

## **SAFETY DATA SHEETS**

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

078356065

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

78057593



## MSDS: Gonak™ Hypromellose Solution, 2.5%

**Manufacturer:** Akorn Incorporated  
72-6 Veronica Avenue  
Somerset, NJ 08873  
**Telephone:** (732) 846-8066  
**Email:** customer.service@akorn.com

### Section 1 - IDENTIFICATION

**TRADE NAME:** GONAK™ Hypromellose Solution, 2.5%  
NDC # 17478-064-12  
**Description:** Sterile, diagnostic ophthalmic demulcent solution for use during gonioscopic examination.

<b>Composition</b>	<b>CAS#</b>	<b>TLV(mg/m<sup>3</sup>)</b>	<b>PEL(mg/m<sup>3</sup>)</b>	<b>%Content</b>
Hypromellose 2906	9004-65-3	N/E	N/E	2.5
Edetate Disodium, USP	6381-92-6	N/E	N/E	0.1
Boric Acid, NF	10043-35-3	6	N/E	1.3
Sodium Borate, NF (decahydrate)	1303-96-4	6	N/E	0.34
Potassium Chloride, USP	7447-40-7	N/E	N/E	0.27
Benzalkonium Chloride, NF	8001-54-5	N/E	N/E	0.01
Hydrochloric Acid, NF	7647-01-0	N/E	N/E	QS
Sodium Hydroxide, NF	1310-73-2	N/E	N/E	QS
Purified Water, USP	7732-18-5	N/E	N/E	QS

**Common name of active ingredient:** Hypromellose 2906  
**Chemical Name:** Hydroxypropyl methylcellulose  
**Legal Category:** Prescription Only

### Section 2 - HAZARDOUS INGREDIENTS

**Principal Hazardous Ingredients:**  
**% Threshold Limit Value:** Not Established  
**Carcinogenicity:** Not Established  
**NTP-** No ingredients listed  
**IARC-** No ingredients listed  
**OSHA-** No ingredients listed

**Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS**

<b>Physical State:</b>	Liquid	<b>Odor:</b>	Odorless
<b>Appearance:</b>	Clear, colorless to slightly yellow.		
<b>Boiling Point:</b>	Not Established	<b>Volatile:</b>	Not Established
<b>Vapor Density:</b>	Not Established		
<b>Vapor Pressure (mm Hg):</b>	Not Established	<b>Viscosity:</b>	Not Established
<b>Solubility in Water:</b>	Soluble	<b>pH Range:</b>	6.0 to 7.8
<b>Specific Gravity Range:</b>	1.00 to 1.04 g/mL	<b>Latex Free:</b>	Yes
<b>Evaporation Rate:</b>	Not Established	<b>Reactivity in Water:</b>	Not Established

**Section 4 – FIRE AND EXPLOSION HAZARD DATA**

<b>Extinguisher Media:</b>	Dry chemical, carbon dioxide, halon, water spray or fog, foam
<b>Hazardous Products:</b>	May emit toxic fumes
<b>Explosion:</b>	Not expected to occur
<b>Fire Fighting Instructions:</b>	In the event of fire, wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

**Section 5 – REACTIVITY DATA**

<b>Stability:</b>	Stable
<b>Incompatibility:</b>	This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.
<b>Hazardous Decomposition Products:</b>	May emit toxic fumes under fire conditions
<b>Hazardous Polymerization:</b>	Should not occur
<b>Conditions to Avoid:</b>	Extreme heat or cold If solution changes color or becomes cloudy, do not use.

**Section 6 – HEALTH HAZARDS**

<b>Route of Entry:</b>	GONAK™ may be absorbed into skin, inhaled or accidentally ingested.
1. <b>Eyes:</b>	May cause irritation in some individuals
2. <b>Skin:</b>	May cause irritation in some individuals
3. <b>Ingestion:</b>	May cause irritation in some individuals
4. <b>Inhalation:</b>	May cause irritation in some individuals

**Acute and Chronic Effects:**

- Allergies - Alert a doctor if you have ever had any unusual or allergic reaction to hypromellose.  
Pregnancy - Hypromellose has not been shown to cause birth defects or other problems in humans.  
Breast-feeding - Hypromellose has not been reported to cause problems in nursing babies.
- Children - Although there is no specific information comparing use of hypromellose in children with use in older age groups, this medicine is not expected to cause different side effects or problems in children than it does in adults.
- Older adults - Although there is no specific information comparing use of hypromellose in the elderly with use in other age groups, this medicine is not expected to cause different side effects or problems in older people than it does in younger adults.

