

**SAFETY DATA SHEET**  
**Neostigmine Methylsulfate Injection USP**



**Caplin Steriles Limited**

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/  
UNDERTAKING**

**Product Identifier** : Neostigmine methylsulfate Injection USP (Caplin Steriles Ltd.)  
**Chemical Family** : Benzene  
**Synonyms** : Benzenaminium,-3-[[[(dimethylamino) carbonyl] oxy]-N, N, N-trimethyl-methyl sulphate

**Relevant identified uses of the substance or mixture and uses advised against**

**Identified Uses** : Neuromuscular blocking agents  
**Details of the Supplier of the Safety Data Sheet** : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.  
**Emergency Telephone Number** : +91-4467901901/02/03

**SECTION 2: HAZARDS IDENTIFICATION**

**Classification**

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

**GHS Label elements, including precautionary statements:**

**Emergency Overview**

The product contains no substances which at their given concentration are considered to be hazardous to health

**Appearance** : Clear, Colorless  
**Physical state** : Liquid  
**Odor** : No information available

**Precautionary Statements**

**Prevention** : None  
**General Advice** : None  
**Storage** : None  
**Disposal** : None

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**Hazard Not Otherwise Classified (HNOC)** : Not applicable

**Other information:**

Neostigmine Methylsulfate Injection is a solution containing neostigmine methylsulfate, a synthetic quarternary ammonium compound that produces cholinergic effects by competing with acetylcholine for acetylcholinesterase. See Section 11 for additional Toxicological Information.

**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**

<b>Ingredient</b>	<b>CAS Number</b>	<b>Weight %</b>
Neostigmine Methylsulfate	51-60-5	0.05 or 0.1
Phenol	108-95-2	0.45

Sodium hydroxide and acetic acid added to adjust pH

**SECTION 4: FIRST AID MEASURES**

**Description of necessary First Aid Measures**

- Eye Contact** : Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician
- Skin Contact** : Wash skin with soap and water
- Inhalation** : Move to fresh air
- Ingestion** : Clean mouth with water and afterwards drink plenty of water

**Most important symptoms/effects, acute and delayed**

- Most Important Symptoms/Effects** : Difficulty in breathing. Drowsiness. Dizziness. Salivation Nausea. Tremors. Headaches. Irregular cardiac activity. Neurological disorders. Impairment of vision.

**Indication of immediate medical attention and special treatment needed, if necessary**

- Notes to Physician** : Neostigmine Methylsulfate Injection is a solution containing neostigmine Methylsulfate a synthetic quarternary ammonium compound that produces cholinergic effects by competing with acetylcholine for acetylcholinesterase. If exposure shall occur, the use of an anticholinergic agent, e.g., atropine sulfate or glycopyrrolate, may prevent or mitigate

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adverse muscarinic cholinergic effects. Ventilatory support may be required if respiratory paralysis is present.

Overdosage of Neostigmine Methylsulfate can cause cholinergic crisis, which is characterized by increasing muscle weakness and muscarinic symptoms (nausea, vomiting, diarrhea, sweating, increased bronchial and salivary secretions, and bradycardia), and through involvement of the muscles of respiration, may result in death. Cholinergic crisis should not be confused with Myasthenic crisis, a similar condition with a different path of treatment.

### **SECTION 5: FIRE FIGHTING MEASURES**

**Suitable Extinguishing Media** : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media : None

**Specific hazards arising Chemical :**  
**No information available**

**Explosion Data** : May include oxides of carbon.

Sensitivity to Mechanical Impact : None

Sensitivity to Static Discharge : None

#### **Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

#### **Personal precautions, protective equipment and emergency procedures**

**Personal Precautions** : Prevent formation of aerosols or mists. Use personal protective equipment. Refer to Section 8 for personal protective equipment.

#### **Environmental Precautions**

**Environmental Precautions** : Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional Ecological Information

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**Methods and materials for containment and cleaning up**

- Methods for Containment** : Prevent further leakage or spillage if safe to do so. Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite:) and place in container for disposal according to local / national regulations (see Section 13).
- Methods for Cleaning Up** : Clean contaminated surface thoroughly.

**SECTION 7: HANDLING AND STORAGE**

**Precautions for safe handling**

- Handling** : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Remove and wash contaminated clothing before re-use.

