

Scientific Documentation

Terbutaline Sulfate, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label

Specification for Terbutaline Sulfate, USP (T1062)

Item Number	T1062
Item	Terbutaline Sulfate, USP
CAS Number	23031-32-5
Molecular Formula	(C ₁₂ H ₁₉ NO ₃) ₂ •H ₂ SO ₄
Molecular Weight	548.65
MDL Number	
Synonyms	2-tert-Butylamino-1-(3,5-dihydroxyphenyl)ethanol Sulfate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	101.0%
CHROMATOGRAPHIC PURITY		1.0 %
ACIDITY (as ACETIC ACID)		0.3 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.2 %
ELEMENTAL IMPURITIES:		
PALLADIUM (Pd)	AS REPORTED	
SELENIUM (Se)	AS REPORTED	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	T1062	Lot Number	2KF0124
Item	Terbutaline Sulfate, USP	Manufacturer Lot	TS(D) /19008
CAS Number	23031-32-5	Manufacturer Code	14118
Molecular Formula	(C ₁₂ H ₁₉ NO ₃) ₂ •H ₂ SO ₄	Molecular Weight	548.65

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	101.0%	99.7 %
CHROMATOGRAPHIC PURITY		1.0 %	< 1.0 %
ACIDITY (as ACETIC ACID)		0.3 %	0.2 %
LOSS ON DRYING		0.5 %	0.2 %
RESIDUE ON IGNITION		0.2 %	0.2 %
ELEMENTAL IMPURITIES:			.
PALLADIUM (Pd)	AS REPORTED		0.024 ppm
SELENIUM (Se)	AS REPORTED		0.14 ppm
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			30-JUN-2024
DATE OF MANUFACTURE			01-JUL-2019
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 1 (solvent) / BENZENE			< 2 ppm
CLASS 2 (solvent) / 1,4-DIOXANE			< 380 ppm
CLASS 2 (SOLVENT) / METHANOL			< 3000 ppm
CLASS 2 (solvent) TOLUENE			< 890 ppm
CLASS 3 (solvent) / ETHANOL			< 5000 ppm
CLASS 3 (solvent) / ETHYL ACETATE			< 5000 ppm

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLASS 3 (solvent) / 2-PROPANOL			< 5000 ppm
MONOGRAPH EDITION			(USP/NF) 2021

Certificate of Analysis Results Entered By:

AJABLONSKI
Andrew Jablonski
15-JUN-21 14:07:01

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AJABLONSKI
Andrew Jablonski
15-JUN-21 14:07:03

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Melody Healthcare Pvt. Ltd. at Plot No. J-73, M.I.D.C. Tarapur Boisar, Palghar, 401506, India. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 10/23/2018

Revision Date: 10/23/2018

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: T1062
Product Name: TERBUTALINE SULFATE, USP

Other means of identification

Synonyms: 1,3-Benzenediol, 5-(2-((1,1-dimethylethyl)amino)-1-hydroxyethyl)-, sulfate (2:1) (salt)
 1-(3,5-Dihydroxyphenyl)-2-tert-butylaminoethanol sulphate
 alpha-((tert-Butylamino)methyl)-3,5-dihydroxybenzyl alcohol sulfate (2:1) (salt)
 Brethine
 Bricanyl
 Terbutaline sulphate

CAS #: 23031-32-5
RTECS # DN9000000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medicinal products.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Reproductive toxicity	Category 2
-----------------------	------------

Label elements

Warning

Hazard statements

Suspected of damaging fertility or the unborn child

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Terbutaline Sulfate	23031-32-5	100

4. FIRST AID MEASURES**First aid measures****General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed**Symptoms**

May cause cardiovascular effects
May cause central nervous system effects
Ingestion may cause vomiting and nausea
May cause eye/skin/respiratory tract irritation

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide (CO₂). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Sulfur Oxides.

Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and

sources of ignition. Protect from light. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Terbutaline Sulfate	23031-32-5	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Terbutaline Sulfate	23031-32-5	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Terbutaline Sulfate	23031-32-5	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:

Safety glasses with side-shields. or Goggles

Skin and body protection:

Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection:

Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to

use an approved/certified respirator or equivalent.

Hygiene measures:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White. Off-white. Grayish White.
Odor: Very faint. Vinegar-like. Odorless.	Taste No information available.	Formula: (C12-H19-N-O3)2.H2-SO4
Molecular/Formula weight (g/mole): 548.65	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Water Slightly soluble in Methanol Insoluble in Chloroform	

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Exposure to light. Avoid dust formation. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Sulfur oxides.

Other Information

Product code: T1062

Product name: TERBUTALINE
SULFATE, USP

5 / 11

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion.

Acute Toxicity

Component Information

Terbutaline Sulfate	
CAS-No.	23031-32-5

LD50/oral/rat = 8700 mg/kg Oral LD50 Rat
LD50/oral/mouse = 205 mg/kg
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 8700 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 205 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.
Eye Contact: Contact with eyes may cause irritation.
Inhalation May cause irritation of respiratory tract.

