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

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

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

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.
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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Employee Exposure Limit</th>
<th>Skin Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance:</td>
<td>Colorless Mixture Blend Slight Yellow Solution</td>
</tr>
<tr>
<td>Odor:</td>
<td>Odorless.</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH:</td>
<td>3 - 3.8</td>
</tr>
<tr>
<td>Boiling Pt. @ 760 mm Hg (°C):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flash Point (°C):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Evaporation Rate at 20°C:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flammability (Solid):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Lower Explosive Limit:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Upper Explosive Limit:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapor Density (Air = 1):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Density, g / mL:</td>
<td>0.995 - 1.005</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Solubility(ies):</td>
<td>Freely soluble in: water.</td>
</tr>
<tr>
<td>Partition coefficient:</td>
<td>Not determined</td>
</tr>
<tr>
<td>n-octanol/water:</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temp. (°C):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Decomposition temperature (°C):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Viscosity (centipoise):</td>
<td>Not determined</td>
</tr>
<tr>
<td>Explosion Severity:</td>
<td>Not determined</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisatracurium Besylate 96946-42-8</td>
<td>LD50 =</td>
<td>50 &lt; LD50 &lt; 500</td>
<td>mg/kg, for a similar material</td>
<td>Rats</td>
</tr>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>LD50 =</td>
<td>1040-3100</td>
<td>mg/kg</td>
<td>Animals</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>LD50 =</td>
<td>2000</td>
<td>mg/kg</td>
<td>Rats</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>LC 50 =</td>
<td>2000</td>
<td>ppm</td>
<td>Rats</td>
</tr>
</tbody>
</table>
Product Name: Nimbex Injection
Issued: Jun-22-2015

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Site of Tumors</th>
<th>Species</th>
<th>Dosage</th>
<th>Route</th>
<th>Units</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>None</td>
<td>Animals</td>
<td>200</td>
<td>Oral</td>
<td>mg/kg</td>
<td>Unspecified</td>
</tr>
</tbody>
</table>

Mutagenicity: Data for component(s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Micronucleus Assay</th>
<th>Ames Test:</th>
<th>Mouse Lymphoma Assay</th>
<th>Chromosomal Abbr. Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisatracurium Besylate 96946-42-8</td>
<td>Negative</td>
<td>Negative</td>
<td>Equivocal results</td>
<td>No Data.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>48h EC50 (daphnia - mg/l) (48HLCD)</th>
<th>Species</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisatracurium Besylate 96946-42-8</td>
<td>0.1-1</td>
<td>14</td>
<td>Daphnia magna</td>
<td>48 Hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>72h IC50 (algae - mg/l) (72HICA)</th>
<th>Species</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisatracurium Besylate 96946-42-8</td>
<td>0.1-1</td>
<td>&gt;4000</td>
<td>Activated sludge</td>
<td>72 Hours</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

Readily biodegradable.

Data for component(s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>% Degradation</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisatracurium Besylate 96946-42-8</td>
<td>0.1-1</td>
<td>82.26</td>
<td>28 days</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential
Product Name: Nimbex Injection
Issued: Jun-22-2015

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 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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>EINECS/ ELINCS</th>
<th>TSCA</th>
<th>DSL</th>
<th>NDSL</th>
<th>PICCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water 7732-18-5</td>
<td>Present</td>
<td>X</td>
<td>X</td>
<td>Not listed.</td>
<td>X</td>
</tr>
<tr>
<td>Cisatracurium Besylate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Not listed.</td>
<td>-</td>
</tr>
<tr>
<td>96946-42-8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>Present</td>
<td>X</td>
<td>X</td>
<td>Not listed.</td>
<td>X</td>
</tr>
</tbody>
</table>
**Product Name:** Nimbex Injection  
**Issued:** Jun-22-2015

### Chemical Name Table

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ENCS</th>
<th>ISHL</th>
<th>IECSC</th>
<th>AICS</th>
<th>KECL</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water 7732-18-5</td>
<td>-</td>
<td>2-(4)-1220</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Present</td>
</tr>
<tr>
<td>Cisatracurium Besylate 960946-42-8</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Benzy1 Alcohol 100-51-6</td>
<td>Present</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Present</td>
<td>HSR001039</td>
</tr>
</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>NTP:</th>
<th>IARC:</th>
<th>ACGIH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>98-99.8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Cisatracurium Besylate</td>
<td>0.1-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Benzy1 Alcohol</td>
<td>0.1-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### SARA 313 Information

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>SARA 313 Chemical:</th>
<th>CERCLA RQ/SARA EHS RQ (lbs):</th>
<th>SARA EHS TPQ (lbs):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>98-99.8</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Cisatracurium Besylate</td>
<td>0.1-1</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Benzy1 Alcohol</td>
<td>0.1-1</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**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.  
4. TSCA = Toxic Substances Control Act.  
5. EC = European Community.  

### 15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.
Section 16. Other information

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

Issued:  Jun-22-2015

Supersedes the SDS dated:  Jun-12-2013

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