


|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP (1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>1 of 10</b> |

### Section 1 - Identification


- (a) **Product Identifier:** Terbutaline Sulfate Injection, USP (1 mg/mL)
- (b) **Product Code:** 70860-801
- Common/Trade Name:** Terbutaline Sulfate
- Chemical Name:** (±)-α-[(tert-butylamino)methyl]-3,5-dihydroxybenzyl alcohol sulfate (2:1) (salt)
- Chemical Family:** Sympathomimetic amine
- (c) **Product Use:** Bronchodilator (Pharmaceutical, Injectable)
- Product Type:** Regulated Prescription Drug
- Container Information:** Single Dose Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification

- (a) **Classification:** None

|  |  |
|--|--|
| <b>(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):</b> | <b>(c) Description of Hazards:</b>   |
| <b>Signal Word:</b>  | Not Available  |
| <b>Emergency Overview</b>  | <p>This material is intended for subcutaneous injection under the supervision of physicians.</p> <p>Overexposure may cause damage to the cardiovascular system. Avoid breathing vapor. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Wash thoroughly after handling.</p> |

- (d) **Unknown Acute Toxicity** N/A

|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>2 of 10</b> |


### Section 3 – Composition / Information on Ingredients

| (a) Chemical Name  | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|--|---------------------------|--------------------------------|-------------|--|
| (±)-α-[(tert-butylamino)methyl]-3,5-dihydroxybenzyl alcohol sulfate (2:1) (salt) | Terbutaline               | 0.1                            | 23031-32-5  | N/A                                    |
| NaCl   | Sodium chloride           | 0.89                           | 7647-14-5   | N/A                                    |
| HCl  | Hydrochloric Acid*        | -                              | 7647-01-0   | N/A                                    |

\*Used for pH adjustment

### Section 4 – First Aid Measures

- Eye Exposure:** Contact may cause irritation. Effects may include stinging, watering, and redness of the eyes. Immediately flush eyes with water for at least 15 minutes. Seek medical attention if redness occurs.
- Skin Exposure:** Contact may cause irritation. Effects may include redness and a burning sensation on the skin. Terbutaline Sulfate is known to be absorbed through the skin. Symptoms similar to those identified under injection may occur. Cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.
- Ingestion:** Although ingestion is not an anticipated route of occupational exposure, this material has a moderate degree of toxicity. Harmful effects from swallowing are not expected. Symptoms similar to those identified under injection may occur. If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO not induce vomiting. If possible do not leave victim unattended and observe closely for adequacy of breathing.
- Injection:** Local redness and pain are the primary symptoms of accidental injection in an occupational setting.

|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>3 of 10</b> |

**Inhalation:** Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers. If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

**Notes to Physician:** Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).
- (b) **Hazardous Combustion Products:** When heated to decomposition, toxic fumes may be emitted. Thermal decomposition or burning may produce noxious products including carbon monoxide, carbon dioxide, sulfur oxides, and nitrogen oxides.
- (c) **Special Protective Equipment / Precautions:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.


### Section 6 - Accidental Release Measures

**Spill:** Wear recommended personal protective equipment.  
Use absorbent towels or brooms to clean-up spill.  
Wipe surface area clean with soap and water.

*For large/uncontrolled releases:* Stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant.

**Release to Air:** If aerosolized, reduce exposures by ventilating area. Clean up immediately.

**Release to Water:** Prevent spilled materials from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Refer to local and regional water authority requirements.

|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>4 of 10</b> |

### Section 7 - Handling and Storage

**General Handling:** When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors.

**Storage Conditions:** Store at 20° to 25°C (68° to 77°F). Protect from light. Retain in carton until time of use. Follow instructions provided in packaging.

### Section 8 - Exposure Controls / Personal Protection

**(a) Exposure Limits**

| Compound            | Issuer | Type | Exposure Limit |
|---------------------|--------|------|----------------|
| Terbutaline Sulfate | OSHA   | TLV  | NE             |
|                     | ACGIH  | PEL  | NE             |


**(b) Engineering Controls**

Ventilation: Use local ventilation if necessary.

