



**BIONICHEPHARMA**

Dedicated to Specialty Injectables

## Material Safety Data Sheet

Material Name: Ultiva (Remifentanyl Hydrochloride for Injection)

### \*\*\* Section 1 - Chemical Product and Company Identification \*\*\*

#### Manufacturer Information

Bioniche Pharma  
272 E Deerpath Road  
Suite 304  
Lake Forest, IL 60045

Phone: 888-258-4199  
Emergency # 888-875-1671

### \*\*\* Section 2 - Hazards Identification \*\*\*

#### Emergency Overview

No data are available to evaluate the health risk of this material.

#### Potential Health Effects: Eyes

No signs and symptoms from occupational exposure are known.

#### Potential Health Effects: Skin

No signs and symptoms from occupational exposure are known.

#### Potential Health Effects: Ingestion

No signs and symptoms from occupational exposure are known.

#### Potential Health Effects: Inhalation

No signs and symptoms from occupational exposure are known.

#### Medical Conditions Aggravated by Exposure

Clinical data suggests the following: headaches, vomiting, nausea, slow heart rate, decreased blood pressure, rash, muscle weakness, numbness, and respiratory depression. Reported to cause the following: chest pain, chest discomfort, seizures, and hypoxemia. Direct contact may cause: opioid effects.

#### HMS Ratings: Health: 1 Fire: 0 HMLS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe \* = Chronic hazard

### \*\*\* Section 3 - Composition / Information on Ingredients \*\*\*

CAS #	Component	Percent
56-40-6	Glycine	70-95
132539-07-2	Remifentanyl Hydrochloride	5-30

### \*\*\* Section 4 - First Aid Measures \*\*\*

#### First Aid: Eyes

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### First Aid: Skin

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### First Aid: Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### First Aid: Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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### First Aid: Notes to Physician

Specific narcotic antagonist, e.g. nalorphine hydrobromide or naloxone hydrochloride are antidotes for respiratory depression produced by active ingredient.

\* \* \* Section 5 - Fire Fighting Measures \* \* \*

### General Fire Hazards

See Section 9 for Flammability Properties.

Not flammable

### Hazardous Combustion Products

Not determined

### Extinguishing Media

Use media appropriate for primary cause of fire.

### Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

### NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

\* \* \* Section 6 - Accidental Release Measures \* \* \*

### Containment Procedures

None necessary.

### Clean-Up Procedures

Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials.

### Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

### Special Procedures

Avoid excessive skin contact with the spilled material.

\* \* \* Section 7 - Handling and Storage \* \* \*

### Handling Procedures

Avoid contact with skin and eyes.

### Storage Procedures

Store according to label instructions.

\* \* \* Section 8 - Exposure Controls / Personal Protection \* \* \*

### A: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

### Engineering Controls

Use in a well ventilated area.

### PERSONAL PROTECTIVE EQUIPMENT

#### Personal Protective Equipment: Eyes/Face

Wear safety glasses with side shields.

#### Personal Protective Equipment: Skin

Use impervious gloves.

#### Personal Protective Equipment: Respiratory

None necessary.

#### Personal Protective Equipment: General

Eye wash fountain is recommended.

\* \* \* Section 9 - Physical & Chemical Properties \* \* \*

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Appearance:	Clear solution	Odor:	ND
Physical State:	Liquid	pH:	ND
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	ND	Melting Point:	ND
Solubility (H <sub>2</sub> O):	ND	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H <sub>2</sub> O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

## \*\*\* Section 10 - Chemical Stability & Reactivity Information \*\*\*

### Chemical Stability

Not Determined

### Chemical Stability: Conditions to Avoid

Not Determined

### Incompatibility

Not Determined

### Hazardous Decomposition

Not Determined

### Possibility of Hazardous Reactions

Not Determined

## \*\*\* Section 11 - Toxicological Information \*\*\*

### Acute Dose Effects

#### A: General Product Information

No information available for the product.

#### B: Component Analysis - LD50/LC50

Ingredients	Acute Test	Value	Units	Species
Remifentanyl Hydrochloride	LD50 >	2000	mg/kg	Rats
Glycine	LD50 =	4920	mg/kg	Mice Rats
	LD50 >	2000	mg/kg	Rabbits

### Carcinogenicity

#### A: General Product Information

No information available for the product.

#### B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

## \*\*\* Section 12 - Ecological Information \*\*\*

### Ecotoxicity

#### A: General Product Information

No information available for the product.

#### B: Component Analysis - Ecotoxicity - Aquatic Toxicity

No ecotoxicity data are available for this product's components.

## \*\*\* Section 13 - Disposal Considerations \*\*\*

### US EPA Waste Number & Descriptions

### Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

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### Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations. See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

\* \* \* **Section 14 - Transportation Information** \* \* \*

### US DOT Information

Shipping Name: Not Regulated

\* \* \* **Section 15 - Regulatory Information** \* \* \*

### US Federal Regulations

#### Component Analysis

None of this product's components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

#### State Regulations

#### Component Analysis - State

None of this product's components are listed on the state lists from CA, MA, MN, NJ, PA, or RI.

#### Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

#### Additional Regulatory Information

#### Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Glycine	56-40-6	Yes	DSL	EINECS
Remifentanyl Hydrochloride	132539-07-2	No	No	No

\* \* \* **Section 16 - Other Information** \* \* \*

#### Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

#### Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration,; NJTSR = New Jersey Trade Secret Registry.

End of Sheet