

Scientific Documentation

Theophylline, Anhydrous, 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



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Specification for Theophylline, Anhydrous, USP (TH110)

Item Number	TH110
Item	Theophylline, Anhydrous, USP
CAS Number	58-55-9
Molecular Formula	C ₇ H ₈ N ₄ O ₂
Molecular Weight	180.17
MDL Number	
Synonyms	Slo-Bid

Test	Specification	
	Min	Max
ASSAY	97.0	102.0 %
LOSS ON DRYING @ 105 C		0.5 %
ORGANIC IMPURITIES:	.	
THEOPHYLLINE RELATED COMPOUND C		0.10 %
THEOPHYLLINE RELATED COMPOUND B		0.10 %
THEOPHYLLINE RELATED COMPOUND D		0.10 %
CAFFEINE		0.10 %
ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
RESIDUE ON IGNITION		0.15 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME MATCHES STANDARD	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	TH110	Lot Number	4MK0036
Item	Theophylline, Anhydrous, USP	Manufacturer Lot	23215
CAS Number	58-55-9	Manufacturer Code	9949
Molecular Formula	C ₇ H ₈ N ₄ O ₂	Molecular Weight	180.17

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY	97.0	102.0 %	100.0 %
LOSS ON DRYING @ 105 C		0.5 %	0.3 %
ORGANIC IMPURITIES:	.		0.0 %
THEOPHYLLINE RELATED COMPOUND C		0.10 %	0.0 %
THEOPHYLLINE RELATED COMPOUND B		0.10 %	0.0 %
THEOPHYLLINE RELATED COMPOUND D		0.10 %	0.0 %
CAFFEINE		0.10 %	0.0 %
ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %	0.0 %
TOTAL IMPURITIES		0.5 %	0.0 %
RESIDUE ON IGNITION		0.15 %	0.057 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME MATCHES STANDARD		RETENTION TIME MATCHES STANDARD
APPEARANCE			YELLOWISH-WHITE COLOR POWDER
EXPIRATION DATE			01-AUG-2027
DATE OF MANUFACTURE			07-AUG-2023
RESIDUAL SOLVENTS	AS REPORTED		MEETS USP CHAPTER <467> REQUIREMENTS

TEST	SPECIFICATION		RESULT
	MIN	MAX	
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
05-FEB-24 11:21:46

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
06-FEB-24 12:51:47

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



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 Shandong Xinhua Pharmaceutical Co Ltd. First Plant at EAST CHEMICAL ZONE OF ZIBO HIGH, NEW TECHNOLOGY DEV. ZONE, Zibo City, Shandong Province 255075, China(CHN). 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

spectrum®



Revision date 14-November-2022

Revision Number 2

1. Identification

Product identifier

Product Name THEOPHYLLINE, ANHYDROUS, USP

Other means of identification

Product Code(s) TH110

UN/ID no UN2811

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral

Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Toxic if swallowed



Appearance Crystalline powder or powder

Physical state Solid

Odor No information 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: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Theophylline, Anhydrous	58-55-9	100

4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a physician.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians

Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon dioxide (CO ₂). Hydrocarbons.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.
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8. Exposure controls/personal protection

Control parameters

Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other
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recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder or powder
Color	White
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks</u> • <u>Method</u>
pH	no data available	None known
Melting point / freezing point	275 °C / 527 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.4	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Slightly soluble in Ether Slightly soluble in Ethanol Slightly soluble in chloroform	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available

Liquid Density No information available
Bulk density No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact May be absorbed through the skin in harmful amounts. Harmful in contact with skin. (based on components).

Ingestion Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Theophylline, Anhydrous 58-55-9	= 225 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 6.7 mg/L (Rat) 4 h

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Theophylline, Anhydrous 58-55-9	-	Group 3 - Not classifiable - Monograph 51 [1991]	-	-

Legend

Reproductive toxicity No information available.

STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

DOT

UN/ID no	UN2811
Proper Shipping Name:	Toxic solids, organic, n.o.s.
Hazard class	6.1
Packing group:	III
Special Provisions	IB8, IP3, T1, TP33
Marine Pollutant	Severe Marine Pollutant
Description:	UN2811, Toxic solids, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III
Emergency Response Guide Number	154

TDG

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	III
Special Provisions	16
Description:	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III

MEX

UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.
Hazard class	6.1
Special Provisions	223, 274
Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III

ICAO (air)

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1

Packing Group:	III
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III

IATA

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	III
ERG Code	6L
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III

IMDG

UN number	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	III
EmS-No	F-A, S-A
Special Provisions	223, 274
Marine pollutant	NP1
Description	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III

