

Scientific Documentation

TI140, Titanium Dioxide, 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

TI140, Titanium Dioxide, USP

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Spectrum[®]



Specification for Titanium Dioxide, USP (TI140)

Item Number	TI140
Item	Titanium Dioxide, USP
CAS Number	13463-67-7
Molecular Formula	TiO ₂
Molecular Weight	79.87
MDL Number	
Synonyms	Titanium (IV) Oxide

Test	Specification		
	Min	Max	
ASSAY (DRIED BASIS)	99.0	100.5 %	
LEAD (Pb)		10 ppm	
ANTIMONY (Sb)		2 ppm	
MERCURY (Hg)		1 ppm	
LOSS ON DRYING		0.5 %	
LOSS ON IGNITION		0.5 %	
WATER-SOLUBLE SUBSTANCES		0.25 %	
ACID-SOLUBLE SUBSTANCES		0.5 %	
ARSENIC (As)		1 ppm	
ELEMENTAL IMPURITIES		AS REPORTED	
IDENTIFICATION	YELLOW RED TO ORANGE-RED COLOR		
CERTIFIED KOSHER			
CERTIFIED HALAL			
APPEARANCE			
EXPIRATION DATE			
DATE OF MANUFACTURE			
RESIDUAL SOLVENTS		AS REPORTED	
MONOGRAPH EDITION			

Spectrum Chemical Mfg Corp

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

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300 310.516.8000



Certificate Of Analysis

Item Number	TI140	Lot Number	1KJ1179
Item	Titanium Dioxide, USP	CAS Number	13463-67-7
Molecular Formula	TiO ₂	Molecular Weight	79.87

TEST	SPECIFICATION		RESULT
1ES1	MIN	MAX	RESUL1
ASSAY (DRIED BASIS)	99.0	100.5 %	99.4 %
LEAD (Pb)		10 ppm	<10 ppm
ANTIMONY (Sb)		2 ppm	<2 ppm
MERCURY (Hg)		1 ppm	<1 ppm
LOSS ON DRYING		0.5 %	0.1 %
LOSS ON IGNITION		0.5 %	0.1 %
WATER-SOLUBLE SUBSTANCES		0.25 %	0.12 %
ACID-SOLUBLE SUBSTANCES		0.5 %	0.3 %
ARSENIC (As)		1 ppm	<1 ppm
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	YELLOW RED TO ORANGE- RED COLOR		YELLOW RED TO ORANGE-RED COLOR
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			WHITE POWDER
EXPIRATION DATE			31-JAN-2024
DATE OF MANUFACTURE			31-JAN-2021
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 43

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



Certificate of Analysis Results Certified By:

Jigisha Patel

VP Regulatory Compliance & Technical Services,

Regulatory

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 <233> 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.





SAFETY DATA SHEET

Preparation Date: 1/27/2015 Revision date 1/15/2019 Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: TI140

Product Name: TITANIUM DIOXIDE, USP

Other means of identification

Titanium (IV) Oxide Synonyms:

Titanium peroxide

Titanox

CAS #: 13463-67-7 RTECS# XR2275000 Not available CI#:

Recommended use of the chemical and restrictions on use

Recommended use: Piament.

No information available Uses advised against

Supplier: Spectrum Chemical Mfg. Corp

14422 South San Pedro St.

Gardena, CA 90248 (310) 516-8000

Distributed by:

VWR International Co 2360 Argentia Road

Mississauga, Ontario Canada L5N 5Z7

Telephone: 1-800-932-5000

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

Emergency telephone number Chemtrec 1-800-424-9300

Tom Tyner (USA - West Coast) **Contact Person:** Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

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

Carcinogenicity Category 2

Label elements

Warning

Hazard statements

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 1/11

Suspected of causing cancer



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Titanium Dioxide	13463-67-7	100

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you

have a poison emergency and need to talk to a poison specialist. Call

1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention if irritation develops.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. In case of shortness of breath, give

oxygen. Obtain medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation

May cause digestive (gastrointestinal) tract irritation

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 2/11

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: The product is not flammable. If it is involved in a fire,

extinguish the fire using an agent suitable for the type of

surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion productsNo information available.

Specific hazards No information available.

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. Avoid contact with skin, eyes and clothing. Use personal

protective equipment.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering

drains.