Ingestion Ingestion may cause nausea, vomiting. May cause flushing and sweating. May affect behavior/central nervous system (tremors, weakness, dizziness, drowsiness). May affect cardiovascular system (chest discomfort or pain, palpitations, increased heart rate).

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Terbutaline Sulfate	23031-32-5	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: May cause adverse reproductive effects based on animal data
Experiments have shown reproductive toxicity effects on laboratory animals

Developmental Effects: May cause adverse developmental effects based on animal data

Teratogenic Effects: May cause birth defects (teratogenic effects) based on animal test data
Showed teratogenic effects in animal experiments

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: Lungs. Heart. Central nervous system. Nervous system.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Terbutaline Sulfate	23031-32-5	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available
Description: No information available

ADR

UN-No: Not regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN-No: Not regulated
Proper Shipping Name: No information available
Hazard Class: No information available

Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Terbutaline Sulfate	23031-32-5	Not Listed	Present KE-11363	Present	Not present	Not present	Present	Present 245-386-3

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Terbutaline Sulfate	23031-32-5	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Terbutaline Sulfate	23031-32-5	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Terbutaline Sulfate	23031-32-5	Not Applicable	Not Applicable

Canada

Product code: T1062

Product name: TERBUTALINE
SULFATE, USP

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Terbutaline Sulfate	23031-32-5	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Terbutaline Sulfate	23031-32-5	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Terbutaline Sulfate	23031-32-5	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Terbutaline Sulfate	23031-32-5	No information

EU - CLP (1272/2008)

R-phrases(s)

Not determined

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Terbutaline Sulfate	23031-32-5		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

not determined

16. OTHER INFORMATION

Preparation Date: 10/23/2018
Revision Date: 10/23/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this

Product code: T1062

Product name: TERBUTALINE
SULFATE, USP

10 / 11

SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, 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. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
T1062	Terbutaline Sulfate, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

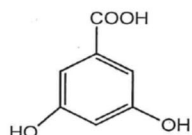
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

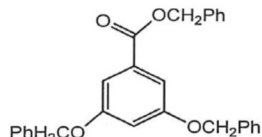
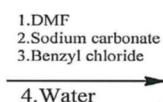
Manufacturing Process Flowchart Terbutaline Sulfate, USP (Cat# T1062)

STAGE-I DD to TS-II



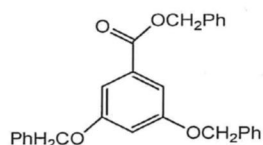
3,5-dihydroxybenzoic acid
Chemical Formula: $C_7H_6O_4$
Molecular Weight: 154.12

DD



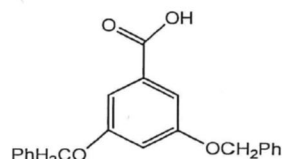
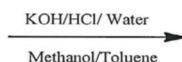
benzyl 3,5-bis(benzyloxy)benzoate or
3,5 dibenzyloxy benzyl phenyl ester
Chemical Formula: $C_{28}H_{24}O_4$
Molecular Weight: 424.49

TS-I



benzyl 3,5-bis(benzyloxy)benzoate or
3,5 dibenzyloxy benzyl phenyl ester
Chemical Formula: $C_{28}H_{24}O_4$
Molecular Weight: 424.49

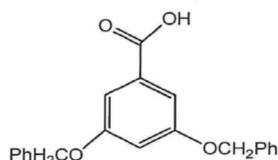
TS-I



3,5-bis(benzyloxy)benzoic acid or 3,5
dibenzyloxy benzoic acid
Chemical Formula: $C_{21}H_{18}O_4$
Molecular Weight: 334.37

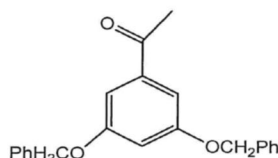
TS-II

STAGE-II TS-II to TS-V



3,5-bis(benzyloxy)benzoic acid or
3,5 dibenzyloxy benzoic acid
Chemical Formula: $C_{21}H_{18}O_4$
Molecular Weight: 334.37

TS-II



1-(3,5-bis(benzyloxy)phenyl)ethanone or 3,5
dibenzyloxy acetophenone
Chemical Formula: $C_{22}H_{20}O_3$
Molecular Weight: 332.39