RID

UN number	UN2811
Proper Shipping Name:	TOXIC SOLID, ORGANIC, N.O.S.
Transport hazard class(es)	6.1
Packing group	III
Classification code	T2
Special Provisions	274, 614
Description:	UN2811, TOXIC SOLID, ORGANIC, N.O.S. (Theophylline, Anhydrous), 6.1, III
Labels	6.1

ADR

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	III
Classification code	T2
Tunnel restriction code	(E)
Special Provisions	274, 614
Description:	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III, (E)
Labels	6.1

ADN

UN/ID No	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing Group	III
Classification code	T2
Special Provisions	274, 614, 802
Description	UN2811, Toxic solid, organic, n.o.s. (Theophylline, Anhydrous), 6.1, III
Hazard label(s)	6.1
Limited quantity (LQ)	5 kg
Equipment Requirements	PP, EP

15. Regulatory information

International Inventories

TSCA	Complies
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DSL/NDL	Complies
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EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 0

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 0
Flammability 0
Physical hazards 0
Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 14-November-2022
Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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
TH110	Theophylline, Anhydrous, 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

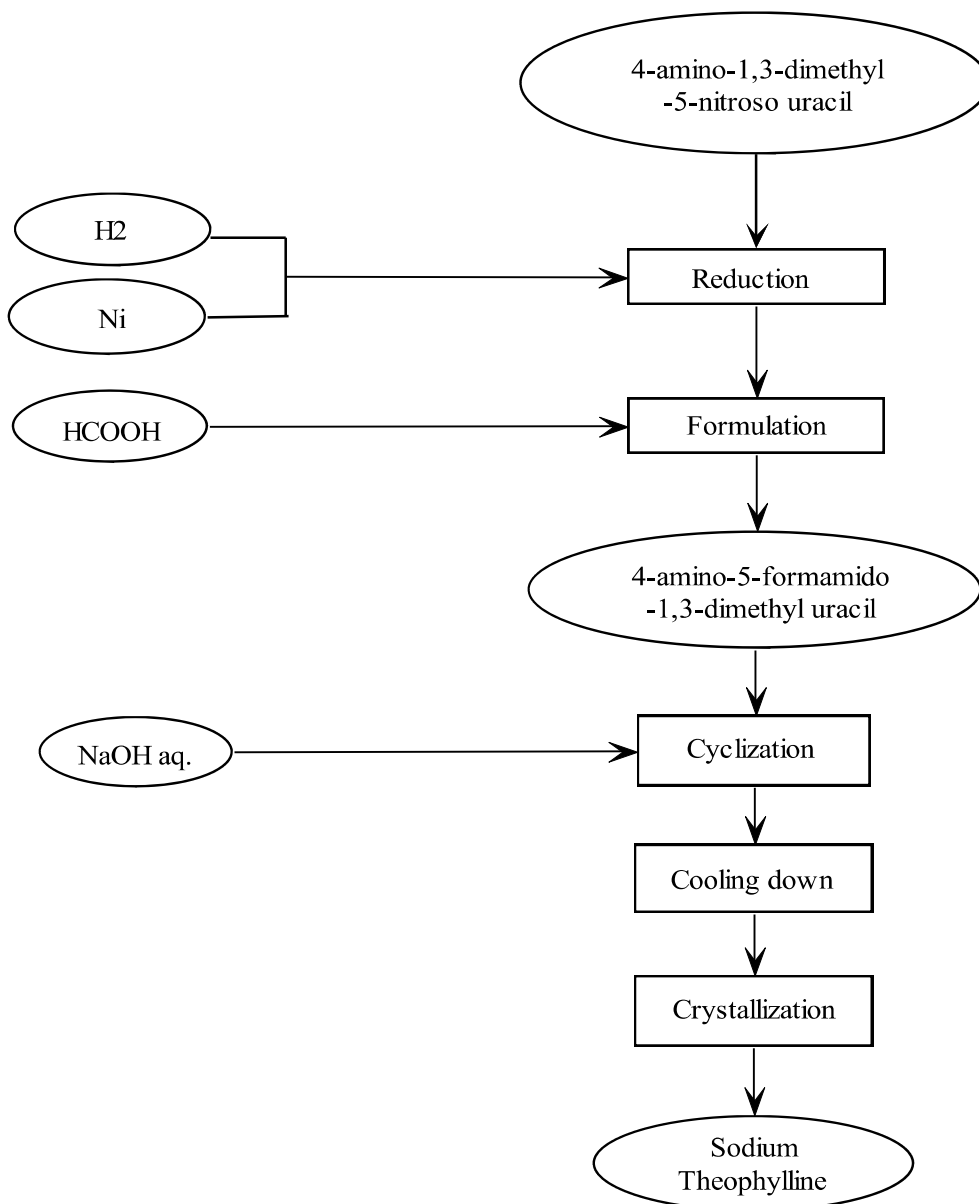
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Theophylline, Anhydrous, USP (Cat# TH110)



