

Scientific Documentation TR106, Triacetin, USP

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> 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

Ver4.02 11.May.2016



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA Senior Manager of Technical Services techservices@spectrumchemical.com

TR106, Triacetin, USP

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Item Number	<u>TR106</u>
Item	Triacetin, USP
CAS Number	102-76-1
Molecular Formula	$C_9H_{14}O_6$
Molecular Weight	218.21
MDL Number	
Synonyms	Glycerol Triacetate ; 1,2,3-Propanetriol Triacetate

Test	Specifi	ication
	Min	Max
ASSAY $(C_0H_{14}O_6)$	97.0 - 100.5 %	
SPECIFIC GRAVITY @ 25°C	1.152 - 1.158	
REFRACTIVE INDEX @ 25 [°] C	1.429 - 1.430	
ACIDITY		TO PASS TEST
WATER		0.2 %
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
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





SAFETY DATA SHEET

Preparation Date: No data available Product identifier Revision Date: 03/17/2015

Revision Number: G1

Product code:	TR106
Product Name:	TRIACETIN, USP

Other means of identification

Synonyms: CAS #: RTECS # CI#: Glyceryl triacetate; Glycerol Triacetate; Glycerin Triacetate; Triacetyl glycerine 102-76-1 AK3675000 Not available

Recommended use of the chemical and restrictions on use

Recommended use: Uses advised against	No information available. No information available
Supplier:	Spectrum Chemicals and Laboratory Products, Inc. 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 not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC) Not Applicable

Other hazards May be harmful if swallowed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Triacetin	102-76-1	100	*
102-76-1			

4. FIRST AID MEASURES

First aid measures General Advice:	Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126)
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
Eye Contact:	Flush eye 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 effec	ts, both acute and delayed

Symptoms Health injuries are not known or expected under normal use.

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:	Do not use a solid (straight) water stream as it may scatter and spread fire.
Specific hazards arising from the chemical	
Hazardous Combustion Products:	Carbon 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. Keep people away from and upwind of spill/leak. 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. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.		
Methods and material for conta	inment and cleaning up		
Methods for containment	Stop leak if you can do it without risk. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.		
Methods for cleaning up	Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Absorb spill with inert material (e.g. vermiculite, dry sand or earth).		
	7. HANDLING AND STORAGE		

Precautions for safe handling

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Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. All equipment used when handling the product must be grounded. 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. Do not ingest. Do not breathe vapours/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. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	None	None	None	None
Triacetin - 102-76-1				

Canada

Components	Alberta	British Columbia	Ontario	Quebec
	None	None	None	None
Triacetin - 102-76-1				

Australia and Mexico

Components	Australia	Mexico
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Triacetin 102-76-1	None	None
Appropriate engineering controls		
Engineering measures to reduce	other engin	equate ventilation. Provide exhaust ventilation of beering controls to keep the airborne ons of vapors and mist below their respective mit value.
Individual protection measures, s	uch as personal protective equipr	nent
Personal Protective Equipment		
Eye protection:	Goggles. Safety glasses with side-s	hields.
Skin and body protection:	Chemical resistant apron. Gloves. L	ong sleeved clothing.
Respiratory protection:	Vapor respirator. Be sure to use an	approved/certified respirator or equivalent.
Hygiene measures:		lothing. Wash hands before breaks and uct. When using, do not eat, drink or smoke.
ç). PHYSICAL AND CHEMICAL F	PROPERTIES
Physical state: Liquid	Appearance: No information available	Color: No information available
Odor: Fruity. Fatty.	Taste Mild. Sweet. Bitter.	Molecular/Formula weight: 218.21
Formula: C9H14O6	Flash point (°C): No data available	Flashpoint (°C/°F): 138°C/280.4°F
Flash Point Tested according to: Closed cup	Lower Explosion Limit (%): 1	Upper Explosion Limit (%): No information available
Autoignition Temperature (°C/°F): 430°-433°C/806°-811.4°F	pH: No information available	Melting point/range(°C/°F): No information available
Boiling point/range(°C/°F): 258°-259°C/496.4°-498.2°F	Decomposition temperature(° No information available	C/°F): Bulk density: No information available
Specific gravity: 1.1562	Vapor pressure @ 20°C (kPa): 0	Density (g/cm3): No information available
Evaporation rate: No information available	Vapor density: 7.52	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): 0.3	Viscosity: No information available
Miscibility: Miscible with Chloroform	Solubility: Soluble in Acetone Soluble in cold water Soluble in diethyl ether Slightly soluble in alcohol Slightly soluble in Benzene Slightly soluble in Carbon Disulf Slightly soluble in Carbon Tetrad	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability Stability:	Stable under recommended storage conditions
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur
Conditions to avoid:	Heat. Ignition sources. Incompatible materials.
Incompatible Materials:	Oxidizing agents.
Hazardous decomposition products:	Carbon oxides.
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: Eyes. Ingestion.

