



MATERIAL SAFETY DATA SHEET

NeoSan Pharmaceuticals, Inc.
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24 Hour Emergency Telephone Number: Tel: 910-254-7240 Mobile: 910-233-0418
Customer Response (MSDS Requests) 8:00 AM to 5:30 PM E.S.T.: 910-254-7300/7190/7030
For Non-Emergency Situation 8:00 AM - 6:00 PM E.S.T: 910-254-7000

SECTION 1. PRODUCT IDENTIFICATION

PRODUCT NAME: Brethine® Ampuls
PRODUCT CODE(S): NDC 0028-7507-01,23
SYNONYMS: Terbutaline sulfate injection USP
THERAPEUTIC CATEGORY: β-adrenergic agonist bronchodilator
GENERIC NAME: None
CHEMICAL NAME: (±)-α-[(tert-butylamino)methyl]-3,5-dihydroxybenzyl alcohol sulfate (2:1) (salt)
CHEMICAL FORMULA: C24H40N2O10S
MOLECULAR WEIGHT: 548.65

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS

Table with 3 columns: COMPOSITION, CAS#, CONCENTRATION (% BY WT.)
Row 1: Terbutaline Sulfate, 23031-32-5, ~99

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

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FINISHED PHARMACEUTICAL PRODUCT
REFER TO PHYSICIANS' DESK REFERENCE
ACTIVE INGREDIENT: TOXIC/ EXPERIMENTAL CARCINOGEN
AFFECTS CARDIOVASCULAR SYSTEM
\*\*\*\*\*



PRIMARY ROUTE (S) OF ENTRY: Not applicable

EFFECTS OF OVEREXPOSURE: Finished pharmaceutical product. Potential for exposure is reduced in this form.

Skin: Direct contact may cause skin irritation.

Eye: Direct contact may cause eye irritation.

Inhalation: No hazard is expected from normal clinical use.

Ingestion: No hazard is expected from normal clinical use.

THERAPEUTIC SIDE EFFECTS: Cardiovascular effects (palpitations, tachycardia), headache, dyspnea, nervousness and drowsiness.

TARGET ORGAN EFFECTS: Prolonged or repeated exposure can cause significant cardiovascular disturbances.

REPRODUCTIVE HAZARDS: There are no known or reported effects on reproductive function or fetal development.

CARCINOGENICITY: Experimental carcinogen. No information is available for humans.

Active ingredient:

ACGIH: Not listed

EPA: Not listed

IARC: Not listed

MAK: Not listed

NIOSH: Not listed

NTP: Not listed

OSHA: Not listed

MUTAGENICITY: Studies of terbutaline sulfate have not been conducted to determine mutagenic potential.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing cardiac disorders or hypersensitivity to terbutaline sulfate.

#### SECTION 4. EMERGENCY AND FIRST AID MEASURES

Skin Contact: Wash contaminated area with soap and water.

Eye Contact: Flush with running water for 15 minutes holding eyelids open.

Inhalation: No specific treatment is necessary since this product is not likely to be hazardous by inhalation.

Ingestion: Get medical attention immediately.



### SECTION 5. FIRE FIGHTING MEASURES

Flash Point: not applicable Method Used: not applicable

Flammable Limits (% in air)

Lower: not applicable Upper: not applicable

Autoignition Temperature:

Not available

Extinguishing Media:

Use media suitable for fire in surrounding area.

Special Fire Fighting Procedures and Precautions:

Evacuate area and fight fire from safe distance.

Fire and Explosion Hazards:

Not available

Fire-Fighting Equipment:

Wear full protective clothing and positive pressure self-contained breathing apparatus.

Decomposition Products:

Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide, nitrogen oxides and sulfur oxides.

NFPA Ratings: Health = 1 Flammability = U Reactivity = 0 Special Hazard = None

Hazard Rating Scales: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe U = Unknown

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Steps to be taken if Material is Released or Spilled: Using appropriate protective equipment, sweep up and containerize spilled material. Avoid contamination of sewers and waterways.

### SECTION 7. HANDLING AND STORAGE

Storage Temperature (Min./Max.): 59°F (15°C)/86°F (30°C)

Shelf Life: Two years

Special Sensitivity:

Protect from light and temperatures below 59°F (15°C) and above 86°F (30°C).

Handling and Storage Precautions:

Do not use if solution is discolored.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection:

Not required under normal conditions of therapeutic administration and use.

Skin Protection:

Not required under normal conditions of therapeutic administration and use.

Respiratory Protection:

Not required under normal conditions of therapeutic administration and use.

Ventilation Requirements:

Not required under normal conditions of therapeutic administration and use.

Additional Measures:

None

**Exposure Limits (Definition of terms):**

ACGIH:	American Conference of Governmental Industrial Hygienists
Ceiling:	Ceiling Value
DTEL:	Derived-Target Exposure Limit
MAK:	Federal Republic of Germany Maximum Concentration Values in the Workplace
NIOSH:	National Institute for Occupational Safety and Health
OSHA:	Occupational Safety and Health Administration [USA]
PEL:	Permissible Exposure Limit
PIEL:	Permissible Internal Exposure Limit [Novartis internal]
REL:	Recommended Exposure Limit
Skin (notation):	absorbed through skin
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Values
TWA:	Time-Weighted Average

ComponentExposure Limit

Terbutaline Sulfate

DTEL = 0.025mg/m<sup>3</sup>**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance:	Solution in ampuls	Odor Threshold:	not available
Color:	Clear, water-white	Vapor Pressure (mm Hg):	not available
pH:	4.0	Vapor Density:	not available
Boiling Point:	not available	Specific Gravity:	not available
Melting Point/Range:	not applicable	% Volatile by Wt:	not available
Freezing Point:	not available	Viscosity:	not available
Soluble In:	Water		

**SECTION 10. STABILITY AND REACTIVITY**

Stable (yes/no):	Yes
Hazardous Polymerization:	Will not occur.
Conditions and Materials to Avoid:	Protect from light. Avoid temperatures exceeding 86°F (30°C).
Incompatibility:	Not known.
Hazardous Decomposition Products:	Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide, nitrogen oxides and sulfur oxides.

