

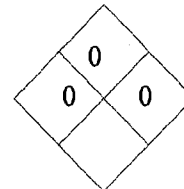
## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078689542

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078705261 078851096



## MATERIAL SAFETY DATA SHEET

NOVARTIS PHARMACEUTICALS CORPORATION  
One Health Plaza  
East Hanover, NJ 07936

24-Hour Emergency Telephone Number: 1-862-778-7000  
Customer Interaction Center (MSDS requests): 1-888-669-6682  
For Technical Information: 1-862-778-3680 (9:00 AM – 5:00 PM E.S.T.)

### SECTION 1. PRODUCT IDENTIFICATION

PRODUCT NAME: **GenTeal<sup>®</sup>, GenTeal<sup>®</sup> Mild, GenTeal<sup>®</sup> Gel, GenTeal<sup>®</sup> PF**  
SYNONYMS: None  
INDICATION: Relief of dryness and irritation to the eyes; protects against further irritation.

### SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

COMPOSITION	CAS#	CONCENTRATION
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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Approval Date: 11 May 04

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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**

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

<b>Written By:</b>	C. Perino	<b>Date:</b>	11 May 04
<b>Approved By:</b>	J. Affuso	<b>Date:</b>	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.