Acute Toxicity

Component Information

Triacetin - 102-76-1

LD50/oral/rat = = 3 g/kg Oral LD50 Rat LD50/oral/mouse = 1100 mg/kg Oral LD50 Mouse LD50/dermal/rat = No information available LD50/dermal/rabbit = >2000 mg/kg Dermal LD50Rabbit LC50/inhalation/rat = 1721 mg/L Inhalation LC50 Rat 4 h LC50/inhalation/mouse = No information available Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = 3000mg/kg

LD50/oral/mouse = Value - Acute Tox Oral = 1100mg/kg

LD50/dermal/rabbit VALUE-Acute Tox Dermal = >2000mg/kg

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

LC50/inhalation/rat

Product code: TR106

VALUE-Vapor = 1721mg/l (4-hr) 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. It may be mildly to moderately irritating in sensitive individuals.
Eye Contact:	Causes mild to moderate eye irritation with burning sensation or pain, and redness of the conjunctiva, but not injury. Conjunctival reactions are mild to moderate and disappear within 6 to 24 hours. No reactions on the cornea and iris
Inhalation Ingestion	May cause irritation of respiratory tract. May affect behavior/central nervous system/nervous system(somnolence, convulsions, stiffness), spastic paralysis, respiration (difficulty breathing, respiratory depression).
Aspiration hazard	No information available
Delayed and immediate effects as	s 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	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Triacetin	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity	No data is available
Reproductive Effects:	No information available
Developmental Effects:	No information available
Teratogenic Effects:	No information available
Specific Target Organ Toxicity	
STOT - single exposure	No information available
STOT - repeated exposure	No information available
Target Organs:	No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

12. ECOLOGICAL INFORMATION

Ecotoxicity effects:	No data available.
Triacetin - 102-76-1	
Freshwater Fish Species Data: Water Flea Data:	170 mg/L LC50 Leuciscus idus 48 h static 1 380 mg/L EC50 Daphnia magna 48 h
Paraiatanaa and daaradahility	No information available
Persistence and degradability:	
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	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Triacetin	None	None	None	None

14. TRANSPORT INFORMATION

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	None
ERG No:	No information available
Marine Pollutant	No data available
DOT RQ (Ibs):	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
Description:	No information available

ADR

	14. TRANSPORT INFORMATION
Classification Code:	No information available
Description:	No information available
CEFIC Tremcard No:	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
Description:	No information available
IMDG Page:	No information available
Marine Pollutant	No information available
MFAG:	No information available
Maximum Quantity:	No information available
RID	Net De sulete d
UN-No:	Not Regulated No information available
Proper Shipping Name: Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Classification Code:	No information available
Description:	No information available
Decemption	
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
Description:	No information available
-	
ΙΑΤΑ	
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
Description:	No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Triacetin	Present	Present KE- 29332	Present	Present (2)- 753 (2)-666	Present	Present	Present 203-051-9

U.S. Regulations

Triacetin

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1901 **FDA - 21 CFR - Total Food Additives** 175.300 175.320 181.27 184.1901

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	Carcinogen	Developmental Toxicity	Male Reproductive	Female Reproductive
			Toxicity	Toxicity:
Triacetin	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous	Section 302 Extremely	Section 302 Extremely	Section 313 -	Section 313 - Reporting
	Substances and their	Hazardous	Hazardous	Chemical Category	de minimis
	Reportable Quantities	Substances and TPQs	Substances and RQs		
Triacetin	None	None	None	None	None

U.S. TSCA

	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Triacetin	Not Applicable	Not Applicable

Canada

WHMIS 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	Canada (DSL)	Canada (NDSL)
Triacetin	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory		
		Reporting		
Triacetin	Not listed	Not listed		

EU Classification

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Triacetin		No information	

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

16. OTHER INFORMATION

Revision Date: Prepared by:

Disclaimer:

03/17/2015 Sonia Owen

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



Manufacturer

Product Covered: TR106, Triacetin, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

