

SAFETY DATA SHEET

1. Identification

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|--------------------------------------|---|
| Product identifier | Zirgan®, ganciclovir ophthalmic gel, 0.15% |
| Other means of identification | |
| Product Code | NDC 24208-535-15, NDC 24208-535-35 |
| Recommended use | Medicinal Product. |

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 medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

| | | |
|-------------------------------|---|----------------|
| Company name | Bausch & Lomb, Inc. | |
| Address | 1400 North Goodman Street Rochester, NY 14609 United States | |
| Telephone | For Information | 1-800-553-5340 |
| E-mail | Not available. | |
| Emergency phone number | For Emergency - US | 1-800-535-5053 |
| | For Emergency - International | 1-352-323-3500 |

2. Hazard(s) identification**Classified hazards**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients**Mixtures**

| Chemical name | Common name and synonyms | CAS number | % |
|-----------------------|---------------------------------|-------------------|--------------|
| WATER | | 7732-18-5 | 80 - < 90 |
| MANNITOL | | 69-65-8 | 5 - < 10 |
| Carbopol 974P | | 9003-01-4 | < 1 |
| GANCICLOVIR | | 82410-32-0 | 0.15 |
| BENZALKONIUM CHLORIDE | | 8001-54-5 | 0.01 |
| SODIUM HYDROXIDE | | 1310-73-2 | to adjust pH |

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

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|---------------------|---|
| Inhalation | Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| Skin contact | Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur. |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. |
| Ingestion | If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. |

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| Most important symptoms/effects, acute and delayed | Irritation of eyes. Exposed individuals may experience eye tearing, redness, and discomfort. |
| Indication of immediate medical attention and special treatment needed | No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. |
| General information | In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |

5. Fire-fighting measures

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| Suitable extinguishing media | Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂). |
| Unsuitable extinguishing media | None known. |
| Specific hazards arising from the chemical | During fire, gases hazardous to health may be formed. |
| Special protective equipment and precautions for firefighters | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| Fire fighting equipment/instructions | Move containers from fire area if you can do so without risk. |
| Specific methods | Use standard firefighting procedures and consider the hazards of other involved materials. |
| General fire hazards | No unusual fire or explosion hazards noted. |

6. Accidental release measures

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| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

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| Precautions for safe handling | Do not handle until all safety precautions have been read and understood. Avoid contact with eyes. Do not taste or swallow. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. |
| Conditions for safe storage, including any incompatibilities | Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Store at a controlled room temperature: 15-25°C (59-77°F). Do not freeze. |

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

| Components | Type | Value |
|-------------------------------------|------|---------------------|
| SODIUM HYDROXIDE (CAS 1310-73-2) | PEL | 2 mg/m ³ |

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|-------------------------------------|---------|---------------------|
| SODIUM HYDROXIDE (CAS 1310-73-2) | Ceiling | 2 mg/m ³ |

US. NIOSH: Pocket Guide to Chemical Hazards

| Components | Type | Value |
|------------|------|-------|
|------------|------|-------|

| | | |
|-------------------------------------|---------|---------|
| SODIUM HYDROXIDE (CAS 1310-73-2) | Ceiling | 2 mg/m3 |
|-------------------------------------|---------|---------|

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls No special controls required during normal clinical use. When handling bulk product Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection required under conditions of intended use.
When handling bulk product: If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection No hand protection required under conditions of intended use.
When handling bulk product: For prolonged or repeated skin contact use suitable protective gloves.

Other

No special precautions needed under conditions of intended use.
When handling bulk product: Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No respiratory protection required under conditions of intended use.
When handling bulk product: Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties**Appearance**

Physical state Liquid.
Form Gel.
Color Clear colorless or nearly colorless

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

| | |
|--|-------------------|
| Solubility(ies) | |
| Solubility (water) | miscible in water |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Specific gravity | 1 |

10. Stability and reactivity

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| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. |

11. Toxicological information

Information on likely routes of exposure

| | |
|---------------------|---|
| Inhalation | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| Skin contact | Health injuries are not known or expected under normal use. |
| Eye contact | Health injuries are not known or expected under normal use. |
| Ingestion | Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure. |

