

# SAFETY DATA SHEET

**Material name:** Neostigmine Methylsulfate and glycopyrrolate solution

Date: March 01, 2023

Version: 1

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY / UNDERTAKING

**Material Name:** Neostigmine Methylsulfate and Glycopyrrolate solution

**Trade Name:** PREVDUO (Neostigmine Methylsulfate and Glycopyrrolate injection)

**Chemical Family:** Mixture

**Use of the Substance/Mixture:** The pharmaceutical product packaged in its final form (5 x 3ml in prefilled syringes) is a fixed dose combination of a cholinesterase inhibitor and antimuscarinic agent, indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration.

## 2. HAZARDS IDENTIFICATION

**Classification of the substance or mixture:** Drugs in the finished state and intended for the final user are not subject to labelling in the US, EU or Canada. Please consult the prescribing/packaging information.

**Appearance:** Liquid

**Health Hazards:**

GHS – Classification

Acute toxicity - oral - Category 4

**Label Elements:**



**Signal Word:** warning

**Hazard Statements:** H302 - Harmful if swallowed.

**Precautionary statements:** P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P301+P312: IF SWALLOWED: Call a Poison Center or doctor/physician if you feel unwell. P330 - Rinse mouth. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Substance/Mixture:** Mixture

**Hazardous components**

Chemical Name	GHS classification	CAS number	%
Neostigmine Methylsulfate	Acute Tox. 2 (Oral), H300	51-60-5	0.10
Glycopyrrolate	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2B, H320 STOT SE 3, H335	596-51-0	0.02
Edetate disodium dihydrate	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315	6381-92-6	0.05

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	Eye Irrit. 2A, H319 STOT SE 3, H335		
Sodium chloride	Not classified	7647-14-5	0.8
Water for injection	Not classified	7732-18-5	QS
Hydrochloric acid	Not classified	7647-01-0	QS to pH
Sodium Hydroxide	Not classified	1310-73-2	QS to pH

## 4. FIRST AID MEASURES

### Description of First Aid Measures:

**Eye Contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects of Exposure/acute and delayed:** Common signs of neostigmine clinical overdosage include nausea, vomiting, diarrhea, excessive salivation and sweating, miosis, bradycardia or tachycardia, cardiospasm, inco-ordination, muscle cramps, fasciculation and paralysis, increased oropharyngeal secretions and bronchospasm.

Signs of glycopyrronium bromide clinical overdosage are tachycardia, ventricular irritability. may be treated by the administration of neostigmine methylsulfate 1.0mg for each 1.0mg of glycopyrronium bromide known to have been administered. As glycopyrronium bromide is a quaternary ammonium agent, symptoms of overdosage are peripheral rather than central in nature.

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

**Chronic Symptoms:** None expected under normal conditions of use.

**Indication of immediate medical attention and special treatment needed:** The treatment of overdosage depends on whether signs of anticholinesterase or anticholinergic overdosage is the predominant presenting feature. If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Unsuitable extinguishing media:** Not known

**Specific hazards arising from the chemical:**

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

**Special protective equipment and precautions for firefighters:** Wear suitable protective equipment

**Fire-fighting equipment/instructions:** Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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**Specific methods:** Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment, and Emergency Procedures:** Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

**Environmental Precautions:** Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up:

**Measures for Cleaning /Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling:

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided.

Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities:

**Storage Conditions:** Store as directed by product packaging. Keep out of reach of children.

**Specific end use(s):** Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Biological limit values (occupational exposure limits):

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) for the pharmacologically active components, Neostigmine metabisulfite and Glycopyrrolate.

**Exposure/Engineering Controls:** None required for normal handling of packaged product. If vials are crushed or broken: Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. 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.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.

**Eyes:** Wear safety glasses as minimum protection.

**Skin:** Wear impervious disposable protective clothing to prevent skin contact.

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**Respiratory protection:** None required for normal handling of packaged product. If vials are crushed or broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.

**Thermal hazards:** Not available.

**General hygiene considerations:** Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid

**Color:** Clear colorless solution

**Odor:** Unknown

**pH:** 3.60

**Molecular Formula:** Mixture

**Molecular Weight:** Mixture

**Water Solubility:** No data available

**Solubility (other):** No data available

**Melting/Freezing Point (°C):** No data available

**Partition Coefficient (logP):** No data available

**Decomposition Temperature (°C):** No data available

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** 1g/ml

**Viscosity:** 1.3 cps

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

## 10. STABILITY AND REACTIVITY

**Reactivity:** No reactivity hazards known

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions:**

**Oxidizing Properties:** No data available

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition:** No data available

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## 11. TOXICOLOGICAL INFORMATION

**Product:** No data for this product/Mixture were identified. The following data presents the active ingredient and/or individual ingredients where applicable.

### Symptoms related to the physical, chemical, and toxicological characteristics:

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following intravenous exposure to this product may include bradycardia, nausea, vomiting, blurred vision and photophobia, xerostomia (dry mouth), urinary hesitancy and retention, blurred vision and photophobia due to mydriasis (dilation of the pupil), cycloplegia, increased ocular tension, tachycardia, bradycardia, palpitation, and decreased sweating.

### Acute toxicity:

#### **Neostigmine methylsulfate:**

Mouse: Oral LD50 - 7.50 mg/kg

#### **Glycopyrrolate:**

Rat: oral LD50 – 709 mg/kg

#### **Edetate disodium dihydrate:**

Rat oral LD50 - 2000 mg/kg

### Skin Corrosion/irritation:

Not classified.

### Eye Irritation

Not classified

### Respiratory or skin sensitisation:

Not classified.

### Germ cell mutagenicity:

Not classified

### Carcinogenicity:

Not classified.

### Reproductive toxicity:

Not classified.

### Specific Target Organ Toxicity (Single Exposure):

Not classified.

### Specific Target Organ Toxicity (Repeated Exposure):

Not classified.

### Aspiration hazard:

Not classified.

## 12. ECOLOGICAL INFORMATION

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**Environmental Overview:** Environmental properties have not been investigated.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

### **Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

**In Accordance with DOT:** Not regulated for transport.

**In Accordance with IMDG:** Not regulated for transport

**In Accordance with IATA:** Not regulated for transport.

## 15. REGULATORY INFORMATION

### **Neostigmine methylsulfate and glycopyrrolate:**

The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed prescription drug products, Neostigmine methylsulfate and glycopyrrolate, approved on the basis of safety and effectiveness by FDA under sections 505 of the Federal Food, Drug, and Cosmetic Act.

### **Edetate disodium dihydrate**

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

SARA Section 311/312 Hazard Classes Health hazard - Acute toxicity (any route of exposure)

Health hazard - Skin corrosion or Irritation

Health hazard - Serious eye damage or eye irritation

Health hazard - Specific target organ toxicity (single or repeated exposure).

## 16. OTHER INFORMATION

### **Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Acute Tox. 2 (Oral): Acute toxicity (oral) Category 2

Acute Tox. 4 (Oral): Acute toxicity (oral) Category 4

Skin Irrit. 2: Skin corrosion/irritation Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation Category 2A

Eye Irrit. 2B: Serious eye damage/eye irritation Category 2B

STOT SE 3: Specific target organ toxicity (single exposure) Category 3

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**Disclaimer:**

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