

Scientific Documentation

Fluocinonide, Micronized, 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 Fluocinonide, Micronized, USP (F1123)

Item Number	F1123
Item	Fluocinonide, Micronized, USP
CAS Number	356-12-7
Molecular Formula	C ₂₆ H ₃₂ F ₂ O ₇
Molecular Weight	494.52
MDL Number	
Synonyms	Fluocinolone Acetonide 21-Acetate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0	103.0%
SPECIFIC ROTATION	+81° to +89°	
CHROMATOGRAPHIC PURITY		TO PASS TEST
LOSS ON DRYING		1.0%
ELEMENTAL IMPURITIES	AS REPORTED	
RESIDUE ON IGNITION		TO PASS TEST
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

Spectrum Chemical Mfg Corp

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

Certificate Of Analysis

Item Number	F1123	Lot Number	4LD0039
Item	Fluocinonide, Micronized, USP	Manufacturer Lot	2154AM1 B0102022
CAS Number	356-12-7	Manufacturer Code	13524
Molecular Formula	C ₂₆ H ₃₂ F ₂ O ₇	Molecular Weight	494.52

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	97.0	103.0%	100.0 %
SPECIFIC ROTATION	+81° to +89°		+87°
CHROMATOGRAPHIC PURITY		TO PASS TEST	PASSES TEST
LOSS ON DRYING		1.0%	0.7 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
RESIDUE ON IGNITION		TO PASS TEST	PASSES TEST
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			30-SEP-2025
DATE OF MANUFACTURE			01-SEP-2020
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST

Certificate of Analysis Results Entered By:

TDAO
Tiffany DAO
26-AUG-22 05:34:45

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
26-AUG-22 14:05:52

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.

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 Farmabios S.p.A. at Via Pavia 1, Gropello Cairoli, Pavia 27027, Italy (ITA). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.



SAFETY DATA SHEET

Preparation Date: 1/23/2019

Revision date 1/23/2019

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: F1123
Product Name: FLUOCINONIDE, MICRONIZED, USP

Other means of identification

Synonyms: Fluocinolide
Fluocinoone Acetonide 21-acetate
CAS #: 356-12-7
RTECS # TU3831000
CI#: Not available

Recommended use of the chemical and restrictions on use

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

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

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

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Tom Tyner (USA - West Coast)

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)

Acute toxicity - Oral	Category 2
Reproductive toxicity	Category 2

Label elements

Danger

Hazard statements

Fatal if swallowed
Suspected of damaging fertility or the unborn child

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

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

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

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Fluocinonide	356-12-7	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.

Inhalation:

Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Call a physician immediately. Immediate medical attention is required.

Most important symptoms and effects, both acute and delayed

Symptoms Glucocorticoids (Corticosteroids): Ingestion may cause osteoporosis and bone fractures, back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia)
Prolonged or repeated skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy)

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

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

5. FIRE-FIGHTING MEASURES

Extinguishing Media

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

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Hydrogen fluoride.

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. Keep people away from and upwind of spill/leak. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

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

Methods for cleaning up Sweep up and shovel. Use appropriate tools to put the spilled solid in a suitable waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

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

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe dust. Do not ingest. 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. Store in a segregated and approved area.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Fluocinonide	356-12-7	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Fluocinonide	356-12-7	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Fluocinonide	356-12-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Safety glasses with side-shields. or Goggles
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White. Cream.
Odor: Slight.	Taste No information available.	Formula C26H32F2O7
Molecular/Formula weight (g/mole): 494.52	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 308-311 °C/586.4-591.8 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Practically insoluble in water	

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability:

Stable under recommended storage conditions.

Possibility of Hazardous Reactions:

Hazardous polymerization does not occur

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

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Hydrogen fluoride.

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

Fluocinonide	
CAS No	356-12-7

LD50/oral/rat = 14 mg/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
Value - Acute Tox = 14 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
Value - Acute Tox = No information available

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

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

LC50/Inhalation/mouse
VALUE-Vapor = No information available

VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation. May cause facial rash or tiny red bumps or rash around the mouth. It may be absorbed through the skin. If absorbed through skin it may cause systemic effects with symptoms similar to those of ingestion.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Fatal if swallowed. Corticosteroids(glucocorticoids): Nausea, vomiting, headache. May cause bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, increased sweating, eye pain, vision changes, mental and personality changes, swelling, lightheadedness, numbness, tremors, Fluid and electrolyte imbalance (sodium and fluid retention), suppression of calcium absorption and increased calcium excretion, potassium loss, hypokalemic alkalosis, Cushing's syndrome, immune system depression.

Aspiration hazard No information available.

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

Chronic Toxicity Prolonged or repeated skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy). Prolonged or repeated eye contact with glucocorticoids/corticosteroids may affect vision (glaucoma, cataracts). Prolonged or repeated ingestion of corticosteroids may cause osteoporosis and bone fractures due to mobilization of calcium (reduced calcium absorption) and phosphorus, hypokalemia due to increase urinary loss of potassium, development of glaucoma and cataracts, muscle weakness/muscle wasting, swelling of the feet or lower legs due fluid and sodium retention, hip or shoulder pain, irregular heartbeat. It may affect the liver, kidneys, pancreas (pancreatitis), blood (changes in serum composition), behavior/central nervous system (anxiety, nervousness or restlessness, trouble sleeping, mental disturbances such as psychosis, euphoria, depression), protein metabolism, lipid metabolism, carbohydrate metabolism causing insulin resistance, hyperglycemia, diabetes, and the immune system (immunosuppressant) causing increased susceptibility to infections), thinning skin. Repeated ingestion of large doses of corticosteroids may also produce other symptoms typical of hyperactivity of the adrenal gland and overproduction of cortisol (Cushing's Syndrome) such moon-face, buffalo hump, increased bruising, ecchymoses, striae, and acne, menstrual irregularities, amenorrhea, sometimes hirsutism (deepening of the voice in women), and excess hair growth (in women).

