

**Product Name:** Nimbex Injection  
**Issued:** Jun-22-2015

**abbvie**  
**SAFETY DATA SHEET**

**Section 1. Identification of the substance/mixture and of the company/undertaking**

**1.1 Product Identifier**

**Product Name:** Nimbex Injection  
**Synonyms:** Nimbex (Cisatracurium Besylate) Injection, 2 mg/mL; Nimbex (Cisatracurium Besylate) Injection, 10 mg/mL; Cisatracurium Besylate Injection; Nimbex; Cisatracurium Injection; Nimbex (Cisatracurium Besylate) Injection Premier ProRx  
**Trade name:** Nimbex  
**List Number:** 4380; 4382; 4378

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

**Recommended use:** Pharmaceuticals

**1.3 Details of the supplier of the safety data sheet**

**Supplier:** Manufactured for:  
AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
+1-847-932-7900  
**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433  
**E-mail Address:** AbbVie.SDS@abbvie.com

**1.4 Emergency telephone number**

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

**Section 2. Hazards identification**

**2.1 Classification of the substance or mixture**

**Regulation (EC) No 1272/2008**

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Indication of danger:** Not classified

**2.2 Label elements**

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

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### 2.3 Other hazards

Not determined

## **Section 3. Composition/information on ingredients**

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Water 7732-18-5	98-99.8	Present		Not Hazardous*	No data available
Cisatracurium Besylate 96946-42-8	0.1-1	NA	T;R25	Acute Tox. 3 (H301)	No data available
Benzyl Alcohol 100-51-6	0.1-1	Present	Xn; R20/22	Acute Inhal. Tox. 3 (H331) Acute Oral Tox. 4 (H302)	No data available

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**

**For the full text of the H-Statements mentioned in this Section, see Section 16**

## **Section 4. First aid measures**

### 4.1 Description of 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 launder 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.
- Protection of First-aiders:** Use personal protective equipment

### 4.2 Most important symptoms and effects, both acute and delayed

**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 pre-existing ailments in the following organs: eyes, central nervous system.

### 4.3 Indication of any immediate medical attention and special treatment needed

**Notes To Physician:** Monitor respiratory system function.

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## **Section 5. Firefighting measures**

### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

### **5.2 Special hazards arising from the substance or mixture**

**Special Exposure Hazards:** Not determined

### **5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

## **Section 6. Accidental release measures**

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

**Personal Precautions:** For personal protection see section 8.

### **6.2. Environmental precautions**

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

### **6.3. Methods and material for containment and cleaning up**

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

### **6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

## **Section 7. Handling and storage**

### **7.1. Precautions for safe handling**

Handle in accordance with good industrial hygiene and safety practice.

### **7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions.

### **7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

## **Section 8. Exposure controls/personal protection**

### **8.1. Control parameters**

**Exposure limits:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
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Water 7732-18-5	Not Applicable	None
Cisatracurium Besylate 96946-42-8	50 mcg/m <sup>3</sup> TWA, 170 mcg/m <sup>3</sup> STEL	None
Benzyl Alcohol 100-51-6	Not Applicable	None

## 8.2. Exposure controls

**Engineering Controls:** No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

**Respiratory Protection:** Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

**Gloves:** Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Not determined

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Appearance:** Colorless Mixture Blend Slight Yellow Solution

**Odor:** Odorless.

**Odor Threshold:** Not determined

**pH:** 3 - 3.8

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

**Melting/Freezing Point (°C):** Not determined

**Flash Point (°C):** Not determined.

**Evaporation Rate at 20°C:** Not determined.

**Flammability (Solid):** Not determined.

**Lower Explosive Limit:** Not determined.

**Upper Explosive Limit:** Not determined.

**Vapor Pressure (mm Hg):** Not determined.

**Vapor Density (Air = 1):** Not determined.

**Density, g / mL:** 0.995 - 1.005

**Specific Gravity:** Not determined.

**Solubility(ies):** Freely soluble in: water.

**Partition coefficient:** Not determined.

**n-octanol/water**

**Autoignition Temp. (°C):** Not determined.

**Decomposition temperature (°C):** Not determined.

**Viscosity (centipoise):** Not determined.

**Explosion Severity:** Not determined.

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**Oxidizer Properties:** Not determined.

### 9.2. Other information

Not determined

## **Section 10. Stability and reactivity**

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

Stable under normal conditions

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Not determined.

### 10.4. Conditions to avoid

Not determined.

