

Safety Data Sheet**BAUSCH+LOMB****Section 1: Identification****Product identifier**

- Product Name** • **VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024%**
- Product Code** • AB50407; AB50496; Core No. 504; NDC 24208-504-05; NDC 24208-504-06
- Product Description** • Ophthalmic solution for eyes.

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

- Recommended use** • VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
- Restrictions on use** • Use only in accordance with label instructions and supplied prescribing information.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb Incorporated
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

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** • May be harmful if swallowed
May cause eye irritation in sensitive individuals

Precautionary statements

- Prevention** • Wash thoroughly after handling.
Avoid release to the environment.
- Response** • If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • Unopened bottle should be stored refrigerated at 2° to 8°C (36° to 46°F). Once a bottle is opened it may be stored at 2° to 25°C (36° to 77°F) for 8 weeks.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Supplemental information • CAUTION: Pharmacologically Active

GHS Other Information • DO NOT USE: If there exists hypersensitivity to any ingredient in this product.

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	%
Latanoprostene Bunod	CAS:860005-21-6	0.024%
Benzalkonium Chloride, 50%	CAS:68391-01-5 EINECS:269-919-4	0.04%
Polysorbate 80 HP	CAS:9005-65-6	< 1%
Citric acid	CAS:77-92-9 EINECS:201-069-1	< 0.1%
Sodium citrate, dihydrate	CAS:6132-04-3	< 1%
EDTA Disodium Dihydrate	CAS:6381-92-6	< 1%
Glycerine	CAS:56-81-5 EINECS:200-289-5	< 5%
Purified Water	CAS:7732-18-5 EINECS:231-791-2	> 95%

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 discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

Ingestion

- If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed**Other information**

- Additional details are provided on the product packaging and/or the product insert.

Section 5: Fire-Fighting Measures**Extinguishing media**

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • Material is non-combustible. In case of fire use media as appropriate for surrounding fire.

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 • None known.

Hazardous Combustion Products • During a fire, thermal decomposition or combustion may generate irritating and highly toxic gases.

Advice for firefighters

- Refer to "Firefighting Procedures"

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

Personal Precautions • Wear suitable protective eyewear, clothing, respiratory protection, rubber boots and rubber gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. 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. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13.

Environmental precautions

- 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 • Refer to "Emergency Procedures"

Section 7 - Handling and Storage**Precautions for safe handling**

Handling • Use only in accordance with product literature. When using this product: do not touch tip of container to any surface to avoid contamination, remove contact lenses before using, and always replace the cap after use. Wash thoroughly with warm water and soap after handling.

Conditions for safe storage, including any incompatibilities

Storage • Protect from light. Keep tightly closed. Store refrigerated at 2-8C (36-46F) to maintain product integrity. Use before expiration date marked on carton and/or bottle.

Special Packaging Materials • Maintain product in original container only.

Incompatible Materials or Ignition Sources • None specified.

Specific end use(s)

- Refer to Section 1.2 - Relevant identified uses.

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	Canada British Columbia	Canada Quebec	OSHA
Glycerine (56-81-5)	TWAs	10 mg/m3 TWA (mist); 3 mg/m3 TWA (mist, respirable)	10 mg/m3 TWAEV (mist)	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)

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

- Not required during normal clinical use. Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. 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.

Thermal hazards

- None known.

General Industrial Hygiene Considerations

- Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Colorless to slightly yellow.
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	Not relevant
Decomposition Temperature	No data available	pH	5.5

Specific Gravity/Relative Density	= 1 Water=1	Viscosity	No data available
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Heat of Combustion (ΔHc)	Not relevant	Flame Height	Not relevant
Ignition Distance	Not relevant		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored refrigerated at 2-8C (36-46F). Use before expiration date marked on carton and/or bottle.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- Keep away from strong oxidizing materials. Avoid exposure to or contact with extreme temperatures, light, and any identified incompatible chemicals.

