

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations Date of Issue: 11/13/2017

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture Product Name: A-Cyst Product Code: 1ACY001

Synonyms: A-Cyst 10 ml sterile vial

1.2. Intended Use of the Product

Use of the Substance/Mixture: Veterinary device: For direct (intravesical) instillation into the bladder

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Bimeda Inc.
One Tower Lane

Oakbrook Terrace Tower Oakbrook Terrace, IL 60181

T 630-928-0361 F 630-928 0362

www.bimedaus.com

1.4. Emergency Telephone Number

Emergency Number : 519-654-8055, 800-424-9300 CHEMTREC (in US); +1 703-527-3887 CHEMTREC

(International and Maritime)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Full text of H-phrases: see section 16

Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions, The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret [29 CFR 1910.1200].

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

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Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. **Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects. **Chronic Symptoms:** None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. **Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None known.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. **Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. **Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Veterinary device: For direct (intravesical) instillation into the bladder

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

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8.2. **Exposure Controls**

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the

> immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles.







Materials for Protective Clothing

Hand Protection

Eye and Face Protection

Skin and Body Protection

Respiratory Protection

: Chemically resistant materials and fabrics.

Wear protective gloves. Chemical safety goggles.

: Wear suitable protective clothing.

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory

protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. **Information on Basic Physical and Chemical Properties**

Physical State : Liquid

Appearance : Clear with slight yellowish tint, viscous liquid

Odor : No data available **Odor Threshold** : No data available : No data available рΗ **Evaporation Rate** : No data available **Melting Point** : No data available : No data available

Freezing Point Boiling Point : No data available **Flash Point** : No data available : No data available **Auto-ignition Temperature Decomposition Temperature** : No data available Flammability (solid, gas) : No data available No data available **Vapor Pressure**

Relative Density Solubility : No data available **Partition Coefficient: N-Octanol/Water** : No data available

Viscosity : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

Relative Vapor Density at 20°C

- **Reactivity:** Hazardous reactions will not occur under normal conditions. 10.1.
- 10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
- Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials. 10.4.
- 10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects 11.1.

Acute Toxicity: Not classified

Skin Corrosion/Irritation: Not classified Serious Eye Damage/Irritation: Not classified Respiratory or Skin Sensitization: Not classified

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: No data available

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Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. **Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

A-Cyst	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

A-Cyst	
Bioaccumulative Potential	Not established.

- **12.4. Mobility in Soil** No additional information available
- 12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

- **14.1.** In Accordance with DOT Not regulated for transport
- 14.2. In Accordance with IMDG Not regulated for transport
- **14.3. In Accordance with IATA** Not regulated for transport

SECTION 15: REGULATORY INFORMATION

- **15.1. US Federal Regulations** Neither this product nor its chemical components appear on any US federal lists.
- **15.2. US State Regulations** Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision

: 11/13/2017

Other Information

: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions, The specific chemical identity and/or exact percentage of composition

have been withheld as a trade secret [29 CFR 1910.1200].

GHS Full Text Phrases:

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 not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)

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