Methods and material for containment and cleaning up

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

spreading.

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

surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

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

Product code: TI140 Product name: TITANIUM DIOXIDE. Page 3/11

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. 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:

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:

Strong oxidizing agents Alkali Metals

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Titanium Dioxide	13463-67-7	15 mg/m³ TWA	None	10 mg/m³ TWA	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Titanium Dioxide	13463-67-7	10 mg/m³ TWA	10 mg/m³ TWA total dust 3 mg/m³ TWA respirable fraction	10 mg/m³ TWA	10 mg/m³ TWAEV total dust

Australia and Mexico

Component	CAS No	Australia	Mexico
Titanium Dioxide	13463-67-7	10 mg/m³ TWA	10 mg/m³ TWA
		_	20 mg/m ³ STEL

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: Goggles or Safety glasses with side-shields.

Skin and body protection: Long sleeved clothing

Chemical resistant apron

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 4/11

Gloves

Respiratory protection: Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator

> under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to

use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and

immediately after handling the product When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color: Solid Powder. White.

Odor: **Taste Formula** Odorless. Tasteless. TiO2

Molecular/Formula weight (g/mole): Flammability (solid, gas) Flashpoint (°C/°F):

no data available No information available

Autoignition Temperature (°C/°F): Flash Point Tested according to: **Lower Explosion Limit (%):** Not applicable No information available No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F): 1800-1850 °C/3272-3362 °F No information available No information available

Boiling point/range(°C/°F): **Bulk density:** Density (q/cm3): 2500-3000 °C/4532-5432 °F No information available No information available

Vapor pressure @ 20°C (kPa): Specific gravity: На

No information available No information available 4.26

Evaporation rate: Vapor density: VOC content (a/L): No information available No information available No information available

Odor threshold (ppm): **Partition coefficient** Viscosity:

No information available No information available (n-octanol/water):

No information available

Miscibility: Solubility:

No information available Insoluble in water

Soluble in Alkalis

Insoluble in diluted sulfuric acid

Insoluble in Nitric acid

Insoluble in Hydrochloric acid Soluble in Hydrofluoric acid

Soluble in hot concentrated Sulfuric

acid

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

A violent or incandescent reaction with metals (aluminum, calcium, magnesium, potassium, sodium, zinc, and lithium) may occur at high temperatures

Chemical stability

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 5/11

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Alkali Metals

Hazardous decomposition

products:

No information available.

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

Titanium Dioxide

CAS No 13463-67-7

LD50/oral/rat = > 10000 mg/kg Oral LD50 Rat LD50/oral/mouse = No information available

LD50/dermal/rabbit = No information available

LD30/definal/fabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =

Value - Acute Toxicity = 10000 mg/kg

LD50/oral/mouse =

Value - Acute Tox = No information available

LD50/dermal/rabbit

Value - Acute Toxicity = No information available

LD50/dermal/rat

VALUE - Acute Tox = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 6/11

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 cause mild skin irritation. It is reported to be a mild

irritant and may cause mechanical irritation (irritation from frictional action). It is

believed not to be absorbed through intact skin.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Not expected to be a health hazard. Ingestion may cause gastrointestinal irritation,

nausea, vomiting and diarrhea. It is not absorbed following ingestion.

Aspiration hazard No information available.

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

Chronic Toxicity Heavy occupational dust exposures may cause chronic rhinitis, chronic bronchitis,

pneumoconiosis, impaired pulmonary function, resemblance of silicosis without

any or very little fibrosis, functional change in trachea or bronchi, chronic

pulmonary edema.

Sensitization: No information available.

Mutagenic Effects: May affect genetic material

Carcinogenic effects: Not classifiable as to its carcinogenicity to humans. Possibly carcinogenic to

humans.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Titanium Dioxide		Possibly Carcinogenic to	Classifiable as	Not listed	Present	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: No information available

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 7/11

Developmental Effects:No information available **Teratogenic Effects:**No information available

Specific Target Organ Toxicity

STOT - single exposure
STOT - repeated exposure
Target Organs:

No information available.
No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soilNo information availableOther adverse effectsNo 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

Component	CAS No	RCRA - F Series	RCRA - K Series	RCRA - P Series	RCRA - U Series
		Wastes	Wastes	Wastes	Wastes
Titanium Dioxide	13463-67-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Class
Packing group:
No information available

