BIOLOGICAL E. LIMITED

SDS: Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Common Name : Neostigmine methylsulfate Injection

Synonyms : Prostigmin methylsulfate Injection

Physical State : Liquid

Product use : A Cholinesterase inhibitor

Manufacturing site: Biological E. Limited,
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Manufacturer Contact Details:

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2. HAZARDS IDENTIFICATION

Emergency Overview

Neostigmine Methylsulfate Injection is a solution containing neostigmine methylsulfate, a synthetic quarternary ammonium compound that produces cholinergic effects by competing with acetylcholine for acetylcholinesterase. Clinically, it is used in the diagnosis and symptomatic treatment of myasthenia gravis. It is also used after surgery to reverse the effects of non-depolarizing neuromuscular blocking agents and to prevent postoperative distention and urinary retention. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the eyes, central and parasympathetic nervous system, glands, kidneys, heart, lungs, gastrointestinal tract, and uterus.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. However, limited information suggests that dilute solutions of neostigmine methylsulfate have some potential for skin and eye absorption. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

No signs or symptoms from occupational exposure are known. In clinical use, adverse events include nausea, vomiting, gastrointestinal upset, cramps, visual impairment, diarrhea, dizziness, headaches, drowsiness, sweating, increased salivation, decreased blood pressure, cardiac changes, bronchospasm, bronchorrhea, rash, excessive urination, spasms, bone and joint pain, flushing, allergic reactions, muscle weakness, premature delivery.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to neostigmine methylsulfate; preexisting eye, heart, muscle, urinary bladder, cardiovascular system, respiratory system, or gastrointestinal system ailments; late pregnancy.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS-No.	Concentration
Neostigmine Methylsulphate	51-60-5	0.05 - 0.1
Phenol USP	108-95-2	0.45
Sodium acetate trihydrate	6131-90-4	0.02
Acetic acid glacial 100 %	64-19-7	pH Adjustment
Sodium Hydroxide	1310-73-2	pH Adjustment

4. FIRST AID MEASURES

Eye Contact:

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.

Skin Contact:

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.

Inhalation:

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

Ingestion:

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

5. FIRE FIGHTING MEASURES

Flammability: None anticipated for this aqueous product.

Fire & Explosion Hazard : None anticipated for this aqueous product.

Extinguishing media: As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures: No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

No special handling required for hazard control under conditions of normal product use.

Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Controls: No data available

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Clear, coloureless solution in liquid vial
Odor	: NA.
Solubility	: Soluble Very soluble in water, Freely soluble in ethanol (96%)
Density	: No information found.
pH	: 5.0 – 6.5
Melting point/Freezing point	: NA
Initial Boiling Point/Boiling Point Range	: NA
Evaporation Rate	: NA
Flammability (solid, gas)	: NA
Upper/Lower Flammability or Explosive Limits: NA	
Vapor Pressure	: NA
Vapor Density	: NA
Specific Gravity	: NA
Auto-ignition temperature	: NA
Decomposition temperature	: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined.

Conditions to avoid Not determined.

Incompatibilities Not determined.

Hazardous decomposition products: Not determined.

During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).

Hazardous Polymerization: Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Neostigmine Methylsulphate	100	LD50	Oral	7.5 - 10.0	mg/kg	Mouse
Neostigmine Methylsulphate	100	LD50	Intravenous	0.16 0.25	mg/kg mg/kg	Mouse Rabbit
Neostigmine Methylsulphate	100	LD50	Intraperitoneal	0.23	mg/kg	Mouse

Aspiration Hazard: None anticipated from normal handling of this product.

Dermal Irritation/Corrosion: None anticipated from normal handling of this product.

Ocular Irritation/Corrosion: None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation with tearing and redness.

Dermal or Respiratory Sensitization: None anticipated from normal handling of this product.

Reproductive Effects: Studies in animals to evaluate the effects of neostigmine methylsulfate on fertility or development have not been conducted. Intravenous administration of anticholinesterase agents to pregnant women near term may cause uterine irritability and premature labor.

Mutagenicity: Studies to evaluate the genotoxic potential of neostigmine methylsulfate have not been conducted.

Carcinogenicity: Studies in animals to evaluate the carcinogenic potential of neostigmine methylsulfate have not been conducted.

Target Organ Effects: Based on clinical use, possible target organs include the eyes, central and parasympathetic nervous system, glands, kidneys, heart, lungs, gastrointestinal tract, and uterus.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined for product

Persistence/Biodegradability: Not determined for product

Bioaccumulation: Not determined for product

Mobility in Soil: Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

USA Regulations	Listed
TSCA Status	Not Listed
CERCLA Status	Not Listed
SARA 302 Status	Not Listed
SARA 313 Status	Not Listed
PROP 65 Status	Not Listed
RCRA Status	Not Listed

U.S. OSHA Classification: Target Organ Toxin Possible Irritant

GHS Classification

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Neostigmine Methylsulfate .

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:

S23 - Do not breathe vapor.

S24 - Avoid contact with skin.

S25 - Avoid contact with eyes.

S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Biological E. Limited provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product individuals receiving the information must excise their independent judgment in determining its appropriateness for a particular purpose. Biological E. Limited will not be responsible for damages resulting from use or reliance upon information.

27/06/19