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic	Australia - Prohibited Carcinogenic
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						Substances	Substances
Fluocinonide	356-12-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

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

Reproductive toxicity

No data is available

Reproductive Effects:

Suspected of damaging fertility or the unborn child

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

Ecotoxicity effects:

No data available.

Persistence and degradability:

No information available

Bioaccumulative potential:

No information available.

Mobility in soil

No information available

Other adverse effects

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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Fluocinonide	356-12-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No:

UN2811

Proper Shipping Name:

Toxic solids, organic, n.o.s.(fluocinonide)

Hazard Class

6.1

Product code: F1123

Product name: FLUOCINONIDE,
MICRONIZED, USP

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Subsidiary Class	No information available
Packing group:	II
Emergency Response Guide Number	154
Marine Pollutant	No data available
DOT RQ (lbs):	No information available
Special Provisions	IB8, IP2, IP4, T3, TP33
Symbol(s):	[DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description:	UN2811, Toxic solids, organic, n.o.s., 6.1, II

TDG (Canada)	
UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard Class	6.1
Subsidiary Risk:	No information available
Packing Group:	II
Marine Pollutant	No Information available
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II

ADR	
UN Number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	II
Subsidiary Risk:	No information available
Special Provisions	274, 614
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II

IMDG	
UN-No:	UN2811
Proper Shipping Name:	Toxic solids, organic, n.o.s.(fluocinonide)
Hazard Class:	6.1
Subsidiary Risk:	No information available
Packing Group:	II
Marine Pollutant	No information available
EMS:	F-A
Special Provisions	274
Description	UN2811, Toxic solid, organic, n.o.s. (FLUOCINONIDE), 6.1, II

RID	
UN Number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Subsidiary Risk:	No information available
Packing group	II
Special Provisions	274, 614
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II

ICAO (air)	
UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard Class	6.1
Subsidiary Risk:	No information available
Packing Group:	II
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II
Special Provisions	A3, A5

IATA

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group II
Precautionary Statements - Response 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

15. REGULATORY INFORMATION**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Fluocinonide	356-12-7	Not Listed	Not present	Not present	Not present	Not listed	Present	Present 206-597-6

U.S. Regulations**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

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

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

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

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Fluocinonide	356-12-7	Not Listed	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
Fluocinonide	356-12-7	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Fluocinonide	356-12-7	Not Applicable	Not Applicable

Canada**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

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

Product code: F1123

Product name: FLUOCINONIDE,
MICRONIZED, USP

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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

Component	CAS No	Canada (DSL)	Canada (NDSL)
Fluocinonide	356-12-7	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Fluocinonide	356-12-7	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Fluocinonide	356-12-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Fluocinonide	356-12-7	Acute Tox. 2 H300 Fatal if swallowed; Repro 2 H361 Suspected of damaging fertility or the unborn child

EU - CLP (1272/2008)

R-phrase(s)

R28 - Very toxic if swallowed

R62 - Possible risk of impaired fertility

R63 - Possible risk of harm to the unborn child

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Fluocinonide	356-12-7		No information	

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

Indication of danger:

T+ - Very toxic

Xn - Harmful

16. OTHER INFORMATION

Preparation Date: 1/23/2019
Revision date 1/23/2019
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may

Product code: F1123

Product name: FLUOCINONIDE,
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pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

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

Catalog Number	Product Name
F1123	Fluocinonide, Micronized, 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", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

F1123, Fluocinonide, Micronized, USP

Source Statement

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

BSE/TSE Statement

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

Allergen Statement

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

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

EU Fragrance Allergen Statement

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

GMO Statement

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

Melamine Statement

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

Nitrosamine Statement

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

Animal Testing Statement

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

Organic Compliance Statement

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

Shelf Life Statement

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

Other Chemicals Statement

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

- Aflatoxins
- Bisphenol A (BPA)
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Fluocinonide, Micronized, USP (Cat# F1123)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

14422 South San Pedro Street
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PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Fluocinonide, Micronized, USP (Cat# F1123)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Residual Solvent	Class	Expected Concentration
Acetonitrile	2	< 410 ppm
<i>N,N</i> -Dimethylformamide	2	< 880 ppm
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Methylisobutylketone	2	< 4500 ppm
Pyridine	2	< 200 ppm
Tetrahydrofuran	2	< 720 ppm
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
Isopropenyl Acetate		< 200 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

Label Information

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

Exp. Date: 01-01-2020





F1123 **SIZ SY**
Fluocinonide
 (Fluocinolone Acetonide 21-Acetate)
 Micronized, USP
 CAS 356-12-7

$C_{28}H_{32}F_2O_7$ F.W. 494.52

DANGER

- Fatal if swallowed • Suspected of damaging fertility or the unborn child.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth. If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN

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

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Dried Basis) 97.0-103.0%
 Specific Rotation +81° to +89°
 Chromatographic Purity To pass test

MAXIMUM LIMITS

Loss on Drying 1.0%
 Residue on Ignition To pass test
 Elemental Impurities As reported
 Residual Solvents To pass test

DOT: UN2811, Toxic solid organic, N.O.S. (Fluocinonide), 8.1, 2.3.2

Chemical Emergency: (800)424-6300
www.SpectrumChemical.com

Repackaged by Spectrum as:

B 8/L9GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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