Number

Marine PollutantNo data availableDOT RQ (lbs):No information availableSpecial ProvisionsNo Information availableSymbol(s):No information availableDescription:No information available

TDG (Canada)

UN-No: Not Regulated

Product code: TI140 Product name: TITANIUM DIOXIDE. Page 8/11

Proper Shipping Name:
Hazard Class
Subsidiary Risk:
Packing Group:
Marine Pollutant
Description:
No information available

ADR

UN Number Not regulated

Proper Shipping Name:
Transport hazard class(es)
Packing group
Subsidiary Risk:

No information available
No information available
No information available

IMDG

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant

No information available
No information available
No information available
No information available

RID

UN Number Not Regulated

Proper Shipping Name:
Transport hazard class(es)
Subsidiary Risk:
Packing group

No information available
No information available
No information available

ICAO (air)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Risk:
Packing Group:

No information available
No information available
No information available

IATA

UN Number Not Regulated

Proper Shipping Name:
Transport hazard class(es)
Subsidiary Risk:
Packing group
Precautionary Statements
No information available
No information available
No information available
No information available

Response

Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Titanium Dioxide	13463-67-7	Present(ACTI VE)	Present KE-33900	Present	Present (5)-5225 (1)-558	Present	Present	Present 236-675-5

U.S. Regulations

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 9/11

Titanium Dioxide

Massachusetts RTK: Present

New Jersey RTK Hazardous Substance List: 1861

Pennsylvania RTK: Present

Minnesota - Hazardous Substance List: Present

FDA - 21 CFR - Total Food Additives 175.105 175.210 175.300 175.380 175.390 176.170 177.1200 177.1210 177.1350 **- List Sourced from EAFUS** 177.1400 177.1460 177.1650 177.1680 177.2260 177.2355 177.2600 177.2800

178.3297 181.30 73.1575 73.2575 73.3126 73.350 73.575

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

Chemicals Known to the State of California to Cause Cancer:

⚠WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause cancer. For more information go to www.p65warnings.ca.gov.

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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male	Female
				Reproductive	Reproductive
				Toxicity	Toxicity:
Titanium Dioxide	13463-67-7	carcinogen	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	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
Titanium Dioxide	13463-67-7	None	None	None	None	None

U.S. TSCA

Component		· · · · · · · · · · · · · · · · · · ·	TSCA 8(d) -Health and Safety Reporting
Titanium Dioxide	13463-67-7	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification

Information:

Component Titanium Dioxide 13463-67-7 (100) WHMIS 2015 Hazard Classification

Carcinogenicity - Category 2: H351 Suspected of causing cancer.

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

DSL/NDSL

	CAS No	Canada (DSL)	Canada (NDSL)
Titanium Dioxide	13463-67-7	Present	Not Listed

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 10 / 11

Component	CAS No	CEPA Schedule I - Toxic Substances
Titanium Dioxide	13463-67-7	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject
		to Mandatory Reporting
Titanium Dioxide	13463-67-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Titanium Dioxide	13463-67-7	

EU - CLP (1272/2008)

R-phrase(s)

Not determined

S -phrase(s)

none

Component	CAS No	Classification		Safety Phrases
			Limits:	
Titanium Dioxide	13463-67-7		No information	

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

Indication of danger:

not determined

16. OTHER INFORMATION

Preparation Date:1/27/2015Revision date1/15/2019Prepared 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

Product code: TI140 Product name: TITANIUM DIOXIDE, Page 11 / 11



December 6, 2021

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	
TI140	Titanium Dioxide, 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,