**Sign and Symptoms of Exposure:** Check with a physician if side effects such as eye pain, blurred vision, matting or stickiness of the eyelashes occur. If eye irritation that was not present before use of this medicine persists for more than 3 days then contact a physician.

**Chemical Listed as Carcinogen or Potential Carcinogen:**

<b>National Toxicology Program:</b>	No ingredients listed
<b>I.A.R.C Monographs:</b>	No ingredients listed
<b>OSHA:</b>	No ingredients listed
<b>OSHA Permissible Exposure Limit:</b>	Not Established
<b>ACGIH Threshold Limit Value:</b>	Not Established

**Emergency and First Aid Procedures:**

- 1. Eyes:** Contact a physician if serious eye pain results or if symptoms become worse.
- 2. Skin:** Remove contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact a physician if skin becomes irritated.
- 3. Ingestion:** Wash out mouth. Give plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.
- 4. Inhalation:** Remove to fresh air. If breathing stops, use artificial respiration. Contact a physician.

**Note to physicians:** Treat symptomatically and supportively

**Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES**

**Storage:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15° - 30°C (59° - 86°F). KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

**Neutralizing Chemical Agent:** Not relevant

**Steps to be taken in case material is released or spilled:** Use personal protective equipment. Contain large spills to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

**Waste Disposal Methods:** Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.



**Section 8 – PROTECTION INFORMATION**

**Airborne Exposure Limits:**

<b>Ventilation:</b>	Recommended
<b>Skin Protection:</b>	Gloves and protective clothing
<b>Eye Protection:</b>	Recommend splash protection or chemical safety glasses
<b>Contaminated Equipment:</b>	Wash contaminated clothing. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

**Section 9 – TOXICOLOGY INFORMATION**

**LD<sub>50</sub> (Acute oral toxicity of hypromellose):**

LD <sub>50</sub> rat, oral	=	Greater Than 10,000 mg/Kg
LD <sub>50</sub> rat, intravenous	=	Not Established
LD <sub>50</sub> rat, intramuscular	=	Not Established
LD <sub>50</sub> mouse, intravenous	=	Not Established
<b>Chronic Effects on Humans:</b>		Not Established

**Section 10 – ECOLOGICAL INFORMATION**

<b>Ecotoxicity:</b>	Not established
<b>BOD<sub>5</sub> and COD:</b>	Not available
<b>Environmental fate information:</b>	Not Established
<b>Other Precautions:</b>	None

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**SDS: GONAK™ Hypromellose Ophthalmic Demulcent  
Solution, 2.5%**

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** GONAK™ Hypromellose Ophthalmic Demulcent Solution, 2.5%

**Synonyms:** GONAK™; GONAK™ Hypromellose Ophthalmic Solution; Hypromellose; Hydroxypropyl Methylcellulose; Hydroxypropyl Methyl Cellulose; HPMC.

**National Drug Code (NDC):** 17478-064-12

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Not classifiable.

**Health Hazards:** Reproductive toxicity Category 2

**Symbol(s):**



**Signal Word:** Warning.

**Hazard Statement(s):** H361 Suspected of damaging fertility or the unborn child.

**Precautionary Statement(s):**

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P308 IF exposed or concerned: Get medical advice/attention.  
+  
P313
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

**Hazards Not Otherwise Classified:** Not classifiable.

## SDS: GONAK™ Hypromellose Ophthalmic Demulcent Solution, 2.5%

Supplementary Information: None.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Hydroxypropyl Methyl Cellulose	9004-65-3	Hypromellose; Hydroxypropyl Methylcellulose; HPMC	Not applicable	Not applicable	2.5%

\*The formula also contains Benzalkonium Chloride (0.01%) as a preservative, Boric Acid (1.2%); Sodium Borate (0.34%); Edetate Disodium (0.1%); Potassium Chloride (0.27%); Purified Water. pH may be adjusted with Sodium Hydroxide and/or Hydrochloric Acid.