TS-III

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

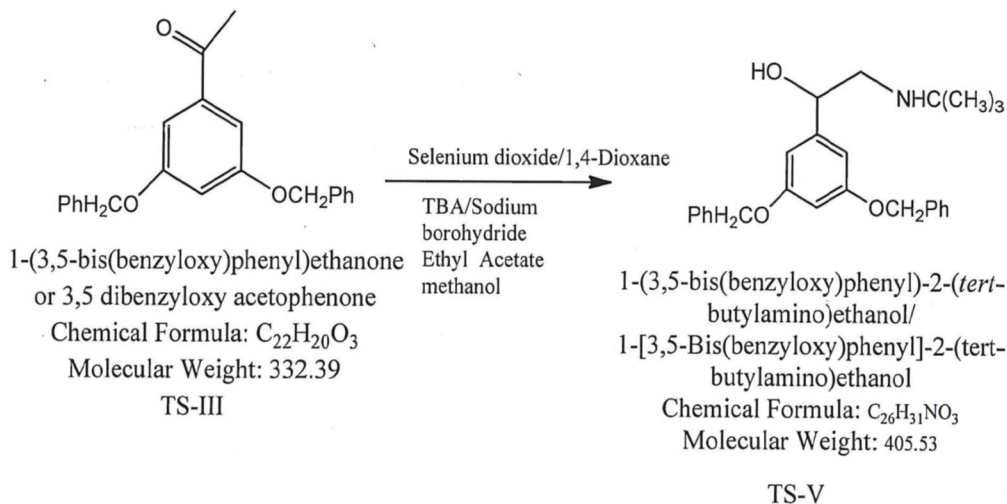
WEST COAST FACILITY

14422 South San Pedro Street

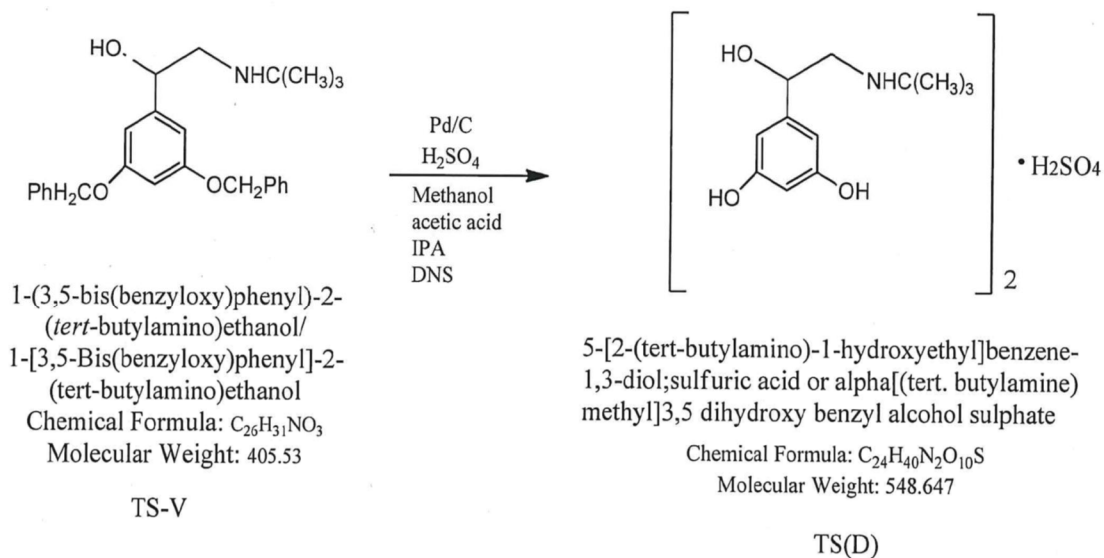
Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



STAGE-III TS-V to TS(D)



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

AN ISO 9001:2015 REGISTERED COMPANY

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

www.spectrumchemical.com

T1062, Terbutaline Sulfate, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Terbutaline Sulfate, USP (Cat# T1062)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.050 ppm
Arsenic	As	1	< 0.148 ppm
Cobalt	Co	2A	< 0.112 ppm
Nickel	Ni	2A	< 0.034 ppm
Thallium	Tl	2B	Not tested
Gold	Au	2B	Not tested
Iridium	Ir	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Lithium	Li	3	< 1.185 ppm
Antimony	Sb	3	< 0.498 ppm
Barium	Ba	3	Not tested
Molybdenum	Mo	3	Not tested
Copper	Cu	3	< 0.120 ppm
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents - Terbutaline Sulfate, USP (Cat# T1062)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Benzene	1	< 2 ppm
1,4-Dioxane	2	< 380 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm
Ethanol	3	< 5000 ppm
Ethyl Acetate	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

No other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

T1062 07-01-2019 BO ghs



WARNING

- Suspected of damaging fertility or the unborn child.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Wear protective gloves, protective clothing, eye protection, face protection.

FIRST AID: If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN

T1062

SIZ SY

Terbutaline Sulfate

USP

CAS 23031-32-5

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$(C_{12}H_{19}NO_{3/2}) \cdot H_2SO_4$ F.W. 548.65

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-101.0%
Chromatographic Purity To pass test

MAXIMUM LIMITS

Acidity (as Acetic Acid) 0.3%
Loss on Drying 0.5%
Residue on Ignition 0.2%
Elemental Impurities As reported
Residual Solvents To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

Repackaged by Spectrum as:

G 10/16GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000