**(c) Individual Protection Measures**

|                                  |   |
|----------------------------------|---|
| Respiratory Protection:          | With satisfactory ventilation, respiratory protection is usually not required.                  |
| Eye Protection:                  | Safety glasses or chemical splash goggles recommended.  |
| Skin Protection:                 | Latex or nitrile gloves recommended. Disposable garments if direct skin contact is anticipated. |
| Other Protective Equipment:      | Wear appropriate chemical resistant clothing.   |
| Additional Exposure Precautions: | Not available.  |

### Section 9 - Physical and Chemical Properties


|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>5 of 10</b> |

|            |   |   |
|------------|---|---|
| <b>(a)</b> | <b>Appearance</b>                                   | White to gray-white crystalline powder in an aqueous solution.          |
| <b>(b)</b> | <b>Odor</b>   | Faint odor of acetic acid   |
| <b>(c)</b> | <b>Odor Threshold</b>                               | Not available   |
| <b>(d)</b> | <b>pH</b>   | 3.0-5.0 target pH of 4.0  |
| <b>(e)</b> | <b>Melting Point:</b>                               | Not available   |
| <b>(f)</b> | <b>Initial Boiling Point:</b>                       | 100° C (212° F)   |
| <b>(g)</b> | <b>Flash Point</b>                                  | Not available   |
| <b>(h)</b> | <b>Evaporation Rate:</b>                            | Not available   |
| <b>(i)</b> | <b>Flammability</b>                                 | Not available   |
| <b>(j)</b> | <b>Upper Lower Flammability or Explosion Limits</b> | Not available   |
| <b>(k)</b> | <b>Vapor Pressure:</b>                              | Not available   |
| <b>(l)</b> | <b>Vapor Density:</b>                               | Not available   |
| <b>(m)</b> | <b>Relative Density</b>                             | Not available   |
| <b>(n)</b> | <b>Solubility(ies)</b>                              | Soluble in water, slightly soluble in methanol, insoluble in chloroform |
| <b>(o)</b> | <b>Partition Coefficient: n-octanol/water</b>       | Not available   |
| <b>(p)</b> | <b>Auto-ignition Temperature</b>                    | Not available   |
| <b>(q)</b> | <b>Decomposition Temperature</b>                    | Not available   |
| <b>(r)</b> | <b>Viscosity</b>                                    | Not available   |


**Section 10 - Stability and Reactivity**

|            |   |   |
|------------|---|---|
| <b>(a)</b> | <b>Reactivity</b>                         | No data available.  |
| <b>(b)</b> | <b>Chemical Stability</b>                 | Material is stable under normal conditions                |
| <b>(c)</b> | <b>Possibility of Hazardous Reactions</b> | No data available.  |
| <b>(d)</b> | <b>Conditions to Avoid</b>                | Avoid storage near oxidizers and water reactive materials |
| <b>(e)</b> | <b>Incompatible Materials</b>             | None known.   |
| <b>(f)</b> | <b>Hazardous Decomposition Products</b>   | No data available.  |

**Section 11 - Toxicological Information**

|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>6 of 10</b> |

|            |   |   |
|------------|---|---|
| <b>(a)</b> | <b>Likely Routes of Exposure</b>  | Inhalation, eye/skin contact or ingestion.  |
| <b>(b)</b> | <b>Symptoms related to the physical, chemical and toxicological characteristics</b>             | None known from workplace exposures. In clinical use, adverse effects may include local effects at the site of injection (cutaneous irritation, erythema, or pain) following parenteral administration. Other adverse effects have included headache, dizziness, fatigue, insomnia, confusion, depression, agitation, tremors, seizures, nausea/vomiting, diarrhea, abdominal pain, increased BUN, decreased creatinine clearance, impaired renal function, obstructive nephropathy and acute renal failure, elevated liver function tests, rash and urticaria. Rarely anemia, neutropenia, thrombocytopenia, thrombocytosis, leukocytosis, and neutrophilia have been reported.  |
| <b>(c)</b> | <b>Delayed and immediate effects and also chronic effects from short and long term exposure</b> | <p><i>Carcinogenic effects:</i> This product as well as all components of this product have NOT been identified as carcinogens by NTP, IARC or OSHA.</p> <p><i>Irritancy of Product:</i> This product can be irritating to contaminated skin, eyes and other tissues.</p> <p><i>Sensitization to the Product:</i> Hypersensitive reactions have not been observed.</p> <p><i>Mutagenic effects:</i> Studies have not been conducted.</p> <p><i>Reproductive toxicity:</i> This material is classified as a Pregnancy Category B: No evidence of risk in humans.</p> <p><i>ACGIH Biological Exposure Indices:</i> Currently there are no Biological Exposures Indices (BEIs) associated with the components of this product.</p> |

