., reduced weight gain)</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; Gastrointestinal:Nausea or vomiting; Gastrointestinal:Other changes</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
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; <i>Gastrointestinal:Hypermotility, diarrhea;</i> Tumorigen / Carcinogen: Intraperitoneal-Rat TDLo • 2500 mg/kg; <i>Tumorigenic:Carcinogenic by RTECS criteria; Endocrine:Tumors; Reproductive Effects:Tumorigenic Effects:Ovarian tumors</i>
Stearic acid (< 1%)	57-11-4	Irritation: Skin-Human • 75 mg 3 Day(s)-Intermittent • Mild irritation; Multi-dose Toxicity: Skin-Rabbit LD50 • >5 g/kg; Tumorigen / Carcinogen: Implant-Mouse TDLo • 400 mg/kg; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Kidney, Ureter, and Bladder:Tumors</i>
dI Alpha tocopheryl acetate (< 15%)	7695-91-2	Reproductive: Ingestion/Oral-Rat TDLo • 500 mg/kg (1-22D preg); <i>Reproductive Effects:Effects on Fertility:Post-implantation mortality</i>
Lutein (< 25%)	127-40-2	Acute Toxicity: In Vitro ICLo • 50 µmol/L 24 Hour(s)

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
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
dl Alpha tocopheryl acetate	7695-91-2	Yes	Yes	Yes
Dibasic calcium phosphate	7789-77-7	Yes	No	No
Microcrystalline cellulose	9004-34-6	Yes	Yes	Yes
Cupric oxide	1317-38-0	Yes	Yes	Yes
L-Ascorbic acid	50-81-7	Yes	Yes	Yes
Lutein	127-40-2	No	Yes	Yes
Crospovidone	9003-39-8	Yes	No	Yes
Silicon dioxide, anhydrous	7631-86-9	Yes	Yes	Yes

Stearic acid	57-11-4	Yes	Yes	Yes
Magnesium stearate	557-04-0	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Zinc oxide	1314-13-2	Not Listed
		1.0 % de minimis

• Zinc oxide as Zinc compounds		concentration (listed under Chemical Category N982)
• Silicon dioxide, anhydrous	7631-86-9	Not Listed
• dl Alpha tocopheryl acetate	7695-91-2	Not Listed
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	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
• Dibasic calcium phosphate	7789-77-7	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
• Lutein	127-40-2	Not Listed

Section 16 - Other Information

Last Revision Date

- 29/May/2015

Preparation Date

- 26/March/2007

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.