

Neostigmine Methylsulfate Injection, USP (0.5 and 1mg/mL)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 01/22/2018 Date of Issue:10/27/2017

Version: 1.1

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Neostigmine Methylsulfate Injection, USP (0.5 and 1mg/mL)

Product Code: NDC 0517-1133-05, NDC 0517-1134-05

Synonyms: Prostigmin methylsulfate Injection, Neostigmine methylsulfate Injection

1.2. Intended Use of the Product

Use of the Substance/Mixture: Cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.

1.3. Name, Address, and Telephone of the Responsible Party

Company

PharmaForce, Inc.
6610 New Albany Road East
New Albany, OH 43054
614-436-2222

www.pharmaforceinc.com

Company

American Reagent
P.O. Box 9001
Shirley NY, 11967

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 (North America) CHEMTREC

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Acute Tox. 4 (Inhalation:dust,mist) H332

Resp. Sens. 1 H334

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.
H332 - Harmful if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.
P271 - Use only outdoors or in a well-ventilated area.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P284 - [In case of inadequate ventilation] wear respiratory protection.
P302+P352 - If on skin: Wash with plenty of water.
P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P312 - Call a poison center or doctor if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.
P363 - Wash contaminated clothing before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

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2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water	(CAS No) 7732-18-5	99.43 - 99.48	Not classified
Phenol	(CAS No) 108-95-2	0.45	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Muta. 2, H341 STOT RE 2, H373 Aquatic Acute 2, H401 Aquatic Chronic 2, H411
Sodium acetate trihydrate	(CAS No) 6131-90-4	0.02	Not classified
Neostigmine methylsulfate	(CAS No) 51-60-5	0.05 - 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 1 (Inhalation:dust,mist), H330 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H335 Comb. Dust
Sodium hydroxide	(CAS No) 1310-73-2	Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Acetic acid	(CAS No) 64-19-7	Used to adjust pH	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Harmful if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization. Common clinical side effects include: Gastrointestinal disturbances, cardiovascular effects, shortness of breath, muscle weakness; muscle cramping.

Symptoms/Injuries After Inhalation: Inhalation is likely to cause adverse health effects including but not limited to: irritation, difficulty breathing, and unconsciousness. Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

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Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Nitrogen oxides. Sulfur compounds. Irritating fumes. Toxic fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions. Ventilate area.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Use only outdoors or in a well-ventilated area.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Protect from light. Store in carton until time of use.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 - 25 °C (68 - 77 °F, See USP Controlled Room Temperature)

7.3. Specific End Use(s)

Cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Phenol (108-95-2)		
USA ACGIH	ACGIH TWA (ppm)	5 ppm
USA ACGIH	ACGIH chemical category	Skin - potential significant contribution to overall exposure by the cutaneous route, Not Classifiable as a Human Carcinogen
USA ACGIH	Biological Exposure Indices (BEI)	250 mg/g Kreatinin Parameter: Phenol with hydrolysis - Medium: urine - Sampling time: end of shift (background, nonspecific)
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	19 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	5 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	60 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	15.6 ppm
USA IDLH	US IDLH (ppm)	250 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	19 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	5 ppm
USA OSHA	Limit value category (OSHA)	prevent or reduce skin absorption

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³

Acetic acid (64-19-7)		
USA ACGIH	ACGIH TWA (ppm)	10 ppm
USA ACGIH	ACGIH STEL (ppm)	15 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	25 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	10 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	37 mg/m ³
USA NIOSH	NIOSH REL (STEL) (ppm)	15 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	10 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when toxic gases may be released.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear
Odor	: Odorless
Odor Threshold	: No data available
pH	: 5.5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Inhalation:dust,mist: Harmful if inhaled.

Neostigmine Methylsulfate Injection, USP (0.5 and 1mg/mL)	
ATE (Dust/Mist)	4.78 mg/l/4h
Neostigmine methylsulfate (51-60-5)	
ATE (Oral)	5.00 mg/kg body weight
ATE (Dermal)	5.00 mg/kg body weight
ATE (Dust/Mist)	0.01 mg/l/4h
Phenol (108-95-2)	
LD50 Oral Rat	340 mg/kg
LD50 Dermal Rabbit	630 mg/kg
ATE (Oral)	100.00 mg/kg body weight
ATE (Dermal)	630.00 mg/kg body weight
ATE (Dust/Mist)	0.50 mg/l/4h
Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg

Skin Corrosion/Irritation: Not classified

pH: 5.5

Serious Eye Damage/Irritation: Not classified

pH: 5.5

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Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Phenol (108-95-2)	
IARC group	3
National Toxicology Program (NTP) Status	Twelfth Report - Items under consideration.

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Inhalation is likely to cause adverse health effects including but not limited to: irritation, difficulty breathing, and unconsciousness. Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Phenol (108-95-2)	
LC50 Fish 1	11.9 - 50.5 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	4.24 - 10.7 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	20.5 - 25.6 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	10.2 - 15.5 mg/l (Exposure time: 48 h - Species: Daphnia magna)

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability

Neostigmine Methylsulfate Injection, USP (0.5 and 1mg/mL)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Neostigmine Methylsulfate Injection, USP (0.5 and 1mg/mL)	
Bioaccumulative Potential	Not established.

Phenol (108-95-2)	
BCF Fish 1	(no significant bioaccumulation)
Log Pow	1.5

Acetic acid (64-19-7)	
Log Pow	-0.31 (at 20 °C)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

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Additional Information: Container may remain hazardous when empty. Continue to observe all precautions. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
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Phenol (108-95-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	1000 lb
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SARA Section 302 Threshold Planning Quantity (TPQ)	500 - 10000 lb
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SARA Section 313 - Emission Reporting	1 %
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Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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Acetic acid (64-19-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	5000 lb
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15.2. US State Regulations

Phenol (108-95-2)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

Acetic acid (64-19-7)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 01/22/2018

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal) Category 1
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Acute Tox. 1 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Muta. 2	Germ cell mutagenicity Category 2
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H300	Fatal if swallowed
H301	Toxic if swallowed
H310	Fatal in contact with skin
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H330	Fatal if inhaled
H331	Toxic if inhaled
H332	Harmful if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H373	May cause damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)