SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: POLYETHYLENE GLYCOL 3350, NF (PEG-75)

PRODUCT CODE: 0289

SUPPLIER:
- MEDISCA Inc.
  Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
  661 Route 3, Unit C, Plattsburgh, NY, 12901
  3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
  6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
- MEDISCA Pharmaceutique Inc.
  Tel.: 1.800.665.6334 | Fax.: 514.338.1693
  4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
  21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
-
- MEDISCA Australia PTY LTD
  Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
  5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE:
- CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
- NSW Poisons Information Centre: 131 126

USES:
Coating agent; plasticizer; solvent; suppository base; tablet or capsule lubricant

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION: Based on available data, the classification criteria are not met.

PICTOGRAM: Not applicable

SIGNAL WORD: Not applicable

HAZARD STATEMENT(S):
- Repeated exposure may cause skin dryness or cracking.

AUSTRALIA-ONLY HAZARDS:
Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S):
- Prevention: Not applicable
- Response: Not applicable
- Storage: Not applicable
- Disposal: Not applicable

HMIS CLASSIFICATION:
- Health Hazard: 1
- Flammability: 1
- Reactivity: 0
- Personal Protection: B

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME: Poly (oxy-1, 2-ethanediyl), α-hydro-ω-hydroxy-

BOTANICAL NAME: Not applicable

SYNONYM: Carbowax 3350; Macrogol

CHEMICAL FORMULA: \(\text{H(OCH}_2\text{CH}_2\text{)}_n\text{OH}\)

CAS NUMBER: 25322-68-3

ALTERNATE CAS NUMBER: Not applicable
SAFETY DATA SHEET

MOLECULAR WEIGHT
3015 - 3685

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYETHYLENE GLYCOL</td>
<td>25322-68-3</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED
Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SYMPTOMS AND EFFECTS
Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Not applicable

FLAMMABLE PROPERTIES
May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS
Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wearrespirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.
SAFETY DATA SHEET

STORAGE CONDITIONS
Store in original container, tightly sealed container, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight containers, protected from direct sunlight. Avoid exposure to excessive heat.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: POLYETHYLENE GLYCOL    CAS #: 25322-68-3

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
<td>10 mg/m³</td>
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<td>N/L</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
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</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>pH</th>
<th>4.5 - 7.5 (5%)</th>
<th>MELTING POINT</th>
<th>53-57°C, (127.4-134.6)°F</th>
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</thead>
<tbody>
<tr>
<td>ODOR THRESHOLD</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>BOILING POINT</td>
<td>&gt;200°C, &gt;392°F</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
<td>1.111 (60°C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOWER FLAMMABLE/</td>
<td>Not available</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT(S)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAPOR PRESSURE</td>
<td>&lt; 0.01 mmHg (20°C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SAFETY DATA SHEET

#### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>&gt; 10</td>
</tr>
<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>Not available</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>&gt;200°C, &gt;392°F</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>90.8 cSt (100°C)</td>
</tr>
</tbody>
</table>

**REACTIVITY**
- Not established

**STABILITY**
- Stable under recommended storage conditions

**MATERIALS TO AVOID**
- Strong oxidants, acids and bases

**HAZARDOUS DECOMPOSITION PRODUCTS**
- Toxic fumes of carbon monoxide, carbon dioxide and other gases may occur

**HAZARDOUS POLYMERIZATION**
- Will not occur

**POSSIBILITY OF HAZARDOUS REACTION**
- Not established

**CONDITIONS TO AVOID**
- Moisture, sunlight and extreme temperatures

#### SECTION 11: TOXICOLOGICAL INFORMATION

**ACUTE TOXICITY**
- Oral: Rat: LD50: (mg/kg): > 10 000
- Dermal: Rabbit LD50: (mg/kg): >20 000
- Inhalation: Rat: LD50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**
- Based on available data, the classification criteria are not met.

**SERIOUS EYE DAMAGE/EYE IRRITATION**
- Based on available data, the classification criteria are not met.

**RESPIRATORY OR SKIN SENSITIZATION**
- Hypersensitivity to macrogols is uncommon but both immediate urticarial reactions and delayed allergic contact dermatitis have been reported.
- Based on available data, the classification criteria are not met.