|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP (1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>7 of 10</b> |

**(d) Acute Toxicity**

| Component           | Type             | Route | Species | Dosage    |
|---------------------|------------------|-------|---------|-----------|
| Terbutaline Sulfate | LD <sub>50</sub> | Oral  | Rat     | 8.7 g/kg  |
|                     | LD <sub>50</sub> | Oral  | Mouse   | 205 mg/kg |
|                     | LD <sub>50</sub> | Oral  | Dog     | 1.5 g/kg  |
|                     | LD <sub>50</sub> | Oral  | Rabbit  | >8g/kg    |
|                     | LD <sub>50</sub> | IV    | Mouse   | 36/mg/kg  |
|                     | LD <sub>50</sub> | IV    | Dog     | 116 mg/kg |
|                     | LD <sub>50</sub> | IV    | Rat     | 69 mg/kg  |
|                     | LD <sub>50</sub> | IV    | Rabbit  | 110 mg/kg |
|                     | LD <sub>50</sub> | IP    | Rat     | 220 mg/kg |
|                     | LD <sub>50</sub> | IP    | Mouse   | 130 mg/kg |
|                     | LD <sub>50</sub> | SC    | Rat     | 130 mg/kg |
|                     | LD <sub>50</sub> | SC    | Mouse   | 260 mg/kg |

**(e) Hazardous Chemical Listings**

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

**Section 12 - Ecological Information**

|  |                    |
|--|--------------------|
| <b>(a) Ecotoxicity</b>                   | No data available. |
| <b>(b) Persistence and degradability</b> | No data available. |
| <b>(c) Bioaccumulative potential</b>     | No data available. |
| <b>(d) Mobility in soil</b>              | No data available. |
| <b>(e) Other Adverse Effects</b>         | No data available. |

**Section 13 - Disposal Considerations**


**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**Section 14 - Transport Information**

**DOT:** N/A

**IATA:** N/A

**IMDG:** N/A

|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>8 of 10</b> |

|            |   |               |
|------------|---|---------------|
| <b>(a)</b> | <b>UN Number</b>  | Not Available |
| <b>(b)</b> | <b>UN Proper Shipping Name</b>  | Not Available |
| <b>(c)</b> | <b>Transport Hazard Class(es)</b>   | Not Available |
| <b>(d)</b> | <b>Packing Group</b>  | Not Available |
| <b>(e)</b> | <b>Environmental Hazards</b>  | Not Available |
| <b>(f)</b> | <b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b> | Not Available |
| <b>(g)</b> | <b>Special Precautions</b>  | Not Available |

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**

- TSCA – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 304: Not regulated
- SARA 313 - Not on this list


**Section 16 - Other Information**

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division  
 10 N. Martingale Road, Suite 230




|  |  |                           |                                |                        |
|--|--|---------------------------|--------------------------------|------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                        |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>9 of 10</b> |

