

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Tracrium Injection  
**Synonyms:** Tracrium Injection, 10 mg/mL: Atracurium Besylate Injection: Tracrium Injection  
Single Dose Vials: Tracrium Injection Multiple Dose Vials  
**Trade name:** Tracrium  
**List Number:** 4440: 4468

#### **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  
1-800-255-5162  
+1-847-937-7433  
**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:** Tracrium Injection  
**Issued:** Jun-12-2013

## Section 2. Hazards identification

### 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<br>7732-18-5                | 98-99   | Present              |                    | Not Hazardous*                             | No data available |
| Atracurium Besylate<br>64228-81-5 | 1-5     | Present              | T; R25             | Acute Tox. 3 (H301)                        | No data available |
| Benzyl Alcohol<br>100-51-6        | 0-1     | Present              | Xn; R20/22         | Acute Tox. 4 (H332)<br>Acute 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:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

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

**Signs and Symptoms:** Available information support the following: altered blood pressure, flushing, muscle weakness.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to the material and/or similar materials.

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

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

**Notes To Physician:** Treat symptomatically

## **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**

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

**Exposure limits:**

| Chemical Name                     | Employee Exposure Limit                               | Skin Notation |
|-----------------------------------|---|---------------|
| Water<br>7732-18-5                | Not Applicable  | None          |
| Atracurium Besylate<br>64228-81-5 | 0.1 mg/m <sup>3</sup> TWA, 0.5 mg/m <sup>3</sup> STEL | None          |
| Benzyl Alcohol<br>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:** Clear Colorless Mixture Blend Slight Yellow Solution

**Odor:** Not determined.

**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.

**Specific Gravity:** Not determined.

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

**Partition coefficient: n-octanol/water** Not determined.

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

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

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

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

Not determined

### **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 |
|-----------------------------------|------------|-----------|-------|---------|
| Atracurium Besylate<br>64228-81-5 | LD50 >     | 50        | mg/kg | Rats    |
|                                   | LD50 <     | 500       | mg/kg | Rats    |
| Benzyl Alcohol<br>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 |
|-----------------------------------|------------|-------|-------|---------|
| Atracurium Besylate<br>64228-81-5 | LD50 >     | 2000  | mg/kg | Rats    |
| Benzyl Alcohol<br>100-51-6        | LD50 =     | 2000  | mg/kg | Rabbits |

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

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

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

**Other Toxicology Data:** Data for component (s) given below:

| Chemical Name                     | Test Type   | Value     | Units | Species      | Comments |
|-----------------------------------|-------------|-----------|-------|--------------|----------|
| Atracurium Besylate<br>64228-81-5 | LD50 (iv) = | 1.3 - 2.0 | mg/kg | Mice<br>Rats |          |
|                                   | LD50 (sc) = | 283       |       | Rats         |          |

**Corrosivity:** Not determined.

**Dermal Irritation:** Active Ingredient : Did not produce skin irritation in rabbits.

**Eye Irritation:** Active Ingredient : Produced mild to moderate eye irritation in rabbits. Recovery after 72 hours.

**Sensitization:** Active Ingredient : Negative in the maximization assay in guinea pigs at challenge concentrations.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Active Ingredient : In animals adverse reproductive effects include: maternal toxicity, fetal abnormalities. Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity  
Data for component (s) given below.

| Chemical Name                     | Species | Dosage | Units | Route        | Duration         |
|-----------------------------------|---------|--------|-------|--------------|------------------|
| Atracurium Besylate<br>64228-81-5 | Rabbits | 0.15   | mg/kg | Subcutaneous | During Gestation |

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

| Chemical Name              | Site of Tumors | Species | Dosage | Route | Units | Duration    |
|----------------------------|----------------|---------|--------|-------|-------|-------------|
| Benzyl Alcohol<br>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 |
|-----------------------------------|--------------------|------------|----------------------|-------------------------|
| Atracurium Besylate<br>64228-81-5 | 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

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

## **Section 12. Ecological information**

### **12.1. Toxicity**

Not determined.

### **12.2. Persistence and degradability**

Not determined.

### **12.3. Bioaccumulative potential**

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

- |  |                |
|--|----------------|
| <b>14.1. UN Number:</b>  | Not applicable |
| <b>14.2. Proper shipping name:</b>   | Not applicable |
| <b>14.3. Hazard class:</b>   | Not applicable |
| <b>14.4. Packing group:</b>  | Not applicable |
| <b>14.5. Environmental hazard:</b>   | Not applicable |
| <b>14.6. Special Provisions:</b>   | Not applicable |
| <b>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b> | Not applicable |

**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

## 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<br>7732-18-5                | Present        | X    | X   | Not listed. | X     |
| Atracurium Besylate<br>64228-81-5 | Present        | -    | -   | Not listed. | -     |
| Benzyl Alcohol<br>100-51-6        | Present        | X    | X   | Not listed. | X     |

| Chemical Name                     | ENCS    | ISHL       | IECSC | AICS | KECL    | New Zealand |
|-----------------------------------|---------|------------|-------|------|---------|-------------|
| Water<br>7732-18-5                | -       | 2-(4)-1220 | X     | X    | Present |             |
| Atracurium Besylate<br>64228-81-5 | -       | -          | -     | -    | -       |             |
| Benzyl Alcohol<br>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   | Not Listed | Not Listed | Not Listed |
| Atracurium Besylate | 1-5     | Not Listed | Not Listed | Not Listed |
| Benzyl Alcohol      | 0-1     | 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   | No                 | Not Applicable               | Not applicable      |
| Atracurium Besylate | 1-5     | No                 | Not Applicable               | Not applicable      |
| Benzyl Alcohol      | 0-1     | 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.



**Product Name:** Tracrium Injection  
**Issued:** Jun-12-2013

**WHMIS Hazard Class:** Not determined.

**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.

|                                      |
|--------------------------------------|
| <b>Section 16. Other information</b> |
|--------------------------------------|

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

**Issued:** Jun-12-2013

**Disclaimer:**

*The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.*