

Product Name: Nimbex Injection
Issued: Jul-10-2005



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott
Global Pharmaceutical Operations
200 Abbott Park Rd.
Abbott Park, Illinois 60064

Customer Service Telephone: HPD : 1-800-222-6883

Emergency Telephone: CHEMTREC (USA): 1 - 800 - 424 - 9300

Product Name: Nimbex Injection

Synonyms: Cistatracurium Injection

Trade Name: Nimbex Injection

List Number: 4380; 4382; 4378

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Cisatracurium Besylate 96946-42-8	1	Not Listed	Not Listed	Not Applicable	50 mcg/m ³ TWA, 170 mcg/m ³ STEL	None

Notes: OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

3. HAZARDS IDENTIFICATION

Emergency Overview:
Liquid.
Odorless.
Non-flammable.
Toxic by ingestion.

Routes of Exposure:
Oral: Unlikely (intact container)
Dermal: Unlikely (intact container)
Inhalation: Unlikely (intact container)

Hazard Information:
Ingestion Rating: Toxic
Skin Absorption Rating: None
Inhalation Rating: Not determined.

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Corrosiveness Rating: None.
Skin Contact Rating: None.
Skin Sensitization Rating: None
Eye Contact Rating: Not determined.
Target Organs: Nervous System , Eyes , Cardiovascular System , Respiratory System .

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Cisatracurium Besylate	1	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating: Not determined.
Health: 2

Signs and Symptoms: Clinical data suggests the following: decreased blood pressure, cardiac changes, flushing, breathing difficulty, rash, respiratory distress.

Medical Conditions Aggravated by Exposure: Data suggest any preexisting ailments in the following organs: eyes, central nervous system.

4. FIRST AID MEASURES

Eye Contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Contact: Remove contaminated clothing and laundry before reuse. Wash with soap and water. Get medical attention if irritation persists.

Inhalation: If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult give oxygen. Get medical attention.

Ingestion: Rinse mouth with water many times. Never give fluids or induce vomiting if the victim is unconscious or having convulsions. Get immediate medical attention.

Notes To Physician: Monitor respiratory system function.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:

Flammability Class: Non-flammable.
Flash Point Method: N/A
Lower Explosive Limit: Not determined.
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Waterspray, carbon dioxide, dry chemical or foam.
Special Exposure Hazards: May emit toxic or irritant fumes when heated.

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6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: For small spills : Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13. For large spills, cover liquid with absorbent materials. Restrict spill area to those equipped with personal protection specified in Section 8. Wash spill area thoroughly with soap and water. Place into an appropriate container for disposal.

Personal Precautions: Keep calm. Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Handle according to label instructions.

Storage: Store according to label instructions.

Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special provisions are required under normal conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid.

Odor: Odorless.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point: Not determined.

Vapor Pressure (mm Hg) Not determined.

Bulk Density at 20°C: Not determined.

Solubility: Not determined.

Specific Gravity: Not determined.

pH: Not determined.

Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Stable. Protect from light.

Self-Heating Tendency: Not determined.

Materials to Avoid: Alkaline materials.

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Hazardous Decomposition Products: Not determined.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Cisatracurium Besylate	1	LD50 < LD50 >	50 500	mg/kg mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Cisatracurium Besylate	1	LD50 >	2000	mg/kg	Rats

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Did not produce skin irritation in rabbits.

Eye Irritation: Active Ingredient : Produced mild to moderate eye irritation in animals.

Sensitization: Not considered to be a skin sensitizer.

Target Organ Effects: In clinical use target organ effects include: central nervous system, central nervous system.

Atracurium besylate is a nonpolarizing muscle relaxant used during surgery.

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Negative in the Ames Assay for mutagenicity in the presence or absence of a metabolic activating system. Negative in the micronucleus test. Mutagenic in Mouse Lymphoma assay.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Cisatracurium Besylate	1	Negative	Equivocal results	Negative	No Data.

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

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Biodegradation: Not determined.

General Notes: Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT/ADR:
Status: Not Regulated.

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

TDG (Canada):
Status: Not Regulated.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Cisatracurium Besylate	1	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: Not determined.
Delayed Health: Not determined.
Fire: Not determined.
Sudden Pressure: Not determined.
Reactivity: Not determined.

TSCA Inventory Status: Not determined.

CERCLA Status: Not determined.

RCRA Status: Not determined.

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Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

EC HAZARD CLASSIFICATION:

Category of Danger: None
Indication of danger: None
ICH Classification: Class 4 - Minimum Hazard.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: D1B TOXIC MATERIALS.



Notes:

1. SARA = Superfund Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

16. OTHER INFORMATION

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