

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Oxytocin Injection

1.2. Intended Use of the Product

Use of the Substance/Mixture: Veterinary Obstetrical and Milk Let-Down.

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

Company

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

Name	Product Identifier	%	GHS-US classification
Water	(CAS No) 7732-18-5	98.5	Not classified
Sodium chloride	(CAS No) 7647-14-5	0.9	Not classified
Chlorobutanol Hemihydrate	(CAS No) 6001-64-5	0.5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Oxytocin, monoacetate (salt)	(CAS No) 6233-83-6	0.003 - 0.005 (20 USP Oxytocin Units per mL)	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1B, H360
Acetic acid	(CAS No) 64-19-7	< 0.001	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

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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.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

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.

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 protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. 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.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material 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 Heading 8. Exposure controls and personal protection. See Section 13, 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.

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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 Products: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Veterinary Obstetrical and Milk Let-Down.

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).

Acetic acid (64-19-7)		
USA ACGIH	ACGIH TWA (ppm)	10 ppm
USA ACGIH	ACGIH STEL (ppm)	15 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	25 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	10 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	37 mg/m ³
USA NIOSH	NIOSH REL (STEL) (ppm)	15 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	10 ppm

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

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: 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, colorless solution
Odor	: Chlorobutanol
Odor Threshold	: No data available
pH	: 3.0 - 5.0
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available

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Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
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

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 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.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Upon thermal decomposition: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Chlorobutanol Hemihydrate (6001-64-5)	
ATE (Oral)	500.00 mg/kg body weight
Sodium chloride (7647-14-5)	
LD50 Oral Rat	3 g/kg
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
Oxytocin, monoacetate (salt) (6233-83-6)	
ATE (Oral)	100.00 mg/kg body weight
ATE (Gases)	700.00 ppmV/4h
ATE (Vapors)	3.00 mg/l/4h
ATE (Dust/Mist)	0.50 mg/l/4h
Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg
LD50 Dermal Rabbit	1060 mg/kg
LC50 Inhalation Rat	11.4 mg/l/4h

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

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.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Chlorobutanol Hemihydrate (6001-64-5)	
LC50 Fish 1	135 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-

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	through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC 50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability

Oxytocin Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Oxytocin Injection	
Bioaccumulative Potential	Not established.
Chlorobutanol Hemihydrate (6001-64-5)	
Log Pow	2.03
Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)
Acetic acid (64-19-7)	
Log Pow	-0.31 (at 20 °C)

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.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

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

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Fire hazard Immediate (acute) health hazard

15.2 US State Regulations

Acetic acid (64-19-7)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

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

Revision Date : 12/01/2015

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Other Information

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

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 3	Flammable liquids Category 3
Repr. 1B	Reproductive toxicity Category 1B
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H226	Flammable liquid and vapor
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H402	Harmful to aquatic life

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)