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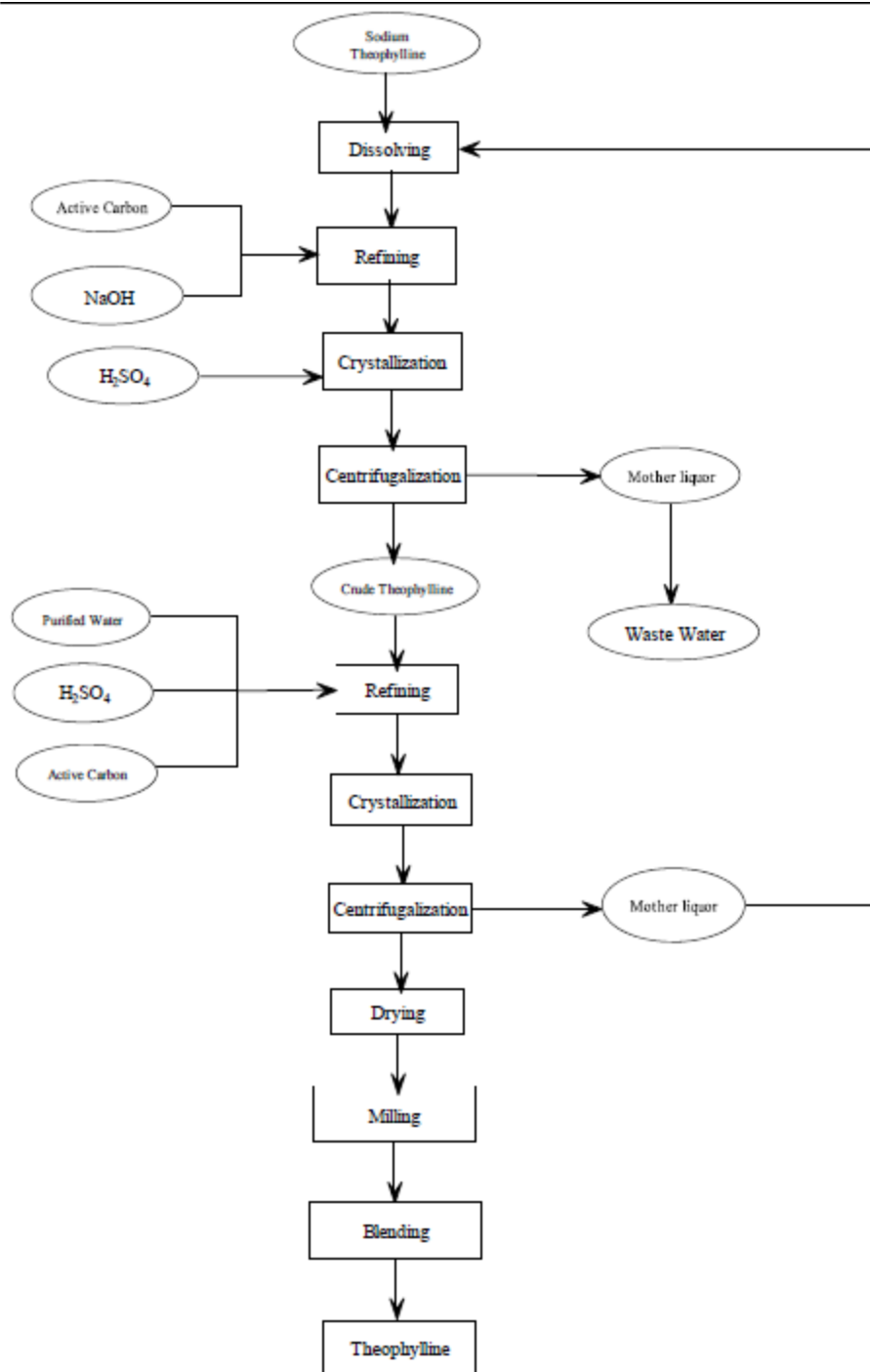
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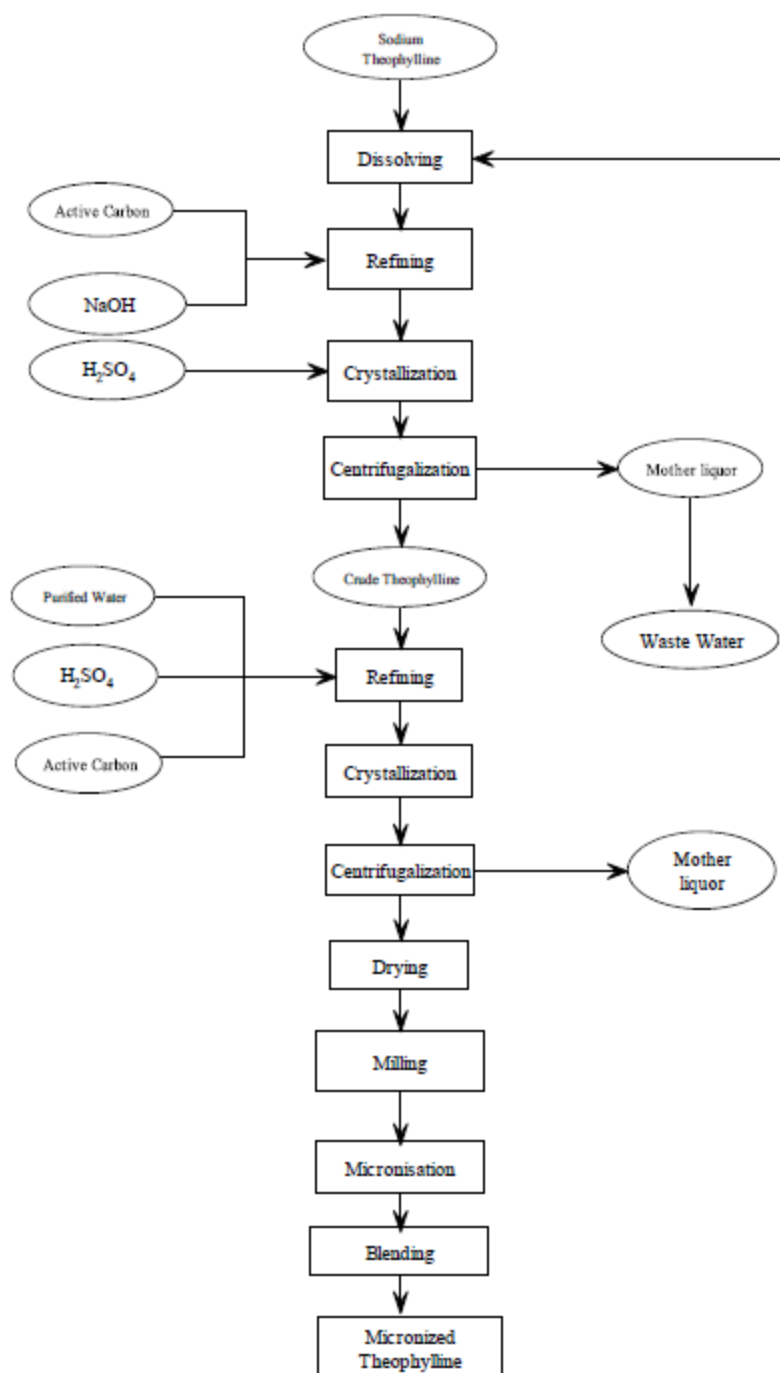
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TH110, Theophylline, Anhydrous, USP

