



PROLARYN[®] GEL SAFETY DATA SHEET (SDS)

Section 1 – Product and Company Identification

Product Trade Name: Prolaryn[®] Gel

Recommended Use: Injectable implant

Distributor: Merz North America, Inc.
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Raleigh, NC 27615

Telephone: 844-469-6379

Hazmat Service Emergency Number: 800-373-7542

International Shipments: +1-484-951-2432

Section 2 – Hazard(s) Identification

- i) **GHS Labeling and Classification:** This product does not meet the definition of a hazardous substance as defined by 29 CFR 1910.1200

Section 3 – Composition/Information on Ingredients

Ingredient	CAS Number	Concentration
Glycerin	56-81-5	Proprietary
Sodium Carboxymethylcellulose	9004-32-4	Proprietary
Sterile Water	7732-18-5	Proprietary
Monobasic Potassium Phosphate	7778-77-0	Proprietary
Dibasic Potassium Phosphate	7758-11-4	Proprietary

Section 4 – First Aid Measures

Take precautions to ensure your own health and safety before responding/providing first aid.

i) **Eye Contact**

If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation persists.

ii) **Skin Contact**

Wash affected skin thoroughly with soap and water. Seek medical attention if irritation develops and persists.



iii) Inhalation

Not expected to be an inhalation hazard under normal use. If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if breathing difficulty continues.

iv) Ingestion

If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

v) Recommendations to Physicians

Treat symptoms

Section 5 – Fire-Fighting Measures

i) Fire Extinguishing Materials: Carbon dioxide, foam, dry chemical, halon, or water spray

ii) Unusual Fire and Explosion Hazards: No known fire or explosion hazards

iii) Special Fire-Fighting Procedures: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

Section 6 – Accidental Release Measures

i) Spill and Leak Response: Personnel should be trained for spill response operations

ii) Spills: Contain spilled material using suitable absorbent material and place spill residue in an appropriate container for disposal

Section 7 – Handling and Storage

i) Work and Hygiene Practices: Handle in accordance with good industrial hygiene and safety practices. Avoid contact with eyes.

ii) Storage and Handling Practices: Store at a controlled room temperature between 15°C and 32°C (59°F and 90°F)

Section 8 – Exposure Controls and Personal Protection

i) Ventilation and Engineering Controls: Use with adequate ventilation to ensure exposure levels are maintained

ii) Respiratory Protection: Not required with this product



- iii) **Eye Protection:** Prevent eye contact as appropriate and safety glasses recommended if risk of eye contact during handling
- iv) **Hand Protection:** Protective gloves recommended
- v) **Body Protection:** Not required with this product. Use body protection appropriate for task. Coveralls, rubber aprons, or chemical protective clothing made from natural rubber are generally acceptable, depending upon the task.

Section 9 – Physical and Chemical Properties

- i) **Appearance:** Clear or translucent, viscous gel
- ii) **Odor:** None
- iii) **pH:** 7.0 ±1.0
- iv) **Melting Point/Freezing Point:** Not determined
- v) **Boiling Point:** Not determined
- vi) **Flash Point:** Not determined
- vii) **Evaporation Rate (n-BuAc=1):** Not determined
- viii) **Upper/Lower Flammability or Explosive Limits:** Not determined
- ix) **Vapor Pressure:** Not determined
- x) **Vapor Density:** Not determined
- xi) **Relative Density:** 1.04 – 1.05 g/cc
- xii) **Specific Gravity:** Not determined
- xiii) **Solubility:** Not determined
- xiv) **Partition Coefficient:** Not determined
- xv) **Auto-ignition Temperature:** Not determined
- xvi) **Decomposition Temperature:** Not determined
- xvii) **Viscosity:** Not determined

Section 10 – Stability and Reactivity

- i) **Stability:** Stable under ordinary conditions of use and storage
- ii) **Incompatible Materials:** Strong bases and strong oxidizers



- iii) **Decomposition Products:** No data available
- iv) **Hazardous Depolymerization:** No data available
- v) **Conditions to Avoid:** No data available

Section 11 – Toxicology Information

- i) **Toxicity Data:** Health effects are not known or expected during intended and reasonably foreseeable use
- ii) **Suspected Cancer Agent:** The components of this product are not listed by agencies tracking the carcinogenic potential of chemical compounds as follows:

Carcinogenicity

NTP Regulated	No
IARC Regulated	No
OSHA Regulated	No

Section 12 – Ecological Information

- i) **Environmental Fate:** Not expected to cause adverse effects in the aquatic environment
- ii) **Persistence and Degradability:** Material is biodegradable
- iii) **Environmental Toxicity:** No data available

Section 13 – Disposal Recommendations

- i) **Disposal:** Dispose of product in accordance with federal, state, and local environmental regulatory requirements – used injection needles may be considered regulated medical waste

Section 14 – Transport Information

- i) **Transport:** Non-hazardous for transport

Section 15 – Regulatory Information

- i) **Toxic Substance Control Act (TSCA):** Chemical ingredients are on the TSCA Inventory or exempt
- ii) **Superfund Reportable Quantity (RQ):** No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302
- iii) **Sara Title III (section 311/312):** None



iv) Sara Title III (section 313): This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313

Section 16 – Other Information

Effective Date: 01 AUG 2019
Revision: 03

The information contained in this SDS is to the best of Merz North America, Inc.'s knowledge and is believed to be accurate and reliable as of the revision date. However, no representation, warranty, or guarantee is implied or expressed regarding the accuracy, reliability, or completeness of this information. Information contained within this SDS is related to occupational exposure.