SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Neostigmine Methylsulfate Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	April 25, 2011
SDS Revision Date:	June 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Germ cell mutagenicity. Category 2.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of causing genetic defects.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure:
Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation. Skin contact may result in allergic-type skin rash and hypersensitivity reactions.
- Inhalation: May cause irritation of respiratory tract. May cause respiratory sensitization with asthma-like symptoms in susceptible individuals.
- Ingestion: May cause irritation.

Signs/Symptoms:
Adverse reactions from therapeutic doses generally are due to an exaggeration of pharmacological effects of which salivation and fasciculation are the most common. Other adverse reactions include: Bowel cramps and diarrhea. Overdosage of neostigmine methylsulfate can cause cholinergic crisis, which is characterized by increasing muscle weakness, and through involvement of the muscles of respiration, may result in death. The immediate use of atropine in cholinergic crisis is recommended; but such use, by masking signs of overdosage, can lead to inadvertent induction of cholinergic crisis. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with known hypersensitivity to the drug and individuals with peritonitis or mechanical obstruction of the intestinal or urinary tract.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Neostigmine Methylsulfate	51-60-5	0.25 % by weight	
Phenol	108-95-2	0.45 % by weight	
Sodium Acetate (anhydrous)	127-09-3	0.02 % by weight	
Water for Injection	7732-18-5	Quantity Sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from light. Retain vial in carton until time of use.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic,

	hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Phenol :

Guideline OSHA:	Skin: Yes.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Odor:	No information.
Odor Threshold:	Not determined.
Boiling Point:	Not established.
Melting Point:	Not established.
Density:	No information.
Specific Gravity:	No information.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
Evaporation Rate:	No information.
pH:	~ 5.9
Molecular Formula:	Mixture
Molecular Weight:	334.39
Viscosity:	No information.
Coefficient of Water/Oil Distribution:	No information.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	No information.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Exposure to light may cause decomposition.

SECTION 11 : TOXICOLOGICAL INFORMATION

Phenol :

IARC:	IARC: Group 3: Unclassifiable as to carcinogenicity to humans.
Acute Effects:	Eye, skin, and respiratory irritation may occur.

Neostigmine Methylsulfate :

RTECS Number:	CY1225000
Skin:	Rash and urticaria

Ingestion:	Oral - Mouse LD50: 7.5 mg/kg (RTEC)
Sensitization:	Allergic reactions and anaphylaxis.
Other Toxicological Information:	Subcutaneous - Rat LD50: 334 ug/kg Intravenous. - Rabbit LD50: 250 ug/kg Intraperitoneal. - Mouse LD50: 230 ug/kg (RTEC)

Phenol :

RTECS Number:	SJ3325000
Eye:	Phenol is corrosive to the rabbit eye.
Skin:	Dermal - Rat LD50 : 660-707 mg/kg (OECD SIDS) Phenol causes severe chemical burns. Prolonged and/or repeated skin contact with this product may cause damage to epidermal tissue.
Inhalation:	Inhalation - Rat LC0 : 900 mg/m³/8 h (ECHA) Prolonged and/or repeated inhalation may cause damage to liver. This product if inhaled may cause upper respiratory irritation and possible central nervous system effects including headaches, nausea, vomiting, dizziness, drowsiness, loss of coordination, impaired judgement, and general weakness.
Ingestion:	Oral - Rat LD50: 340 mg/kg (OECD SIDS) Prolonged and/or repeated oral exposure may cause damage to nervous system.
Mutagenicity:	Phenol should be regarded as a somatic cell mutagen.

Sodium Acetate (anhydrous) :

RTECS Number:	AJ4300010
Eye:	Rabbit, not irritating. (TS : potassium acetate)
Skin:	Dermal - Rabbit LD50 > 10000 mg/kg (CHEMINFO) Rabbit, not irritating.
Inhalation:	Inhalation - Rat LC50 > 5.6 mg/L/4 h (OECD Guideline 403) (TS: calcium diacetate) (ECHA)
Ingestion:	Oral - Rat LD50 : 5200 mg/kg (CHEMINFO)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

Neostigmine Methylsulfate :

Ecotoxicity:	No data were available.
Biodegradation:	No data were available.
Bioaccumulation:	No data were available.

Phenol :

Ecotoxicity:	Rainbow trout (Oncorhynchus mykiss) LC50 (96hr) : 5.02 mg/L Mrigal carp (Cirrhina mrigala) NOEC (60d) 0.077mg/L Water flea (Ceriodaphnia dubia) LC50 (48hr) 3.1mg/L, EC10 (16d) 0.46 mg/L Green algae (Selenastrum capricornutum) EC50 (96hr) : 61.1 mg/L Marine diatom (Skeletonema costatum) NOEC (120h) : 13 mg/L (OECD SIDS)
Biodegradation:	Phenol is readily biodegradable (OECD 301C: 85 % after 14 d).
Bioaccumulation:	Potential to bioaccumlate is low (BCF = 17.5).

Sodium Acetate (anhydrous) :

Ecotoxicity:	Zebrafish (Danio rerio) LC50 (96hr) > 100 mg/L (OECD Guideline 203, GLP) Water flea (Daphnia magna) EC50 (48hr) > 919 mg/L (OECD Guideline 202, GLP) (TS : potassium acetate) Marine diatom (Skeletonema costatum) EC50 (72hr) > 1000 mg/L (TS : potassium acetate) (ECHA)
Biodegradation:	Readily biodegradable (86% after 7 days).
Bioaccumulation:	Potential to bioaccumlate is low (BCF 3.162).

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Not Regulated.
IATA UN Number:	Not Regulated.
IMDG UN NUmber :	Not Regulated.
IMDG Shipping Name :	Not Regulated.
RID UN Number :	Not Regulated.

RID Shipping Name :	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Phenol :

TSCA Inventory Status:	Listed
EINECS Number:	203-632-7
SARA:	EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
Section 302 EHS:	EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500/10,000 Lbs.
Section 304 RQ:	EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 1,000 Lbs.
Canada DSL:	Listed
Canada IDL:	: 250 ppm

Sodium Acetate (anhydrous) :

TSCA Inventory Status:	Listed
EINECS Number:	204-823-8
Canada DSL:	Listed

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

SDS Creation Date:	April 25, 2011
SDS Revision Date:	June 01, 2015
MSDS Revision Notes:	GHS MSDS
SDS Format:	
Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.