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 48 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 - Theophylline, Anhydrous, USP (Cat# TH110)

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

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WEST COAST FACILITY

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PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Theophylline, Anhydrous, USP (Cat# TH110)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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


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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.

A  **L**


Exp. Date: 03-31-2030

C **DANGER**

- Toxic 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: Immediately call a POISON CENTER or physician. Rinse mouth.

KEEP FROM CHILDREN

B 

spectrum®
CHEMICAL MFG CORP

TH110 **D** **F** **2.5 KG**

Theophylline

E Anhydrous
USP

G CAS 58-55-9

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

I DOT: UN2811, Toxic solid, organic, n.o.s. (theophylline), 6.1, PG III

J **Chemical Emergency: (800)424-9300**

K **Repackaged by Spectrum as:**

M **Lot No. 062233**

O **Storage Color Band**

C₇H₈N₄O₂ **K** **F.W. 180.17**

Manufacturer/Supplier Code?

Manufacturer Lot Number?

Assay 97.0-102.0%

MAXIMUM LIMITS

Loss on Drying 0.5%

Organic Impurities:

Theophylline Related Compound C 0.10%

Theophylline Related Compound B 0.10%

Theophylline Related Compound D 0.10%

Caffeine 0.10%

Any Other Individual Unspecified Impurity 0.10%

Total Impurities 0.5%

Residue on Ignition 0.15%

Elemental Impurities As reported

Residual Solvents To pass test

B 10/J2GHS-A

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|---|--|---|
| A Bar Code | F Size/Quantity | K Empirical Formula, Formula Weight and Technical Specifications Panel |
| B GHS Hazard Pictograms | G Chemical Abstracts Service (CAS) Registry Number | L Expiration Information |
| C Warning, Safety Data and Precautionary Information | H Caution Information | M Lot Number |
| D Product Catalog Number | I DOT Shipping Information | N Kosher Certified by Kosher Supervision of America (KSA). |
| E Item Name, Form, Grade | J Toll-Free 24-Hour Chemical Emergency Telephone Number | |
| O Storage Color Band | | |

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

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