

Material Safety Data Sheet

Material Name: Enlon-Plus® (Edrophonium Chloride, USP and Atropine Sulfate, USP) 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

May be harmful if swallowed. Cardiovascular effects. Respiratory effects. Neurologic effects. Gastrointestinal effects. Musculoskeletal effects.

Potential Health Effects: Eyes

May cause irritation and/or allergic reactions.

Potential Health Effects: Skin

May cause irritation and/or allergic reactions.

Potential Health Effects: Ingestion

May be harmful if swallowed.

Potential Health Effects: Inhalation

Inhalation not likely under normal use conditions.

HMIS Ratings: Health: 1 Fire: 0 HMIS 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
7732-18-5	Water	>98
116-38-1	Edrophonium chloride	1
108-95-2	Phenol	0-0.5
7757-83-7	Sodium sulfite	<0.5
55-48-1	Benzeneacetic acid, α -(hydroxymethyl)- 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester endo-(\pm)-, sulfate (2:1) (salt)	<0.1

*** Section 4 - First Aid Measures ***

First Aid: Eyes

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

First Aid: Skin

In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation develops.

First Aid: Ingestion

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

First Aid: Inhalation

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

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First Aid: Notes to Physician

See patient package insert in shipping carton for complete information.

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

General Fire Hazards

See Section 9 for Flammability Properties.

None

Hazardous Combustion Products

Not Determined

Extinguishing Media

Use foam or all purpose dry chemicals to extinguish.

Fire Fighting Equipment/Instructions

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout 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 ***

Personal Precautions

Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

None necessary.

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

Handling Procedures

Wash thoroughly after handling.

Storage Procedures

Keep containers tightly closed in a cool, well-ventilated place. Store between 15-26°C (59 to 78°F).

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

A: Component Exposure Limits

Phenol (108-95-2)

- ACGIH: 5 ppm TWA
Skin - potential significant contribution to overall exposure by the cutaneous route
- OSHA: 5 ppm TWA; 19 mg/m³ TWA
Prevent or reduce skin absorption
- NIOSH: 5 ppm TWA; 19 mg/m³ TWA
15.6 ppm Ceiling (15 min); 60 mg/m³ Ceiling (15 min)
Potential for dermal absorption

Engineering Controls

No special containment is required. Good general ventilation should be sufficient to control airborne levels.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Safety glasses. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

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Personal Protective Equipment: Skin

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use chemical resistant, impervious gloves.

Personal Protective Equipment: Respiratory

Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Personal Protective Equipment: General

Eye wash fountain is recommended.

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

Appearance:	Aqueous solution	Odor:	NA
Physical State:	Liquid	pH:	4.0-5.0
Vapor Pressure:	NA	Vapor Density:	NA
Boiling Point:	NA	Melting Point:	NA
Solubility (H2O):	Soluble	Specific Gravity:	NA
Evaporation Rate:	NA	VOC:	NA
Octanol/H2O Coeff.:	NA	Flash Point:	NA
Flash Point Method:	NA	Upper Flammability Limit (UFL):	NA
Lower Flammability Limit (LFL):	NA	Burning Rate:	NA
Auto Ignition:	NA		

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

Chemical Stability

Stable under recommended storage conditions.

Chemical Stability: Conditions to Avoid

None

Incompatibility

None

Hazardous Decomposition

Not available.

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression).

B: Component Analysis - LD50/LC50

Water (7732-18-5)

Oral LD50 Rat: >90 mL/kg

Phenol (108-95-2)

Oral LD50 Rat: 317 mg/kg; Dermal LD50 Rat:525 mg/kg; Dermal LD50 Rabbit:630 mg/kg; Inhalation LC50 Rat:316 mg/m3/4H

Sodium sulfite (7757-83-7)

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Inhalation LC50 Rat: >5.5 mg/L/4H; Inhalation LC50 Rat:>22 mg/L/1H; Oral LD50 Rat:820 mg/kg

**Benzeneacetic acid, α -(hydroxymethyl)- 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester endo-(±)-, sulfate (2:1)
(salt) (55-48-1)**

Oral LD50 Rat: 600 mg/kg

Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

Phenol (108-95-2)

ACGIH: A4 - Not Classifiable as a Human Carcinogen

IARC: Monograph 71 [1999], Monograph 47 [1989] (Group 3 (not classifiable))

Sodium sulfite (7757-83-7)

IARC: Monograph 54 [1992] (listed under Sulfur dioxide and some sulfites bisulfites and metabisulfites)
(Group 3 (not classifiable))

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

Phenol (108-95-2)

Test & Species

	Conditions
96 Hr LC50 Pimephales promelas	24 mg/L [flow-through]
96 Hr LC50 Oncorhynchus mykiss	8.9 mg/L [flow-through]
96 Hr LC50 Lepomis macrochirus	23.88 mg/L [static]
96 Hr LC50 Oncorhynchus mykiss	5-12 mg/L [flow-through]
96 Hr LC50 Poecilia reticulata	40 mg/L [static]
96 Hr LC50 Brachydanio rerio	27.8 mg/L
96 Hr EC50 Selenastrum capricornutum	150 mg/L
48 Hr EC50 water flea	23.0 mg/L
48 Hr LC50 Daphnia magna	13 mg/L

Conditions

Sodium sulfite (7757-83-7)

Test & Species

	Conditions
96 Hr LC50 Leuciscus idus	220-460 mg/L [static]
24 Hr LC50 Psammechinus miliaris	330 mg/L

Conditions

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

Phenol (108-95-2)

RCRA: waste number U188

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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

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Phenol (108-95-2)

SARA 302: 500 lb lower threshold TPQ; 10000 lb upper threshold TPQ
CERCLA: 1000 lb final RQ; 454 kg final RQ

State Regulations

Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
Phenol	108-95-2	Yes	Yes	Yes	Yes	Yes	Yes

Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Water	7732-18-5	Yes	DSL	EINECS
Edrophonium chloride	116-38-1	No	No	EINECS
Phenol	108-95-2	Yes	DSL	EINECS
Sodium sulfite	7757-83-7	Yes	DSL	EINECS
Benzeneacetic acid, α -(hydroxymethyl)- 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester endo-(±)-, sulfate (2:1) (salt)	55-48-1	Yes	NDSL	EINECS

*** 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.