SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
POLYSORBATE 80, NF (Tween 80)

PRODUCT CODE
0526

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
Unit 7, Heritage Business Park
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
Emulsifying and/or solubilizing agent; tablet and/or capsule lubricant; wetting and/or solubilizing agent

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Eye Irritation (Category 2B)
Skin Irritation (Category 3)

PICTOGRAM
Not Applicable

SIGNAL WORD
Warning

HAZARD STATEMENT(S)
Causes eye irritation.
Causes mild skin irritation.

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

PRECAUTIONARY STATEMENT(S)
Prevention
Wash thoroughly after handling.

Response
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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
Polyoxyethylene (20) sorbitan monooleate

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable
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CHEMICAL FORMULA: C₃₂H₆₀O₁₀

CAS NUMBER: 9005-65-6

ALTERNATE CAS NUMBER: Not applicable

MOLECULAR WEIGHT: 604.816

COMPOSITION:

<table>
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<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tr>
<td>POLYSORBATE 80</td>
<td>9005-65-6</td>
<td>100</td>
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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: 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 breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers.

CLEANUP PROCEDURE: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, 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.

Chemical family: Ester

Last Revision: 11/2017
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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.

STORAGE CONDITIONS
Store in original container, tightly sealed container, protected from direct sunlight, in a dry, 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. Store in an airtight container, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: POLYSORBATE 80    CAS #: 9005-65-6

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<th>TWA</th>
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</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. Fumehood, eye wash station, and safety shower.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Liquid

DESCRIPTION
Lemon to amber-colored, oily liquid having a faint, characteristic odor.

SOLUBILITY
Very soluble in water, producing an odorless and practically colorless solution; soluble in alcohol and in ethyl acetate; insoluble in mineral oil.

ODOR
Faint characteristic odor

FLAMMABILITY
May be combustible at high temperature

ODOR THRESHOLD
Not available

PH
5 - 8 (5%)

MELTING POINT
25 °C, 77 °F

BOILING POINT
100 °C, 212 °F

FREEZING POINT
25 °C, 77 °F

FLASH POINT
148.0 °C, 298.4 °F (CC)
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SECTION 10: STABILITY AND REACTIVITY

REACTIVITY
Not established

STABILITY
Stable under recommended storage conditions

MATERIALS TO AVOID
Strong oxidants, bases, heavy metal salts

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): > 5,000
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION
Causes mild skin irritation: pH 5 - 8 (5%)

SERIOUS EYE DAMAGE/EYE IRRITATION
Causes eye irritation: pH 5 - 8 (5%)

RESPIRATORY OR SKIN SENSITIZATION
Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Based on available data, the classification criteria are not met. Maximisation Assay (Magnusson and Kligman). Result: Negative. Species: Guinea pig. Organ: Skin

GERM CELL MUTAGENICITY
Based on available data, the classification criteria are not met.
Ames test (Salmonella typhimurium), with and without activation. Result: Negative.
Chromosome aberration. Result: Positive.
Mutagenicity, DNA inhibition test in human lymphocytes and mouse cells. Result: Positive.
Mutagenicity, Human lymphocytes mutagenicity test. Result: Inconclusive.
Mutagenicity, Sister chromatid exchange assay. Result: Negative.

CARCINOGENICITY
OSHA POLYSORBATE 80 is not listed.
NTP POLYSORBATE 80 is not listed.
IARC POLYSORBATE 80 is not evaluated.
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ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
50000 ppm Carcinogenicity, No evidence of carcinogenicity in female mice. Forestomach ulcers and increased incidence of squamous hyperplasia and inflammation of the forestomach in female mice. Species: Mouse. Test Duration: 103 weeks
50000 ppm Carcinogenicity, No evidence of carcinogenicity in female rats. Equivocal evidence of pheochromocytomas of the adrenal medulla in male rats. Species: Rat. Test Duration: 103 weeks
Carcinogenicity - rat - Subcutaneous
Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Tumorigenic: Tumors at site or application.
Carcinogenicity - mouse - Skin
Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Skin and Appendages: Other: Tumors. Tumorigenic: Tumors at site or application.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met. Polysorbates have not been associated with adverse effects on development in experimental animals.
10 mg/kg/day Reproductivity, No evidence of fetal toxicity or increased incidence of developmental defects with intravenous doses. Species: Rabbit
16 ml/kg Reproductivity, Lower body weight in postnatal offspring but no adverse effects on neurodevelopment with administration in drinking water. Species: Rat
7000 mg/kg/day Reproductivity, No evidence of fetal toxicity or increased birth defects with oral doses. Species: Rat
Reproductivity, No evidence of birth defects with injection in chick eggs. Species: Chick
Reproductive toxicity: Rat: Oral. Effects on Newborn: Viability index (e.g., # alive at day 4 per # born alive).
Effects on Newborn: Weaning or lactation

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE

Symptoms related to the physical, chemical, and toxicological characteristics
Gastrointestinal disturbances.

POTENTIAL HEALTH EFFECTS

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion: May be harmful if swallowed.
Skin: May be harmful if absorbed through skin. Causes mild skin irritation.
Eyes: Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Very soluble in water.

OTHER ADVERSE EFFECTS

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

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.
### 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

| Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania Right-to-know New Jersey Massachusetts California Prop 65 |
|---------------------|---------------------------|------------------------------------|-------------------------------|---------------------------------|-------------------|
| POLYSORBATE 80 9005-65-6 | N/L | N/L | N/L | N/L | N/L |

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>
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</table>

### SECTION 16: OTHER INFORMATION

#### REFERENCES
Available upon request
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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

11/2017

SUPERSEDES

09/2014

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.