

Scientific Documentation

Pentoxifylline, BP

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



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Specification for Pentoxifylline, BP (P1196)

Item Number	P1196
Item	Pentoxifylline, BP
CAS Number	6493-05-6
Molecular Formula	C ₁₃ H ₁₈ N ₄ O ₃
Molecular Weight	278.35
MDL Number	
Synonyms	Oxpentifyllin ; 3,7-Dimethyl-1-(5-oxohexyl)xanthine

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	99.0	101.0%
APPEARANCE OF SOLUTION	TO PASS TEST	
ACIDITY	TO PASS TEST	
RELATED SUBSTANCES	TO PASS TEST	
CHLORIDE (Cl)		100 ppm
SULPHATE		200 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
LOSS ON DRYING		0.5%
SULPHATED ASH		0.1%
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

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	P1196	Lot Number	4MI0003
Item	Pentoxifylline, BP	Manufacturer Lot	PBPNTNF001
CAS Number	6493-05-6	Manufacturer Code	13524
Molecular Formula	C ₁₃ H ₁₈ N ₄ O ₃	Molecular Weight	278.35

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	99.0	101.0%	100.5 %
APPEARANCE OF SOLUTION	TO PASS TEST		RohitRanjith11!
ACIDITY	TO PASS TEST		PASSES TEST
RELATED SUBSTANCES	TO PASS TEST		PASSES TEST
CHLORIDE (Cl)		100 ppm	<100 ppm
SULPHATE		200 ppm	<200 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
LOSS ON DRYING		0.5%	0.1 %
SULPHATED ASH		0.1%	0.03 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-MAY-2025
DATE OF MANUFACTURE			01-JUN-2020
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (solvent) / N,N-DIMETHYLFORMAMIDE			<880 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm
CLASS 2 (solvent) TOLUENE			<890 ppm
OTHER RESIDUAL SOLVENTS			6-CHLOROHEXNONE <1000 ppm
OTHER RESIDUAL SOLVENTS			PYRAN <1000 ppm
MONOGRAPH EDITION			BP 2023

Certificate of Analysis Results Entered By:

SVANGOOR
Swetha Vangoor
11-SEP-23 12:28:02

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA
Genaro Herrera
11-SEP-23 12:30:16

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 Sun Pharmaceutical Industries Limited at Plot No 24/2, 25, Phase IV, GIDC, Panoli, Bharuch, Gujarat 394116, India (IND). 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: 8/7/2015

Revision Date: 7/10/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: P1196
Product Name: PENTOXIFYLLINE, BP

Other means of identification

Synonyms: Theobromine, 1-(5-oxohexyl)-
 1-(5-Oxohexyl)-3,7-dimethylxanthine
 1-(5-Oxohexyl)theobromine
 1H-Purine-2,6-dione, 3,7-dihydro-3,7-dimethyl-1-(5-oxohexyl)- (9CI)
 3,7-Dihydro-3,7-dimethyl-1-(5-oxohexyl)-1H-purine-2,6-dione
 3,7-Dimethyl-1-(5-oxohexyl)-1H,3H-purin-2,6-dione
 3,7-Dimethyl-1-(5-oxohexyl)xanthine
 Dimethyloxohexylxanthine
 Oxpentifylline
 Pentoxifyllin
 Pentoxiphyllium
 Pentoxyphylline
CAS #: 6493-05-6
RTECS # XH2475000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Drug. Medication.
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)

Acute toxicity - Oral	Category 4
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Label elements

Warning**Hazard statements**

Harmful if swallowed

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Pentoxifylline	6493-05-6	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. Consult a physician if necessary.

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:

Harmful if swallowed. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

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

May cause eye/skin/respiratory tract irritation
May cause gastrointestinal disturbances
May cause cardiovascular effects

May affect behavior/central nervous system (tremor, convulsions)
Central nervous system effects
May affect the liver

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: Dry chemical. Carbon dioxide (CO₂). 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.

Specific hazards: May be combustible at high temperatures. When heated to decomposition it emits toxic fumes.

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. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid dust formation. Remove all sources of ignition. All equipment used when handling the product must be grounded.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

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 Use appropriate tools to put the spilled solid in a suitable waste disposal container. 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. All equipment used when handling the product must be grounded. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities**Technical Measures/Storage Conditions:**

Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. 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
Pentoxifylline	6493-05-6	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Pentoxifylline	6493-05-6	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Pentoxifylline	6493-05-6	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: Chemical resistant apron
Long sleeved clothing

Gloves

Respiratory protection: Effective dust mask. or. Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent. 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. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystals.	Color: White.
Odor: Odorless.	Taste No information available.	Formula: C13H18N4O3
Molecular/Formula weight: 278.35 g/mol	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): 105°C/221°F	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): 0.12	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Water Soluble in Benzene	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

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

Product code: P1196

Product name: PENTOXIFYLLINE,
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Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx).

