

Prolaryn Gel

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Issue date: 04/20/2023 Revision date: 04/20/2023 Version: 5.0



SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Prolaryn Gel
Further information : Injectable implant

1.2. Recommended use and restrictions on use

Recommended use : Pharmaceuticals, Injectable implant

1.3. Supplier

Merz North America, Inc
6501 Six Forks Road
Raleigh, NC 27615
USA

T +1 844-469-6379

www.merzusa.com

E-mail address of competent person responsible for the SDS: nick.nogalski@merz.com

1.4. Emergency telephone number

Emergency number : Hazmat Service Emergency Number: 800-373-7542
International Shipments: +1-484-951-2432

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Aqueous solution

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012

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SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

No additional information available

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Do not use a solid water stream as it may scatter and spread fire.

5.2. Specific hazards arising from the chemical

Fire hazard	: Product does not burn, fire-extinguishing activities according to surrounding.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with eyes, skin or mucous membrane.
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6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area.
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6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Not expected to present a significant hazard under anticipated conditions of normal use.
Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep cool.
Storage temperature	: 15 – 32 °C
Information on mixed storage	: Keep away from food, drink and animal feeding stuffs.
Storage area	: Keep out of frost. Store away from direct sunlight or other heat sources.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Environmental exposure controls	: Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Not required for normal conditions of use. Use protective gloves in the event of intensive contact

Eye protection:

Not required for normal conditions of use. Use splash goggles when eye contact due to splashing is possible

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

No personal breathing protective equipment is normally required. Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: gel.
Color	: Colorless
Odor	: odorless
Odor threshold	: No data available
pH	: 6 – 8
pH solution concentration	: 100 %
Melting point	: No data available

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Freezing point	: No data available
Boiling point	: > 100 °C
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Density	: 1.04 – 1.05 g/cm ³ (20 °C)
Solubility	: Water: Miscible
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Product is not explosive.
Oxidizing properties	: Non oxidizing material.

9.2. Other information

VOC content : 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong acids, strong bases and oxidation agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified pH: 6 – 8
Serious eye damage/irritation	: Not classified pH: 6 – 8

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Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with DOT / TDG / IMDG / IATA

DOT	TDG	IMDG	IATA
14.1. UN number			
No dangerous goods as defined by the transport regulations			
14.2. Proper Shipping Name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable

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DOT	TDG	IMDG	IATA
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available			

14.6. Special precautions for user

DOT

No data available

TDG

No data available

IMDG

No data available

IATA

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

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All components are listed on the DSL Inventory

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

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Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Abbreviations and acronyms	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds

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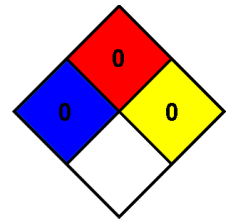
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Abbreviations and acronyms	
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard - Materials that will not burn

Physical : 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.