



MATERIAL SAFETY DATA SHEET

NOVARTIS PHARMACEUTICALS CORPORATION

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SECTION 1. PRODUCT IDENTIFICATION

PRODUCT NAME: GenTeal[®], GenTeal[®] Mild, GenTeal[®] Gel, GenTeal[®] PF
SYNONYMS: None
INDICATION: Relief of dryness and irritation to the eyes; protects against further irritation.

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>COMPOSITION</u>	<u>CAS#</u>	<u>CONCENTRATION</u>
Hydroxypropyl Methylcellulose	9004-65-3	0.2 – 0.3%

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

FINISHED PHARMACEUTICAL PRODUCT
REFER TO PACKAGE INSERT
MAY CAUSE VARYING DEGREES OF EYE IRRITATION, ITCHING AND BURNING
MAY CAUSE VARYING DEGREES OF BLURRED VISION

PRIMARY ROUTE (S) OF ENTRY: Ocular

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EFFECTS OF OVEREXPOSURE: Finished pharmaceutical product. Potential for exposure is reduced in this form.

Skin: No hazard is expected from normal clinical use.

Eye: May cause irritation, itching and burning. May also cause blurred vision and mucous discharge.

Inhalation: No hazard is expected from normal clinical use.

Ingestion: No hazard is expected from normal clinical use.

THERAPEUTIC SIDE EFFECTS: Mild dry eye sufferers may experience gritty sensation, tearing, mild redness, burning, and mild itching. Moderate dry eye sufferers may experience irritation, redness, itching, significant burning, and mucous discharge. Severe dry eye sufferers may experience pain, persistent redness, blurred vision, severe itching, and frequent mucous discharge.

TARGET ORGAN EFFECTS: Unknown

REPRODUCTIVE HAZARDS: No tests have been performed to assess reproductive toxicity potential.

CARCINOGENICITY: No tests have been performed to assess carcinogenic potential.

MUTAGENICITY: No tests have been performed to assess mutagenic potential.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to GenTeal or any components of the formulation.

SECTION 4. EMERGENCY AND FIRST AID MEASURES

Skin Contact: Wash contaminated area with soap and water.

Eye Contact: Flush with running water for no less than 5 minutes.

Inhalation: No specific treatment is necessary since this product is not likely to be hazardous by inhalation.

Ingestion: Seek medical attention immediately and show the label.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: not available **Method Used:** not available

Flammable Limits (% in air)

Lower: not available Upper: not available

Autoignition Temperature: Not available

Extinguishing Media: Use media suitable for fire in surrounding area.

Special Fire Fighting Procedures and Precautions: Evacuate area and fight fire from safe distance.

Fire and Explosion Hazards: Not available

Fire-Fighting Equipment: Wear full protective clothing and positive pressure self-contained breathing apparatus.

Decomposition Products: Not available

NFPA Ratings: Health = 0 Flammability = 0 Reactivity = 0 Special Hazard = None

Hazard Rating Scales: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe U = Unknown

SECTION 6. ACCIDENTAL RELEASE MEASURES

Steps to be taken if Material is Released or Spilled: Using disposable towels moistened with an appropriate cleaning agent and place in a sealable, properly labeled waste disposal bag. All wastes must be disposed of in accordance with local, state and federal laws and regulations. Avoid disposal in sewers and waterways.

SECTION 7. HANDLING AND STORAGE

Storage Temperature: Store at 15 - 30° C (59° - 86° F).
Shelf Life: Expiration dating listed on each package.
Special Sensitivity: Unknown
Handling and Storage Precautions: Store at recommended storage temperature.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection: Not required under normal conditions of therapeutic administration and use.
Skin Protection: Not required under normal conditions of therapeutic administration and use.
Respiratory Protection: Not required under normal conditions of therapeutic administration and use.
Ventilation Requirements: Not required under normal conditions of therapeutic administration and use.
Additional Measures: None

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear solution or gel	Odor Characteristics:	Not available
Odor Threshold:	Not available	Vapor Pressure (mm Hg):	Not available
pH:	Not available	Vapor Density:	Not available
Boiling Point:	Not available	Specific Gravity:	Not available
Melting/Freezing Pt.:	Not applicable	Viscosity:	Not available
Soluble In:	Unknown		

SECTION 10. STABILITY AND REACTIVITY

Stable (yes/no): Yes
Hazardous Polymerization: Will not occur.
Conditions and Materials to Avoid: Temperature extremes.
Incompatibility: Not available.
Hazardous Decomposition Products: Not determined.

SECTION 11. TOXICOLOGICAL INFORMATION

Eye Irritation: No animal data available. However, finished product may cause varying degrees of irritation, itching, burning and mucoid discharge based on human use.

Skin Irritation/Sensitization: No data available.

Oral Toxicity: No data available.

Dermal Toxicity: No data available.

Inhalation Toxicity: No data available.

Chronic/Carcinogenicity: No data available.

Mutagenicity: No data available.

Reproductive Effects: No data available.

SECTION 12. ECOLOGICAL INFORMATION

No data available.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method: Using appropriate protective equipment, take up and containerize spilled material. All wastes must be disposed of in accordance with local, state and federal laws and regulations. Avoid disposal in sewers and waterways.

EPA Hazardous Waste Number: None

SECTION 14. TRANSPORTATION INFORMATION**GROUND/RAIL/VESSEL REGULATIONS**

DOT Proper Shipping Name: Not regulated for Transportation

AIR REGULATIONS

IATA-DGR: Not regulated for Transportation
IATA Proper Shipping Name: Not regulated for Transportation

SECTION 15. REGULATORY INFORMATION

OSHA (Occupational Safety & Health Administration): This Material Safety Data Sheet contains the information required by the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).

OSHA PSM (Process Safety Management): Not listed (29 CFR 1910.119, Appendix A).

NJ TCPA (Toxic Catastrophe Prevention Act): This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.

TSCA (Toxic Substance Control Act): Not applicable

CERCLA (Comprehensive Response Compensation & Liability Act): Not listed

SARA Title III (Superfund Amendments & Reauthorization Act):

Section 302 Extremely Hazardous Substances:	Not listed
Section 311/312 Hazard Categories:	None
Section 313 Reportable Ingredients:	Not listed

RCRA (Resource Conservation & Recovery Act): Not listed

Other State Regulatory Information:

New Jersey:	NJ RTK Threshold Planning Quantity = 10,000 lbs.
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Other USA Regulations: None

California Proposition 65: The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. *This product contains no ingredients known to the State of California to cause cancer or reproductive toxicity.*

Canada: WHMIS Ingredient Disclosure List
Not listed

EEC Classification (European Economic Community): Warning Symbol: not available
Risk Phrases: not available
Safety Phrases: not available

SECTION 16. OTHER INFORMATION

Reason for Issue: New

Written By:	C. Perino	Date:	11 May 04
Approved By:	J. Affuso	Date:	19 May 04

To the best of our knowledge, the information contained herein is accurate. However, Novartis Pharmaceuticals Corporation does not assume any liability whatsoever for the accuracy or completeness of the information contained

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herein except for the product's administration/use as intended. Final determination of the 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, which exist.