**Conditions for safe storage, including any incompatibilities**

- Storage** : Keep containers tightly closed in a dry, cool and well-ventilated
- Incompatible Products** : None known based on information supplied

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

Control Parameters

Exposure Guidelines

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>OSHA PEL</b>	<b>NIOSH IDLH</b>
PHENOL 108-95-2	TEA-5ppm S*	TWA: 5 ppm TWA: 19 mg/m3 (vacated) TWA: 5 ppm (vacated) TWA: 19 mg/m3 (vacated) S* S*	IDLH: 250 ppm Ceiling: 15.6 ppm 15 min Ceiling: 60 mg/m3 15 min TWA: 5 ppm TWA: 19 mg/m3

**Appropriate engineering controls**

- Engineering Measures** : Showers  
Eyewash stations  
Ventilation systems

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**Individual protection measures, such as personal protective equipment**

- Eye/Face Protection** : No protective equipment is needed under normal use conditions. If splashes are likely to occur, wear: Safety glasses with side-shields.
- Skin and Body Protection** : Wear protective gloves/clothing.
- Wear protective gloves/clothing. None required under normal usage. In case of mist, spray or aerosol exposure wear suitable personal respiratory protection
- Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

- Physical State** : Liquid
- Appearance** : Clear, Colorless
- Odor** : No information available
- Odor Threshold** : No information available

<b>Property</b>	<b>:</b>	<b>Values</b>	<b>Remarks/- Method</b>
<b>pH</b>	:	5.5	None Known
<b>Melting point /range (°C)</b>	:	No data available.	None Known
<b>Boiling Point / Boiling Range (°C)</b>	:	No data available.	None Known
<b>Flash Point</b>	:	No data available.	None Known
<b>Evaporation rate</b>	:	No data available.	None Known
<b>Flammability (soild,gas)</b>	:	No data available.	None Known
<b>Flammability limit in Air</b>	:		
<b>Upper Flammability limit</b>	:	No data available.	None Known
<b>Lower Flammability limit</b>	:	No data available.	None Known

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<u>Property</u>	<u>Values</u>	<u>Remarks/- Method</u>
Vapor pressure	: No data available.	None Known
Vapor Density	: No data available.	None Known
Relative Density	: No data available.	None Known
Specific Gravity	: No data available.	None Known
Water Solubility	: Very soluble	None Known
Solubility in other solvents	: No data available.	None Known
Partition coefficient: n-octanol/water	: No data available.	None Known
Autoignition Temperature	: No data available.	None Known
Decomposition Temperature	: No data available.	None Known
Viscosity	: No data available.	None Known
Flammable Properties	: No flammable	
Explosive Propertie	: No data available.	
Oxidizing Properties	: No data available.	
<u>Other Information</u>		
VOC Content (%)	: No data available.	

**SECTION 10: STABILITY AND REACTIVITY**

Reactivity	: Not reactive under normal conditions
Chemical Stability	: Stable under recommended storage conditions
Possibility of Hazardous Reactions	: None under normal processing
Conditions to Avoid	: None known based on information supplied
Incompatible Materials	: None known based on information supplied.
Hazardous Decomposition Products	: None known based on information supplied.

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**SECTION 11: TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Product Information**

- Inhalation** : Inhalation of mist may cause irritation to the respiratory system.
- Eye Contact** : May cause irritation
- Skin Contact** : May cause irritation
- Ingestion** : May be harmful if swallowed. Ingestion of large quantities may cause spasms or respiratory paralysis

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Water	90 mL/kg ( Rat )	-	-
Phenol	= 317 mg/kg ( Rat )	= 525 mg/kg ( Rat ) = 630 mg/kg (Rabbit )	= 316 mg/m3 (Rat) 4 h
Neostigmine metisulfate	7.5 - 10 mg/kg (mouse)	-	-

**Symptoms related to the physical, chemical and toxicological characteristics**

Symptoms

Clinical side effects include, but are not limited to, salivation, muscle twitches, gastrointestinal effects including bowel cramps, diarrhea, and nausea, allergic reactions including rash, urticaria, and anaphylaxis, central nervous system effects including dizziness, convulsions, loss of consciousness, drowsiness, headache, and visual changes, cardiovascular effects including cardiac arrhythmias, decreased blood pressure, and cardiac arrest, respiratory effects including respiratory depression, respiratory arrest and bronchospasm, and musculoskeletal including muscle cramps and spasms. Overdosage has been associated with cholinergic crisis, characterized by increasing muscle weakness.

**Delayed and immediate effects and also chronic effects from short and long term exposure**

- Sensitization** No information available
- Mutagenic Effects** Mutagenetic testing of the active ingredient did not result in positive results.  
 Contains a known or suspected mutagen: Phenol
- Carcinogenicity** There are no known carcinogenic chemicals in this product

Chemical Name	ACGIH	IARC	NTP	OSHA
Phenol		Group 3		

IARC: (International Agency for Research on Cancer)

