



MSDS: Gonak™ Hypromellose Solution, 2.5%

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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.

Composition	CAS#	TLV(mg/m ³)	PEL(mg/m ³)	%Content
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

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

Section 4 – FIRE AND EXPLOSION HAZARD DATA

Extinguisher Media:	Dry chemical, carbon dioxide, halon, water spray or fog, foam
Hazardous Products:	May emit toxic fumes
Explosion:	Not expected to occur
Fire Fighting Instructions:	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

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

Section 6 – HEALTH HAZARDS

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

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

Ventilation:	Recommended
Skin Protection:	Gloves and protective clothing
Eye Protection:	Recommend splash protection or chemical safety glasses
Contaminated Equipment:	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**LD₅₀ (Acute oral toxicity of hypromellose):**

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

Section 10 – ECOLOGICAL INFORMATION

Ecotoxicity:	Not established
BOD₅ and COD:	Not available
Environmental fate information:	Not Established
Other Precautions:	None

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