Oralia Chavez

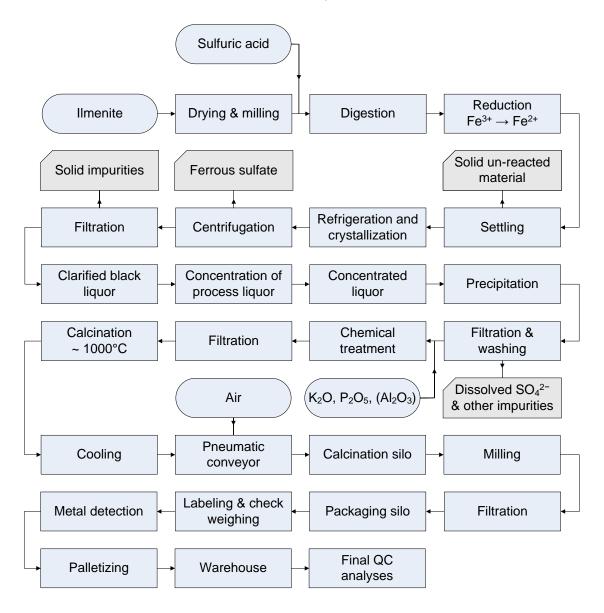
Quality Assurance Specialist

Oulu Clony



Manufacturing Process Flowchart

Titanium Dioxide, USP - TI140



Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



TI140, Titanium Dioxide, USP

Source Statement

The above mentioned catalog item is manufactured from mineral origin. 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

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 been tested on animals for regulatory compliance purposes only.

Organic Compliance Statement

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

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Titanium Dioxide, USP (Cat# TI140)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 5 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 1 ppm
Cobalt	Co	2A	< 1 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 5 ppm
Thallium	TI	2B	< 1 ppm
Gold	Au	2B	< 1 ppm
Palladium	Pd	2B	< 1 ppm
Iridium	Ir	2B	< 1 ppm
Osmium	Os	2B	< 5 ppm
Rhodium	Rh	2B	< 1 ppm
Ruthenium	Ru	2B	< 1 ppm
Selenium	Se	2B	< 5 ppm
Silver	Ag	2B	< 5 ppm
Platinum	Pt	2B	< 1 ppm
Lithium	Li	3	< 5 ppm
Antimony	Sb	3	< 10 ppm
Barium	Ba	3	< 20 ppm
Molybdenum	Мо	3	< 5 ppm
Copper	Cu	3	< 5 ppm
Tin	Sn	3	< 5 ppm
Chromium	Cr	3	< 5 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These

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



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

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PHONE 310.516.8000
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RE: Residual Solvents - Titanium Dioxide, USP (Cat# TI140)

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.

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CORPORATE HEADQUARTERS

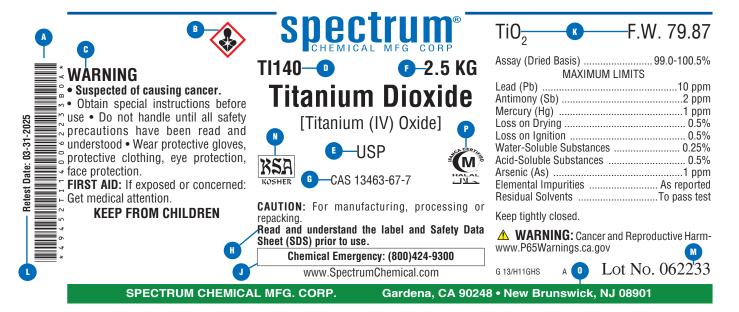
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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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 Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Size/Quantity

- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).
- Storage Color Band
- Halal Certified by IFANCA
- bioCertified

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.

Spectrum Chemical Mfg Corp

Corporate Headquarters:West C769 Jersey Ave.14422New Brunswick, NJ 08901Garder732.214.1300310.51

West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000





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: Zl0928 = 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
- 4 = Pharmacy, NJ 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 quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,

Quality Assurance Specialist

Ordu Anny

CORPORATEHEADQUARTERS

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PHONE 310.516.8000

FAX 310.516.9843



The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.

S-0032

14422 S. San Pedro Street Gardena CA 90248 USA

Product Name TI140, Titanium Dioxide, USP

Brand Spectrum

UKD-ID KSAV3-E5E0E73

D/P/M P

Symbol Required KSA

Special Conditions

This certificate expires on **Feb 01, 2022**

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.



شهادة حلال FANCA HALAL PRODUCT CERTIFICATE

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: November 02, 2021

Document #: 11205.11206.II214430

Company Name & Address: Spectrum Laboratory Products, Inc. 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA

Plant Name & Address: Spectrum Laboratory Products, Inc. 769-Jersey Ave New Brunswick, New Jersey 08901 USA

ProductNameProduct CodeHalal-IDProduct Certificate #1. Titanium Dioxide, USPTI140C22456HC-21SPFS02

Halamand Munir Chaulm Muhammad Munir Chaudry, Ph.D.





This Certificate is valid until **August 31, 2022** and subject to renewal at that time.



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