Group 3: Not Classifiable as to its Carcinogenicity to Humans

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Reproductive Toxicity	No adequate or well controlled studies in animals or humans concerning the reproductive effects of the active ingredient. Anticholinesterase drugs may cause uterine irritability and induce premature labor when given intravenously to pregnant women near term.
Developmental Toxicity	Pregnancy Category C. Animal reproduction studies have not been conducted with the active ingredient. There is also no adequate or well controlled studies in humans
STOT - single exposure	See listed target organs below.
STOT - repeated exposure	In clinical use, target organ effects include: See listed target organs below.
Target Organ Effect	Central nervous system (CNS). Peripheral Nervous System (PNS) Gastrointestinal tract (GI). Cardiovascular system. Musculoskeletal system. Respiratory system
Aspiration Hazard	No information availabl
Numerical measures of toxicity - Product	
Acute Toxicity	See Section 11 for additional Toxicological Information

**SECTION 12: ECOLOGICAL INFORMATION**

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Phenol 108-95-2	EC50 96 h: = 46.42 mg/L (Pseudokirchneriella subcapitata) EC50 96 h: 0.0188 - 0.1044 mg/L static (Pseudokirchneriella subcapitata) EC50 72 h: 187 - 279 mg/L static (Desmodesmus subspicatus	LC50 96 h: 11.9 - 50.5 mg/L flow-through (Pimephales promelas) LC50 96 h: 20.5 - 25.6 mg/L static (Pimephales promelas) LC50 96 h: = 32 mg/L (Pimephales promelas) LC50 96 h: 5.449 - 6.789 mg/L flow-through (Oncorhynchus mykiss) LC50 96 h: 7.5 - 14 mg/L	EC50 21 - 36 mg/L 30 min EC50 = 23.28 mg/L 5 min EC50 = 25.61 mg/L 15 min EC50 = 28.8 mg/L 5 min EC50 = 31.6 mg/L 15 mi	EC50 48 h: 4.24 - 10.7 mg/L Static (Daphnia magna) EC50 48 h: 10.2 - 15.5 mg/L (Daphnia magna)



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		static (Oncorhynchus mykiss) LC50 96 h: 4.23 - 7.49 mg/L semi-static (Oncorhynchus mykiss) LC50 96 h: 5.0 - 12.0 mg/L (Oncorhynchus mykiss) LC50 96 h: = 13.5 mg/L static (Lepomis macrochirus) LC50 96 h: 11.9 - 25.3 mg/L flow-through (Lepomis macrochirus) LC50 96 h: = 11.5 mg/L semi-static (Lepomis macrochirus) LC50 96 h: 34.09 - 47.64 mg/L static (Poecilia reticulata) LC50 96 h: = 31 mg/L semi-static (Poecilia reticulata) LC50 96 h: = 27.8 mg/L (Brachydanio rerio) LC50 96 h: = 0.00175 mg/L semi-static (Cyprinus carpio) LC50 96 h: 33.9 - 43.3 mg/L flow-through (Oryzias latipes) LC50 96 h: 23.4 - 36.6 mg/L static (Oryzias latipes)		
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**Persistence and Degradability**

Bo information available

Bioaccumulation

No information available

Chemical Name	Low Pow
Phenol	1.47

Other Adverse Effects : No information available

**SECTION 13: DISPOSAL CONSIDERATIONS**

Waste Disposal Methods                      Dispose of in accordance with federal, state, and local regulations  
 Contaminated Packaging                      Do not re-use empty containers.  
 California Hazardous Waste Codes        311

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California Waste Code Legend

Pharmaceutical waste

<b>Chemical Name</b>	<b>California Hazardous Waste</b>
Phenol	Toxic Corrosive

**SECTION 14: TRANSPORT INFORMATION**

<b><u>DOT</u></b>	Not regulated
<b><u>TDG</u></b>	Not regulated
<b><u>IATA</u></b>	Not regulated
<b><u>IMDG /IMO</u></b>	Not regulated

**SECTION 15: REGULATORY INFORMATION**

**International Inventories**

<b><u>TSCA</u></b>	Exempt
DSL	Exempt

**Legend**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances Lis

**U.S. Federal Regulations**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Acute Health Hazard <b>Exemp</b>	Exempt
Chronic Health Hazard	Exempt

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Fire Hazard Exempt

Sudden Release of Pressure Hazard Exempt

Reactive Hazard Exempt

**Clean Water Act**

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Phenol	1000 lb	X	X	X

**CERCLA**

Chemical Name	Hardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Phenol	1000 lb	1000 lb	<b>RQ 1000 lb final RQ</b> <b>RQ 454 kg final RQ</b>

**U.S. State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulation**

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Phenol	1000 lb	X	X	X	X

**U.S. EPA Label Information**

EPA Pesticide Registration Number : Not applicable

**SECTION 16: OTHER INFORMATION**

<u>NFPA</u>	Health Hazard 1	Flammability 0	Instability 0	Physical and chemical Hazard -
<u>HMIS</u>	Health Hazard 1*	Flammability 0	Physical Hazard 0	Personal protection x

**\*Indicates a chronic health Hazard**

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**Prepared by** : Caplin Steriles Limited

**General Disclaimer**

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text

**----End of Safety Data Sheet---**