847-886-9515

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

|            |   |
|------------|---|
| ACGIH      | American Conference of Governmental Industrial Hygienists               |
| AICS       | Australian Inventory of Chemical Substances                             |
| AIHA       | American Industrial Hygiene Association                                 |
| ANSI       | American National Standards Institute                                   |
| CAS Number | Chemical Abstract Service Registry Number                               |
| CERCLA     | Comprehensive Environmental Response Compensation and Liability Act (of |
| CHAN       | Chemical Hazard Alert Notice  |
| CHEMTREC   | Chemical Transportation Emergency Center                                |
| DOT        | Department of Transportation  |
| DSL        | Domestic Substances List  |
| ECHA       | European Chemicals Agency   |
| EINECS     | European Inventory of Existing Commercial Chemical Substances           |
| ELINCS     | European List of Notified Chemical Substances                           |
| EPA        | Environmental Protection Agency   |
| GHS        | Globally Harmonized System of Classification and Labelling of Chemicals |
| HEPA       | High Efficiency Particulate Air (Filter)                                |
| HMIS       | Hazardous Materials Identification System                               |
| IARC       | International Agency for Research on Cancer                             |
| ICAO/IATA  | International Civil Aviation Organization/International Air Transport   |
| IMO        | International Maritime Organization                                     |
| KOW        | Octanol/Water Partition Coefficient                                     |
| LEL        | Lower Explosive Limit   |
| MSDS       | Material Safety Data Sheet  |
| MSHA       | Mine Safety and Health Administration                                   |
| NA         | Not Applicable, except in Section 14 where NA = North America           |
| NE         | Not Established   |
| NADA       | New Animal Drug Application   |
| NAIF       | No Applicable Information Found   |
| NCI        | National Cancer Institute   |
| NDSL       | Non-Domestic Substances List  |
| NFPA       | National Fire Protection Association                                    |
| NIOSH      | National Institute for Occupational Safety and Health                   |
| NPDES      | National Pollutant Discharge Elimination System                         |
| NOS        | Not Otherwise Specified   |
| NTP        | National Toxicology Program   |
| OSHA       | Occupational Safety and Health Administration                           |
| OEL        | Occupational Exposure Limit   |
| PEL        | Permissible Exposure Limit (OSHA)                                       |
| RCRA       | Resource Conservation and Recovery Act                                  |
| RQ         | Reportable Quantity   |
| RTECS      | Registry of Toxic Effects of Chemical Substances                        |
| SARA       | Superfund Amendments and Reauthorization Act                            |
| SDS        | Safety Data Sheet   |
| STEL       | Short Term Exposure Limit   |
| TLV        | Threshold Limit Value (ACGIH)   |

|  |  |                           |                                |                         |
|--|--|---------------------------|--------------------------------|-------------------------|
| <br><b>Pharmaceutical Division</b> | <b>Terbutaline Sulfate Injection, USP<br/>(1mg/mL)</b> |                           | <b>Safety Data Sheet (SDS)</b> |                         |
|  | Effective Date:<br><b>07JUN2017</b>                    | SDS No.:<br><b>SDS010</b> | Revision No:<br><b>01</b>      | Page<br><b>10 of 10</b> |

|       |  |
|-------|--|
| TPQ   | Threshold Planning Quantity                          |
| TSCA  | Toxic Substances Control Act                         |
| TWA   | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL   | Upper Explosive Limit                                |
| UN    | United Nations                                       |
| USP   | United States Pharmacopeia                           |
| WEEL  | Workplace Environmental Exposure Level (AIHA)        |
| WHMIS | Workplace Hazardous Materials Information System     |

## Signature Manifest

**Document Number:** SDS010

**Revision:** 01

**Title:** Terbutaline Sulfate Injection, USP (1 mg/mL)

All dates and times are in Eastern Standard Time.

**SDS010**

### Change Request

| Name/Signature               | Title               | Date                     | Meaning/Reason |
|------------------------------|---------------------|--------------------------|----------------|
| Michael Scribner (MSCRIBNER) | Director of Quality | 05 Jun 2017, 05:32:36 PM | Approved       |

### Dept Approval

| Name/Signature         | Title                    | Date                     | Meaning/Reason |
|------------------------|--------------------------|--------------------------|----------------|
| Tom Moutvic (TMOUTVIC) | VP of Regulatory Affairs | 06 Jun 2017, 10:40:00 AM | Approved       |

### Final QA Approval/Set Effective Date

| Name/Signature        | Title                   | Date                     | Meaning/Reason |
|-----------------------|-------------------------|--------------------------|----------------|
| Sheila Moran (SMORAN) | VP of Quality Assurance | 06 Jun 2017, 11:08:14 AM | Approved       |