Symptoms related to the physical, chemical and toxicological characteristics

Irritation of eyes. Exposed individuals may experience eye tearing, redness, and discomfort.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

| Components | Species | Test Results |
|---------------------------------------|---------|--------------|
| BENZALKONIUM CHLORIDE (CAS 8001-54-5) | | |
| Acute | | |
| <i>Dermal</i> | | |
| LD50 | Rat | 1420 mg/kg |
| <i>Oral</i> | | |
| LD50 | Mouse | 150 mg/kg |
| | Rat | 240 mg/kg |
| <i>Other</i> | | |
| LD50 | Rat | 13.9 mg/kg |
| MANNITOL (CAS 69-65-8) | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Mouse | 22 g/kg |
| | Rat | 13500 mg/kg |
| <i>Other</i> | | |
| LD50 | Mouse | 7470 mg/kg |
| | Rat | 9690 mg/kg |

| Components | Species | Test Results |
|--|--|--------------|
| SODIUM HYDROXIDE (CAS 1310-73-2) | | |
| Acute | | |
| <i>Other</i> | | |
| LD50 | Mouse | 40 mg/kg |
| * Estimates for product may be based on additional component data not shown. | | |
| Skin corrosion/irritation | Prolonged skin contact may cause temporary irritation. | |
| Serious eye damage/eye irritation | Causes eye irritation. | |
| Respiratory or skin sensitization | | |
| Respiratory sensitization | Not available. | |
| Skin sensitization | This product is not expected to cause skin sensitization. | |
| Germ cell mutagenicity | Ganciclovir - At levels significantly higher than the therapeutic dose, ganciclovir caused mutagenic changes during in vitro studies. Therefore, it should be considered a mutagen. | |
| Carcinogenicity | Ganciclovir - At levels significantly higher than the therapeutic dose, ganciclovir caused tumors in mice and in vitro studies. Therefore, it should be considered a potential carcinogen in humans. | |
| IARC Monographs. Overall Evaluation of Carcinogenicity | | |
| Carbopol 974P (CAS 9003-01-4) | 3 Not classifiable as to carcinogenicity to humans. | |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) | | |
| Not listed. | | |
| Reproductive toxicity | Suspected of damaging fertility or the unborn child. Ganciclovir - At levels significantly higher than the therapeutic dose, ganciclovir caused aspermatogenesis and teratogenicity in animal and in vitro studies. Therefore, it should be considered a potential teratogen in humans. It may cause birth defects and/or death to the exposed fetus. | |
| Specific target organ toxicity - single exposure | Not classified. | |
| Specific target organ toxicity - repeated exposure | Not classified. | |
| Aspiration hazard | Not available. | |
| Chronic effects | Prolonged inhalation may be harmful. | |
| Further information | Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects. | |

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

| Components | Species | Test Results |
|---------------------------------------|---------|--|
| BENZALKONIUM CHLORIDE (CAS 8001-54-5) | | |
| Aquatic | | |
| Fish | LC50 | Guppy (Poecilia reticulata) 1.3 mg/l, 96 hours |
| SODIUM HYDROXIDE (CAS 1310-73-2) | | |
| Aquatic | | |
| Crustacea | EC50 | Water flea (Ceriodaphnia dubia) 34.59 - 47.13 mg/l, 48 hours |
| Fish | LC50 | Western mosquitofish (Gambusia affinis) 125 mg/l, 96 hours |

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

MANNITOL -3.1

Mobility in soil

Mobility in general

Other adverse effects Not available.

13. Disposal considerations

| | |
|--|---|
| Disposal instructions | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations. |
| Local disposal regulations | Dispose in accordance with all applicable regulations. |
| Hazardous waste code | The waste code should be assigned in discussion between the user and the waste disposal company. |
| Waste from residues / unused products | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground. |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

SODIUM HYDROXIDE (CAS 1310-73-2) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

SODIUM HYDROXIDE (CAS 1310-73-2)

US. New Jersey Worker and Community Right-to-Know Act

SODIUM HYDROXIDE (CAS 1310-73-2)

US. Pennsylvania Worker and Community Right-to-Know Law

SODIUM HYDROXIDE (CAS 1310-73-2)

US. Rhode Island RTK

SODIUM HYDROXIDE (CAS 1310-73-2)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

GANCICLOVIR (CAS 82410-32-0) Listed: August 26, 1997

US - California Proposition 65 - CRT: Listed date/Developmental toxin

GANCICLOVIR (CAS 82410-32-0) Listed: August 26, 1997

US - California Proposition 65 - CRT: Listed date/Male reproductive toxin

GANCICLOVIR (CAS 82410-32-0) Listed: August 26, 1997

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 12-11-2014**Version #** 01

Disclaimer Bausch & Lomb, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.