

Avalon Medical

Innovative Veterinary Surgical Products

Safety Data Sheet

Section I -- Identification

Product Identifier: ReGain Injectable Bulking Agent

Manufacturer Information:

Avalon Medical	Emergency Phone: 888-289-1890
1052 Curve Crest Blvd.	Phone for Information: 888-289-1890
Stillwater, MN 55082	Date Prepared: 6/17/2021

Recommended Use: Bulking agent for canine incontinence.

Recommended Restrictions: Do not use with patients known to have hypersensitivity to bovine implanted products.

Section II – Hazard Identification

Physical hazards	Not classified
Health hazards	Not classified
OSHA defined hazards	Not classified
Label Elements	None
Hazard symbols	None
Signal word	Bovine hypersensitivity, glutaraldehyde
Hazard statement	None
Precautionary statement	May irritate skin or eyes
Prevention	Observe good industrial hygiene practices
Response	Wash hands after handling.
Storage	Store in refrigerator between 36°-38°F
Disposal	May be disposed of in standard trash receptacle.
Hazards not otherwise Classified (HNOC)	None known

ReGain™ is a sterile, purified, Type I insoluble crosslinked bulking agent in physiological saline intended for the treatment of urinary incontinence.

Section III – Composition/Information on Ingredients

Ingredients List by weight per syringe:

Ingredient	Percentage	Weight	Country of Origin
Bovine Achilles Tendon	6.3%	.15g	USA
Isotonic saline	93.7%	2.34975g	USA
Glutaraldehyde	0.0001%	0.00025g	USA

Section IV – First Aid Measures

- Inhalation:** If symptomatic, move to fresh air. Seek medical attention if symptoms persist.
- Skin Contact:** Wash with soap and water. Seek medical attention if symptoms occur.
- Eye Contact:** Material that contacts the eye should be rinsed out immediately with water. Seek medical attention if symptoms occur.
- Ingestion:** Seek medical advice.
- Most important symptoms/Effects, Acute or Delayed:**
Direct contact with eyes may cause temporary irritation.
- Indication of Immediate Need of Medical/Special Attention:**
Treat symptomatically.

Section V – Fire-Fighting Measures

- Suitable Extinguishing Media:** Water, water fog, foam, dry chemical and Carbon Dioxide
- Unsuitable Extinguishing Media:** None known
- Specific hazards arising from product:** None known
- Special Protective Equipment and Precautions for Firefighters:**
Follow general fire precautions

Section VI – Accidental Release Measures

- Personal Precautions, Protective Equipment and Emergency Procedures:**
Wear regular nitrile gloves.
- Methods & Materials for Containment and Cleaning Up:**
Scoop up and remove.
For waste removal, see Section XIII of this SDS
- Environmental Precautions:** Avoid discharge into drains, water courses or onto the ground.

Section VII – Handling & Storage

- Precautions for Safe Handling:** Wear appropriate personal protective equipment (See Section VIII.)
Wash thoroughly after handling.
Observe good industrial hygiene practices.
- Conditions for Safe Storage:** Store in a refrigerated, dry environment.

Section VIII – Personal Protections

Biological Limit Values:	No biological exposure limits noted for the ingredients
Appropriate Engineering Controls:	Ensure adequate ventilation.
Individual Protection Measures, inc. PPE:	Normal eye protection practices should be used.
Skin Protection:	Regular nitrile gloves.
Thermal Hazard:	None.
General Hygiene:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section IX – Physical and Chemical Properties

Appearance:	
Form	Gel
Physical State	Gel
Color	White
Odor	Not available
Odor Threshold	Not available
Ph (in water at 25°C)	7.0
Melting/Freezing Point	32°F
Softening Temperature	Not measured
Initial Boiling Point & Boiling Range	Not applicable
Flash Point	Not applicable
Evaporation Rate	Not available
Flammability	Non flammable
Upper/Lower Flammability or Explosive Limits	
Flammability Limit – Lower	Not applicable
Flammability Limit – Upper	Not applicable
Vapor Pressure	Not available
Vapor Density	Not applicable
Relative Density	Not available
Solubility	
Solubility (water)	Not soluble
Partition Coefficient	No data available
Auto-Ignition Temperature	Not applicable
Decomposition Temperature	Not applicable
Viscosity	Not applicable
Specific Gravity	Not measured
Refractive Index	Not measured

Section X – Stability & Reactivity

Reactivity: This product is stable and non-reactive under normal conditions of use, storage and transportation.

Possibility of Hazardous Reactions: None known.

Chemical Stability: Stable under the prescribed storage conditions.

Incompatible materials: None.

Section XI – Health Hazard Data

Ingestion: No harmful effects expected in amounts likely to be ingested by accident.

Inhalation: No harmful effects expected in amounts likely to be inhaled.

Skin Contact: May cause skin sensitization in sensitive individuals or aggravate existing dermatitis.

Eye Contact: Direct contact with eyes may cause temporary irritation.

Carcinogenicity: This product is not considered to be a carcinogen.

Section XII – Precautions for Safe Handling & Disposal

Disposal Instructions: May be disposed of in typical waste receptacle.

Section XIII – Date of Preparation or Last Revision

Issue Date: 6/21/21

Revision Date:

Version: 1