**SECTION 11. TOXICOLOGICAL INFORMATION****On Finished Pharmaceutical Product:**LD<sub>50</sub> (oral-rat) > 5,000 mg/kgLD<sub>50</sub> (iv-rat) = 61.5 mg/kgLD<sub>50</sub> (iv-mouse) = 48.4 mg/kg

**On Active Ingredient:****Eye Irritation:**

Minimally irritating to the eyes of albino rabbits.

**Skin Irritation/Sensitization:**

Minimally irritating to the skin of albino rabbits. No evidence of hypersensitivity-type response observed.

**Oral Toxicity:**LD<sub>50</sub> (mice) = 205 mg/kgLD<sub>50</sub> (rats) = 8,700 mg/kg**Dermal Toxicity:**LD<sub>50</sub> (rabbits) = 3,038 mg/kg.**Inhalation Toxicity:**No deaths were observed in rats after 14 days following a 4 hour exposure; LC<sub>50</sub> >2,180 mg/m<sup>3</sup> air. Hypoactivity was observed in all rats at 185 minutes and lasted 55 minutes.**Subchronic:**

No well-controlled studies have been performed.

**Chronic/Carcinogenicity:**

A 2-year oral carcinogenesis bioassay in rats caused a significant dose-related increase in changes in the female genital system at doses corresponding to 5,000, 50,000, 100,000 and 200,000 times the maximum recommended human subcutaneous dose. An 18 month oral study in mice revealed no evidence of tumorigenicity at doses up to 200 mg/kg (20,000 times the recommended human subcutaneous dose).

**Mutagenicity:**

Studies of terbutaline sulfate have not been conducted to determine mutagenic potential.

**Reproductive Effects:****FDA Use-in-Pregnancy Category B:** No evidence of risk in humans  
Reproduction studies performed in mice, rats or rabbits at doses up to 1,500 times the subcutaneous maximum daily human dose of 0.01 mg/kg have revealed no evidence of impaired fertility or harm to the fetus. Increased levels of maternal and fetal blood glucose have been observed after intravenous administration of terbutaline into near-term pregnant baboons at doses up to 4 times the maximum recommended human subcutaneous dose.**SECTION 12. ECOLOGICAL INFORMATION**

No data available.

**SECTION 13. DISPOSAL CONSIDERATIONS****Waste Disposal Method:**

All wastes must be disposed of in accordance with local, state and federal laws and regulations. (Contact local or state environmental agency for specific rules).

**EPA Hazardous Waste Number:**

None



## SECTION 14. TRANSPORTATION INFORMATION

### Ground Regulations:

Proper Shipping Description:	Drugs, N.O.I., NMFC Item 60000
DOT Proper Shipping Name:	Not Applicable
DOT Hazard Class:	Not Applicable
DOT Identification Number:	Not Applicable
Packing Group:	Not Applicable
Hazard Label:	Not Applicable
Package Weight Limits:	Not Applicable
Special Requirements:	Not Applicable
Exceptions:	Not Applicable
Non-Bulk Requirements:	Not Applicable
Bulk Requirements:	Not Applicable
Reportable Quantity (lbs.):	Not Applicable
Stowage:	Not Applicable
Other Requirements:	Not Applicable

### Air Regulations:

Proper Shipping Description:	Drugs, N.O.I., NMFC Item 60000
IATA Proper Shipping Name:	Not Applicable
IATA Hazard Class:	Not Applicable
IATA Identification Number:	Not Applicable
Packing Group:	Not Applicable
Hazard Label:	Not Applicable
Special Requirements:	Not Applicable
Max. wgt/pkg - Passgr. Aircraft:	Not Applicable
Max. wgt/pkg - Cargo Only Air:	Not Applicable

## SECTION 15. REGULATORY INFORMATION

OSHA (Occupational Safety & Health Administration):	This Material Safety Data Sheet contains the information required by the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).
OSHA PSM (Process Safety Management):	Not listed (29 CFR 1910.119, Appendix A).
NJ TCPA (Toxic Catastrophe Prevention Act):	This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.
TSCA (Toxic Substance Control Act):	Not applicable
CERCLA (Comprehensive Response Compensation & Liability Act):	Not listed
SARA Title III (Superfund Amendments & Reauthorization Act):	
Section 302 Extremely Hazardous Substances:	Not listed



Section 311/312 Hazard Categories:	Acute health effects
Section 313 Reportable Ingredients:	Not listed
RCRA (Resource Conservation & Recovery Act):	Not listed
Other State Regulatory Information:	
New Jersey:	NJ RTK Threshold Planning Quantity = 10,000 lbs.
Other USA Regulations:	None
California Proposition 65:	The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. <i>This product contains no chemicals known to the State of California to cause cancer or reproductive toxicity.</i>
Canada:	<u>WHMIS Ingredient Disclosure List</u> Not listed
EEC Classification (European Economic Community):	Warning Symbol: not available Risk Phrases: not available Safety Phrases: not available

**SECTION 16. OTHER INFORMATION**

Reason for Issue: Company and Emergency Telephone number changed.

Supersedes Date: New

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