Hazardous decomposition products

- When exposed to extreme temperatures, this material may generate carbon monoxide, carbon dioxide, and nitrogen oxides.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Polysorbate 80 HP (< 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); <i>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;</i> Tumorigen / Carcinogen: Ingestion/Oral-Rat TDLo • 2163 g/kg 2 Year(s)-Continuous; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Endocrine:Adrenal cortex tumors</i>
Citric acid (< 0.1%)	77-92-9	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3 g/kg; Irritation: Eye-Rabbit • 750 µg 24 Hour(s) • Severe irritation; Skin-Rabbit • 0.5 mL • Moderate irritation
Sodium citrate, dihydrate (< 1%)	6132-04-3	Acute Toxicity: In Vitro IC50 • 22 mmol/L 24 Hour(s)
EDTA Disodium Dihydrate (< 1%)	6381-92-6	Mutagen: Cytogenetic analysis • Hamster • Lung (Somatic cell) • 200 mg/L
		Acute Toxicity: Ingestion/Oral-Rat LD50 • 12600 mg/kg; <i>Behavioral:General anesthetic; Behavioral:Muscle weakness; Liver:Other changes;</i> Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation;

Glycerine (< 5%)	56-81-5	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; Lungs, Thorax, or Respiration:Tumors;</i> <i>Tumorigenic:Facilitates action of known carcinogen</i>
Purified Water (> 95%)	7732-18-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >90 mL/kg

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)**
 - Unlikely to be hazardous when used as directed. However, if actively concentrated and inhaled, it may cause respiratory tract irritation.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - Not expected to cause skin irritation.
- Chronic (Delayed)**
 - No data available.

Eye

- Acute (Immediate)**
 - May cause eye irritation in sensitive individuals.
- Chronic (Delayed)**
 - No data available.

Ingestion

- Acute (Immediate)**
 - May cause gastrointestinal irritation or other disturbances.
- Chronic (Delayed)**
 - No data available.

Other

- Chronic (Delayed)**
 - Latanoprostene bunod may have some genotoxic effects.

Mutagenic Effects

- No data available.

Carcinogenic Effects

- No data available.

Carcinogenic Effects		
	CAS	NTP
Polysorbate 80 HP	9005-65-6	Evidence of Carcinogenicity

Reproductive Effects

- Glycerine (CAS# 56-81-5): Overexposure may cause reproductive disorders based on tests with laboratory animals.

Section 12 - Ecological Information**Toxicity**

- No data available

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 data available

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**

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
EDTA Disodium Dihydrate	6381-92-6	Yes	No	No
Benzalkonium Chloride, 50%	68391-01-5	Yes	Yes	Yes

Citric acid	77-92-9	Yes	Yes	Yes
Glycerine	56-81-5	Yes	Yes	Yes
Latanoprostene Bunod	860005-21-6	No	No	No
Sodium citrate, dihydrate	6132-04-3	No	No	No
Polysorbate 80 HP	9005-65-6	Yes	No	Yes
Purified Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS 1988 - Classifications of Substances

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Uncontrolled product according to WHMIS classification criteria
• Glycerine	56-81-5	Uncontrolled product according to WHMIS classification criteria
• Citric acid	77-92-9	E (including 40%)
• EDTA Disodium Dihydrate	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Purified Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Latanoprostene Bunod	860005-21-6	Not Listed

Canada - WHMIS 1988 - Ingredient Disclosure List

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	1 %
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
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• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

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

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

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

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

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

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

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

• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed

• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• Benzalkonium Chloride, 50%	68391-01-5	Not Listed
• Polysorbate 80 HP	9005-65-6	Not Listed
• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• EDTA Disodium Dihydrate	6381-92-6	Not Listed
• Purified Water	7732-18-5	Not Listed
• Latanoprostene Bunod	860005-21-6	Not Listed

Section 16 - Other Information

Revision Date	<ul style="list-style-type: none"> • 21/July/2016
Last Revision Date	<ul style="list-style-type: none"> • 21/July/2016
Preparation Date	<ul style="list-style-type: none"> • 27/September/2012
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