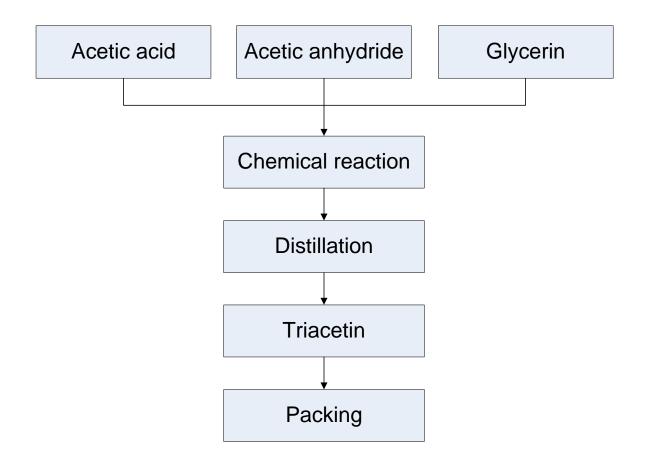
Sincerely,

Alan Wang, MSQA, ASQ CQA Senior Manager of Technical Services techservices@spectrumchemical.com



Manufacturing Process Flowchart

Triacetin, USP - TR106



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

Certificate of Registration



This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Frc

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA 755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum's two manufacturing facilitates by: selecting and gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01 Initial Certification Date: 27 December 1994 Certificate Issue Date: Certificate Expiry Date:

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



CERTIFICATION



Intertek Intertek

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

Certificate of Registration



This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: Certificate Number: Certificate Issue Date: Certificate Expiry Date: 77762704-8 111310001-01 17 November 2015 14 September 2018



014

Authorised Signature: Calin Moldovean – President, Business Assurance Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone. The annual validity of the certificate a also be checked through the website <u>http://www.cnca.gov.cn</u> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.



March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are 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.

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: Spectrum-New Brunswick, NJ: Spectrum -Shanghai, China: 2020632 2246824 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



May 9, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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
TR106	Triacetin, 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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



May 5, 2016

Re: Triacetin, USP- TR106

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Triacetin, USP- TR106

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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



May 5, 2016

Re: Triacetin, USP- TR106

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Triacetin, USP- TR106

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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



May 5, 2016

Re: Triacetin, USP- TR106

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Triacetin, USP- TR106

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

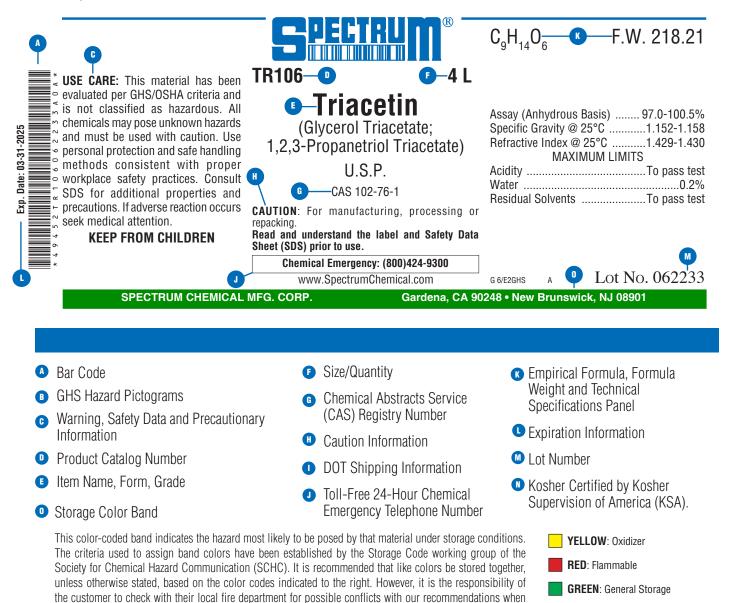
This document has been produced electronically and is valid without a signature



BLUE: Health Hazard WHITE: Corrosive

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.



Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901

storing hazardous chemicals.

West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000

Spectrum®

Certificate Of Analysis

Item Number	TR106	Lot Number	1EL0334
Item	Triacetin, USP		
CAS Number	102-76-1		
Molecular Formula	C ₉ H ₁₄ O ₆	Molecular Weight	218.21

Test	Specif	Result	
	min	max	
ASSAY $(C_0 H_{14} O_6)$	97.0 - 100.5 %		99.83
SPECIFIC GRAVITY @ 25° C	1.152 - 1.158		1.156
REFRACTIVE INDEX @ 25°C	1.429 - 1.430		1.4294
ACIDITY		TO PASS TEST	PASSES TEST
WATER		0.2 %	0.007 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			17-SEP-2017
RESIDUAL SOLVENTS		TO PASS TEST	
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm
CLASS 3 (solvent) / ISOBUTYL ACETATE			<5000 ppm
APPEARANCE			COLORLESS LIQUID
MANUFACTURE DATE			18-SEP-2015

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Adan Hernandez Quality Control Manager Spectrum Chemicals & Laboratory Products

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



January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility 2 = New Brunswick, NJ Facility 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: TR106, Triacetin, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, TR106, Triacetin, USP, is assigned a 24 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

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Corporate Headquarters 769 Jersey Avenue New Brunswick, NJ 08901-3605