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Pentoxifylline	
CAS-No.	6493-05-6

LD50/oral/rat = 1170 mg/kg oral LD50 rat (RTECS)
230 mg/kg Oral LD50 Rat (IUCLID)
LD50/oral/mouse = 1225 mg/kg oral LD50 mouse
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 = 230 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 1225 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:	May cause eye irritation.
Inhalation	May cause irritation of respiratory tract.
Ingestion	Harmful if swallowed. May cause gastrointestinal disturbances. May affect behavior/central nervous system (convulsions, headache, tremors, dizziness, drowsiness, agitation). May affect the cardiovascular system (hypotension, cardiac arrhythmias, agina, palpitations, bradycardia, antrioventricular block). May affect respiration (respiratory depression). May affect liver.
Aspiration hazard	No information available.

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

Chronic Toxicity Chronic exposure may cause dermatitis. Prolonged or repeated ingestion may affect the blood. Prolonged or repeated ingestion may affect the liver (Hepatitis, jaundice).

Sensitization: No information available.

Mutagenic Effects: May affect genetic material based on animal test data
Animal experiments showed mutagenic effects
Mutagenic effects in mammalian somatic cells
Cytogenic analysis (hamster lung)
Cytogenic Analysis: human lymphocyte
Sister Chromatid Exchange (human lymphocyte)

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Pentoxifylline	6493-05-6	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 No data is available

Reproductive Effects: It is poorly excreted into breastmilk
Developmental Effects: No information on developmental toxicity effects on humans was found
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Target Organs: Blood. Liver. Skin.

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
Pentoxifylline	6493-05-6	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

Product code: P1196

Product name: PENTOXIFYLLINE,
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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.
Pentoxifylline	6493-05-6	Not Listed	Present KE-10624	Not present	Not present	Present	Present	Present 229-374-5

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:
Pentoxifylline	6493-05-6	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Product code: P1196

Product name: PENTOXIFYLLINE,
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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
Pentoxifylline	6493-05-6	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
Pentoxifylline	6493-05-6	Not Applicable	Not Applicable

Canada

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

WHMIS 1988 Hazard Class

Non-controlled

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Pentoxifylline	6493-05-6	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Pentoxifylline	6493-05-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Pentoxifylline	6493-05-6	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Pentoxifylline	6493-05-6	

EU - CLP (1272/2008)

R-phrases(s)

R22 - Harmful if swallowed.

S -phrase(s)

S36 - Wear suitable protective clothing.

Components	CAS-No.	Classification	Concentration	Safety Phrases
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Product code: P1196

Product name: PENTOXIFYLLINE,
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			Limits:	
Pentoxifylline	6493-05-6		No information	

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

Indication of danger:

Xn - Harmful.

Xn



16. OTHER INFORMATION

Preparation Date: 8/7/2015
Revision Date: 7/10/2018
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 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
P1196	Pentoxifylline, BP

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,

Oralia Chavez
Quality Assurance Specialist

P1196, Pentoxifylline, BP

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 - Pentoxifylline, BP (Cat# P1196)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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.

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 - Pentoxifylline, BP (Cat# P1196)

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
N,N-Dimethylformamide	2	< 880 ppm
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Toluene	2	< 890 ppm

No Class 1, Class 3 or 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.




WARNING

- Harmful if swallowed.
- Do not eat, drink or smoke when using this product • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF SWALLOWED: Rinse mouth. Call a POISON CENTER or physician if you feel unwell.

KEEP FROM CHILDREN

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



P1196

SIZ SY

Pentoxifylline
[3,7-Dimethyl-1-(5-oxohexyl)-
xanthine]

BP
CAS 6493-05-6

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

$C_{13}H_{18}N_4O_3$ F.W. 278.35

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 99.0-101.0%
Appearance of Solution To pass test
Acidity To pass test

MAXIMUM LIMITS

Related Substances To pass test
Chlorides 100 ppm
Sulfates 200 ppm
Elemental Impurities As reported
Loss on Drying 0.5%
Sulfated Ash 0.1%
Residual Solvents To pass test

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

Repackaged by Spectrum as:
Lot No. XQ####

G7/K3GHS-A ?

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