### 4. First Aid Measures

#### Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

#### Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### Protection of First-Aiders:

Use personal protective equipment (see section 8).



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**Signs and Symptoms:** Eye irritation; blurred vision; bloating; flatulence; laxative or constipating effect; cramping; heartburn. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to any components of this product; glaucoma.

**Notes to Physician:** Treat supportively and symptomatically.

### 5. Firefighting Measures

**Suitable Extinguishing Media:** Use extinguishing media for type of surrounding fire.

**Unsuitable Extinguishing Media:** Not determined.

#### Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** These products include carbon oxides and toxic fumes.

**Other Specific Hazards:** Closed containers may explode from the heat of fire.

**Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizers.

**Specific End Use:** Pharmaceuticals.



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**8. Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

<b>Common or Chemical Name</b>	<b>Employee Exposure Limits</b>
Hydroxypropyl Methyl Cellulose	OEL*: 10 mg/m <sup>3</sup> , 8 Hour TWA
Boric Acid	ACGIH TLV: 2 mg/m <sup>3</sup> ** TWA; 6 mg/m <sup>3</sup> ** STEL

\* An Occupational Exposure Levels (OEL) has been established by private industry.

\*\* Inhalable fraction; TLV listed under Borate compounds, Inorganic.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:** Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:** Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:** Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

**9. Physical and Chemical Properties**

**Physical State/Color:** Liquid/Colorless to slightly yellow.  
**Odor:** Odorless.  
**Odor Threshold:** No data available.  
**pH:** 6.0 – 7.8.  
**Melting Point:** No data available.  
**Freezing Point:** No data available.  
**Boiling Point:** No data available.  
**Flash Point:** No data available.  
**Evaporation Rate:** No data available.  
**Flammability (solid, gas):** No data available.  
**Flammability Limit - Lower:** No data available.  
**Flammability Limit - Upper:** No data available.  
**Vapor Pressure:** No data available.  
**Vapor Density:** No data available.  
**Relative Density:** No data available.

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**Solubility(ies):** Miscible in water.  
**Partition Coefficient (n-octanol/water):** No data available.  
**Auto-Ignition Temperature:** No data available.  
**Decomposition Temperature:** No data available.  
**Viscosity:** No data available.

**10. Stability and Reactivity**

**Reactivity:** No data available.  
**Chemical Stability:** Stable under recommended storage conditions.  
**Possibility of Hazardous Reactions:** No data available.  
**Conditions to Avoid (e.g., static discharge, shock, or vibration):** No data available.  
**Incompatible Materials:** Oxidizers, acids, bases, alkali metals, and alkali hydrides.  
**Hazardous Decomposition Products:** No data available.

**11. Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.  
**Ingestion:** May be harmful if swallowed.  
**Skin Contact:** May be harmful if absorbed through the skin. May cause irritation.  
**Eye Contact:** May cause eye irritation.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Hydroxypropyl Methyl Cellulose	Rat	Oral	LD <sub>50</sub>	>10,000 mg/kg

**Acute Toxicity – Dermal:** No data available.  
**Acute Toxicity – Inhalation:** No data available.  
**Corrosivity:** No data available.  
**Dermal Irritation:** No data available.

## SDS: GONAK™ Hypromellose Ophthalmic Demulcent Solution, 2.5%

<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	No data available.
<b>Reproductive Effects:</b>	Suspected of damaging fertility or the unborn child (Boric Acid).
<b>Carcinogenicity:</b>	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.

### 12. Ecological Information

#### Ecotoxicity

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

### 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. Transport Information

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.



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### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):**

This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

**CERCLA Hazardous Substance and Reportable Quantity:**

Not listed.

**SARA 313:**

Not listed.

**SARA 302:**

Not listed.

#### State Regulations

**Massachusetts:**

Not listed.

**New Jersey:**

Hydroxypropyl Methyl Cellulose; Boric Acid.

**Pennsylvania:**

Hydroxypropyl Methyl Cellulose; Boric Acid.

**California Proposition 65:**

Not listed.

### 16. Other Information

Not made with natural rubber latex.

**Revision Date:** 06/29/2015

**Revision Number:** 2

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