**GERM CELL MUTAGENICITY**
- In vitro genetic toxicity studies were negative. Animal genetic toxicity studies were negative.
- Based on available data, the classification criteria are not met.

**CARCINOGENICITY**
- **OSHA**
  - POLYETHYLENE GLYCOL is not listed.
- **NTP**
  - POLYETHYLENE GLYCOL is not listed.
- **IARC**
  - POLYETHYLENE GLYCOL is not evaluated.
- **California Proposition 65**
  - This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**ADDITIONAL CARCINOGENICITY INFORMATION**
- Did not cause cancer in laboratory animals.
- Based on available data, the classification criteria are not met.

**REPRODUCTIVE TOXICITY**
- For similar material(s): In animal studies, did not interfere with reproduction.
- Based on available data, the classification criteria are not met.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**
- Due to lack of data the classification is not possible.
Recent findings of kidney failure and death in burn patients, as well as some studies using animal burn models, suggest that polyethylene glycol may have been a factor. The use of topical applications containing this material may not be appropriate in severely burned patients or individuals with impaired renal function. Based on available data, repeated exposures are not anticipated to cause significant adverse effects.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Based on available data, the classification criteria are not met.

**ASPIRATION HAZARDS**

Not expected to present a significant hazard under anticipated conditions of normal use.

**SIGNS AND SYMPTOMS OF EXPOSURE**

Macrogols appear to have relatively low toxicity, although any toxicity appears to be greatest with the macrogols of low molecular weight. They may cause stinging when used topically, especially on mucous membranes, and have been associated with hypersensitivity reactions such as urticaria. Hyperosmolality, metabolic acidosis, and renal failure have been reported after topical application of macrogols to burn patients. Topical preparations with a macrogol base should therefore be used with caution in patients with renal impairment and/or large areas of raw surfaces, burns, or open wounds.

Hypersensitivity to macrogols is uncommon but both immediate urticarial reactions and delayed allergic contact dermatitis have been reported following the topical application of preparations with a macrogol vehicle or base. An anaphylactic reaction has been associated with the ingestion of macrogols in a multivitamin tablet. The manufacturers of preparations containing macrogols and electrolytes for bowel cleansing have reported isolated instances of skin reactions and rhinorrhea.

**SYMPTOMS RELATED TO THE PHYSICAL, CHEMICAL, AND TOXICOLOGICAL CHARACTERISTICS**


Medical conditions aggravated by exposure

Gastrointestinal tract obstruction. Gastric retention. Coitis.

**ACUTE TOXICITY**

Based on available data, the classification criteria are not met.

**POTENTIAL HEALTH EFFECTS**

Inhalation

At room temperature, exposure to vapor is minimal due to low volatility; single exposure is not likely to be hazardous.

Ingestion

Very low toxicity if swallowed. Harmful effects not anticipated from swallowing small quantities.

Skin

May be harmful if absorbed through skin. Prolonged contact may cause slight skin irritation with local redness. Prolonged skin contact is unlikely to result in absorption of harmful amounts.

Eyes

May cause slight temporary eye irritation. Corneal injury is unlikely.

**SECTION 12: ECOLOGICAL INFORMATION**

**TOXICITY**

LC50: 96 Hr: Fish: (mg/L): >1000

IC50: 72 Hr: Algae: (mg/L): Not available

EC50: 48 Hr: Daphnia magna: (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Material is expected to be readily biodegradable.

BOD5=5-17%; BOD10=34.5-38%; BOD20=40.2-70%

**BIOACCUMULATIVE POTENTIAL**

No bioconcentration is expected because of the relatively high water solubility.

**MOBILITY IN SOIL**

Freely soluble in water

**OTHER ADVERSE EFFECTS**

This product is not intended to be released into the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**
WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME
Not dangerous good
UN NUMBER
Not applicable
CLASS
Not applicable
PACKING GROUP
Not applicable

AUSTRALIA
UN PROPER SHIPPING NAME
Not dangerous good
UN NUMBER
Not applicable
CLASS
Not applicable
PACKING GROUP
Not applicable
HAZCHEM
Not Applicable

ENVIRONMENTAL HAZARDS
Not available

SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYETHYLENE GLYCOL 25322-68-3</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYETHYLENE GLYCOL 25322-68-3</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request
ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION

04/2017

SUPERSEDES

12/2016

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.