### 10.5 Incompatible materials

Bases, and, Alkaline materials

### 10.6 Hazardous decomposition products

Not determined

## **Section 11. Toxicological information**

### 11.1. Information on toxicological effects

#### **Routes of Exposure:**

**Oral:** Yes  
**Dermal:** Yes  
**Inhalation:** Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Cisatracurium Besylate 96946-42-8	LD50 =	50 < LD50 < 500	mg/kg, for a similar material	Rats
Benzyl Alcohol 100-51-6	LD50 =	1040-3100	mg/kg	Animals

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

Chemical Name	Acute Test	Value	Units	Species
Benzyl Alcohol 100-51-6	LD50 =	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Benzyl Alcohol 100-51-6	LC 50 =	2000	ppm	Rats

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**Corrosivity:** Not determined.

**Dermal Irritation:** Active Ingredient : A similar formulation is not a skin irritant.

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

**Sensitization:** Active Ingredient : A similar material is not a skin sensitizer.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Minor Ingredient : Not carcinogenic in animal study.  
Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Benzyl Alcohol 100-51-6	None	Animals	200	Oral	mg/kg	Unspecified

**Mutagenicity:** Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Cisatracurium Besylate 96946-42-8	Negative	Negative	Equivocal results	No Data.

**Aspiration hazard:** Not determined

**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

## Section 12. Ecological information

### 12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Cisatracurium Besylate 96946-42-8	0.1-1	14	Daphnia magna	48 Hours

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Cisatracurium Besylate 96946-42-8	0.1-1	>4000	Activated sludge	72 Hours

### 12.2. Persistence and degradability

Readily biodegradable.

Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Cisatracurium Besylate 96946-42-8	0.1-1	82.26	28 days

### 12.3. Bioaccumulative potential

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Not determined

#### **12.4. Mobility in soil**

Not determined.

#### **12.5. Results of PBT or vPvB assessment**

Chemical safety report is not required for this substance/product.

#### **12.6. Other adverse effects**

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.

### **Section 13. Disposal considerations**

#### **13.1 Waste treatment methods**

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

### **Section 14. Transport information**

#### **ADR, DOT, ICAO/IATA, IMDG/IMO**

**Status:** Not regulated

- 14.1. UN Number:** Not applicable  
**14.2. Proper shipping name:** Not applicable  
**14.3. Hazard class:** Not applicable  
**14.4. Packing group:** Not applicable  
**14.5. Environmental hazard:** Not applicable  
**14.6. Special Provisions:** Not applicable  
**14.7. Transport in bulk** Not applicable

according to Annex II of  
MARPOL 73/78 and the IBC

**Code:**

### **Section 15. Regulatory Information**

#### **15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

#### **International Inventories**

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Water 7732-18-5	Present	X	X	Not listed.	X
Cisatracurium Besylate 96946-42-8	-	-	-	Not listed.	-
Benzyl Alcohol 100-51-6	Present	X	X	Not listed.	X

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Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Water 7732-18-5	-	2-(4)-1220	X	X	Present	
Cisatracurium Besylate 96946-42-8	-	-	-	-	-	
Benzyl Alcohol 100-51-6	Present	-	X	X	Present	HSR001039

**Legend**

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List  
PICCS - Philippines Inventory of Chemicals and Chemical Substances  
ENCS - Japan Existing and New Chemical Substances  
ISHL - Japan Industrial Safety and Health Law  
IECSC - China Inventory of Existing Chemical Substances  
AICS - Australian Inventory of Chemical Substances  
KECL - Korean Existing and Evaluated Chemical Substances

**Carcinogenicity Rating:**

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Water	98-99.8	Not Listed	Not Listed	Not Listed
Cisatracurium Besylate	0.1-1	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	0.1-1	Not Listed	Not Listed	Not Listed

**SARA 313 Information**

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	98-99.8	No	Not Applicable	Not applicable
Cisatracurium Besylate	0.1-1	No	Not Applicable	Not applicable
Benzyl Alcohol	0.1-1	No	Not Applicable	Not applicable

**Immediate Health:** Yes  
**Delayed Health:** No  
**Fire:** No  
**Sudden Pressure:** No  
**Reactivity:** No

**RCRA Status:** Not determined.

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

**WHMIS Hazard Class:** D1B TOXIC MATERIALS.

**NFPA Rating:**  
Health: 1  
Fire: 0  
Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, 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.

**15.2. Chemical safety assessment**

Chemical safety assessment has not been conducted on the substance/product.



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## Section 16. Other information

**Document Authored By:** Global Occupational Toxicology (D-03QC)

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**Supersedes the SDS dated:** Jun-12-2013

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