

SECTION 1: PRODUCT IDENTIFICATION

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|------------------------|--|
| 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

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| 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 Reactivity 0 | Flammability 1 Personal Protection B | |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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| CHEMICAL NAME | Polyoxyethylene (20) sorbitan monooleate |
| BOTANICAL NAME | Not applicable |
| SYNONYM | Not applicable |

| CHEMICAL FORMULA | C ₃₂ H ₆₀ O ₁₀ | | | | | | |
|----------------------|--|---------------|------------|-------------|----------------|-----------|-----|
| CAS NUMBER | 9005-65-6 | | | | | | |
| ALTERNATE CAS NUMBER | Not applicable | | | | | | |
| MOLECULAR WEIGHT | 604.816 | | | | | | |
| COMPOSITION | <table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>POLYSORBATE 80</td> <td>9005-65-6</td> <td>100</td> </tr> </tbody> </table> | CHEMICAL NAME | CAS NUMBER | % BY WEIGHT | POLYSORBATE 80 | 9005-65-6 | 100 |
| CHEMICAL NAME | CAS NUMBER | % BY WEIGHT | | | | | |
| POLYSORBATE 80 | 9005-65-6 | 100 | | | | | |
| NOTES | <p>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.</p> <p>Chemical family: Ester</p> | | | | | | |

SECTION 4: FIRST-AID MEASURES

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| 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

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| 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, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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

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| 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. |

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

| | TWA | Ceiling | STEL | REL | IDLH | Remarks |
|--------------------------|-----|---------|------|-----|------|---------|
| OSHA PEL | N/L | N/L | - | - | - | - |
| ACGIH TLV | N/L | N/L | N/L | - | - | - |
| NIOSH | N/L | N/L | N/L | N/L | N/L | - |
| AIHA WEEL | N/L | N/L | N/L | - | - | - |
| Safe Work Australia HSIS | N/L | N/L | N/L | - | - | - |
| HSE | N/L | N/L | N/L | - | - | - |

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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| SPECIFIC GRAVITY | 1.06 - 1.09 | EVAPORATION RATE | Not available | EXPLOSIVE LIMIT | Not available |
| UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S) | Not available | LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S) | Not available | VAPOR PRESSURE | < 1 mm Hg (20 °C) |
| VAPOR DENSITY (AIR = 1) | Not available | RELATIVE DENSITY (WATER = 1) | 1.10 | log P (OCTANOL-WATER) | Not available |
| AUTO-IGNITION TEMPERATURE | Not available | DECOMPOSITION TEMPERATURE | Not available | VISCOSITY | 300 - 500 mPa·s (25°C) |

SECTION 10: STABILITY AND REACTIVITY

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| 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

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| 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%) Irritancy. Result: Irritant. Species: Rabbit. Organ: Skin. Severity: Mild. Irritancy. Result: Negative. Species: Human. Organ: Skin |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Causes eye irritation: pH 5 - 8 (5%) 150 mg Draize test. Result: Irritant. Species: Rabbit. Organ: Eye. Severity: Mild Irritancy. Result: Negative. Species: Rabbit. Organ: Eye |
| 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 | <p>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.</p> <p>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.</p> |
| REPRODUCTIVE TOXICITY | <p>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</p> |
| 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 | Due to lack of data the classification is not possible. |
| SIGNS AND SYMPTOMS OF EXPOSURE | <p>Not expected to present a significant hazard under anticipated conditions of normal use.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics Gastrointestinal disturbances.</p> |
| POTENTIAL HEALTH EFFECTS | <p>Inhalation May be harmful if inhaled. May cause respiratory tract irritation.</p> <p>Ingestion May be harmful if swallowed.</p> <p>Skin May be harmful if absorbed through skin. Causes mild skin irritation.</p> <p>Eyes Causes eye irritation.</p> |

SECTION 12: ECOLOGICAL INFORMATION

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| TOXICITY | <p>EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available IC50: 72 Hr: Algae: (mg/L): Not available</p> |
| PERSISTENCE AND DEGRADABILITY | Not available |
| BIOACCUMULATIVE POTENTIAL | Not available |
| MOBILITY IN SOIL | Very soluble in water. |
| OTHER ADVERSE EFFECTS | <p>Not available</p> <p>This product is not intended to be released into the environment</p> |

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

| Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 | | Pennsylvania | Right-to-know | | California Prop 65 |
|--------------------------|--------------------------------|---|---------------------|------------|--------------|---------------|---------------|-----------------------|
| | | | Appendix A | Appendix B | | New Jersey | Massachusetts | |
| POLYSORBATE 80 9005-65-6 | N/L | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

| Chemical Name & CAS | Poisons and Therapeutic Goods Regulation | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors |
|--------------------------|--|-----------------------|---|
| POLYSORBATE 80 9005-65-6 | Not Listed | Not Listed | Not Listed |

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

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.