



SAFETY DATA SHEET

Preparation Date: 6/27/2018 Revision Date: 6/27/2018 Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: ME171

Product Name: METHYLPREDNISOLONE ACETATE, MICRONIZED, USP

Other means of identification

Synonyms: 11,17,21-Trihydroxy-6-methyl-1,4-pregnadiene-3,20-dione acetate

Methylprednisolone 21-acetate 6-Methylprednisolone acetate 6-alpha-Methylprednisolone acetate

Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-6-methyl-,

(6-alpha,11-beta)-

CAS #: 53-36-1 RTECS # TU4154050 CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use:
Uses advised against
No information available.
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 numberChemtrec 1-800-424-9300Contact Person:Martin LaBenz (West Coast)Contact Person:Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

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

Reproductive toxicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2

Label elements

Warning

Hazard statements

Suspected of damaging fertility or the unborn child

Product code: ME171 Product name:

METHYLPREDNISOLONE ACETATE,

May cause damage to organs through prolonged or repeated exposure



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

May be harmful in contact with skin

Precautionary Statements - Prevention

Obtain special instructions before use Do not handle until all safety precautions have been read and understood Use personal protective equipment as required Do not breathe dust/fume/gas/mist/vapors/spray

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Methylprednisolone Acetate	53-36-1	100

4. FIRST AID MEASURES

First aid measures

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

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

1-800-222-1222.

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

shoes. Get medical attention if irritation develops. Consult a physician if necessary.

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

irritation persists, consult a specialist.

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give Inhalation:

oxygen. Obtain medical attention.

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

unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin/respiratory tract irritation

Product code: ME171 **Product name:**

METHYLPREDNISOLONE ACETATE, MICRONIZED, USP

Glucocorticoids (Corticosteroids) may cause osteoporisis 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, electrolye imbalance (sodium and fluid retention, potassium loss (hypokalemia)

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.

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. Avoid contact with skin, eyes and clothing. Avoid breathing

dust. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter 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

Product name:METHYLPREDNISOLONE ACETATE,
MICRONIZED, USP

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 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. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

I	Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
ſ	Methylprednisolone Acetate	53-36-1	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Methylprednisolone Acetate	53-36-1	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Methylprednisolone Acetate	53-36-1	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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

Product code: ME171 **Product name:** 4/12

Eye protection: Goggles or Safety glasses with side-shields

Skin and body protection: Long sleeved clothing

apron Gloves

Respiratory protection: Effective dust mask. 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: Appearance: Color:

Solid Crystalline powder. White. Nearly White.

Odor:TasteFormula:Odorless.No information available.C24-H32-O6

Molecular/Formula weight:Flammability:Flashpoint (°C/°F):416.51Not FlammableNo information available.

The members are

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%): Not available

No information available

No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F):

No information available 206-225 °C/402.8-437 °F No information available

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

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

Evaporation rate: Vapor density: VOC content (g/L):

No information available

No information available

Odor threshold (ppm): Partition coefficient Viscosity:

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

 $\log Kow = 1.62$

Miscibility:Solubility:No information availableInsoluble in water

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Product code: ME171 Product name:

METHYL PREDNISOLONE ACETATE

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

Incompatible Materials: Strong 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:

Inhalation. Ingestion.

Acute Toxicity

Component Information

Methylprednisolone Acetate	
CAS-No.	53-36-1

LD50/oral/rat = > 10 g/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 LC50information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = > 10000 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = No information available

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

Product code: ME171

VALUE-Vapor = No information available

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

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May affect behavior/central nervous system (somnolence). May cause flushing or

redness of skin. May cause excessive sweating. May cause diarrhea. May cause constipation. 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,

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 eye contact with glucocorticoids/corticosteroids may affect

vision (glaucoma, cataracts). Prolonged or repeated skin contact with corticosteroids/glucosteroids may cause dryness, folliculitis, acne, hypopigmentaton, dermatitis, thinning of skin (skin atrophy). 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). Corticosteroids may also have an inhibitory effect on wound healing. This may affect persons who have experienced recent nasal ulcers, nasal surgergy or nasal

trauma.

Sensitization: No information available.

Mutagenic Effects: No information available

Product code: ME171

Carcinogenic effects: Not considered carcinogenic.

	Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
N	lethylprednisolone Acetate	53-36-1	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) Group 3 - Not classifiable as to its carcinogenicity to humans

NTP (National Toxicology Program)

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

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: No information available

Developmental Effects: May cause adverse developmental effects based on animal data

Possible risk of harm to the unborn child

Glucocorticoid medication used during pregnancy has been associated with an

increased risk of cleft palate and impaired fetal growth by some studies

(REPROTOX)

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure

STOT - repeated exposure

Target Organs:

No information available.

May cause damage to organs through prolonged or repeated exposure.

No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Product code: ME171

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Methylprednisolone Acetate	53-36-1	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

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

ADR

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
No information available

IMO / 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-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
No information available
No information available
No information available
No information available

ICAO

UN-No: Not Regulated

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

No information available
No information available
No information available

IATA

UN-No: Not Regulated

Proper Shipping Name: No information available Hazard Class: No information available

Product code: ME171 Product name:

Subsidiary Risk:No information availablePacking Group:No information availableERG Code:No information availableSpecial ProvisionsNo information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Methylprednisolone Acetate	53-36-1	Not Listed	Not present	Not present	Present (9)-488	Not present	Present	Present 200-171-3

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:

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male	Female
		_		Reproductive	Reproductive
				Toxicity	Toxicity:
Methylprednisolone Acetate	53-36-1	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Methylprednisolone Acetate	53-36-1	None	None	None	None	None

U.S. TSCA

Components			TSCA 8(d) -Health and Safety Reporting
Methylprednisolone Acetate	53-36-1	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

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

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

D2A Very toxic materials

Product code: ME171 Product name:

METHYLPREDNISOLONE ACETATE,

MICRONIZED, USP

Canada Controlled Products Regulation:

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

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
	53-36-1	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances	
Methylprednisolone Acetate	53-36-1	Not listed	
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject	
		to Mandatory Reporting	
Methylprednisolone Acetate	53-36-1	Not listed	

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
	53-36-1	No information

EU - CLP (1272/2008)

R-phrase(s)

R63 - Possible risk of harm to the unborn child.

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

S36/37 - Wear suitable protective clothing and gloves.

Components	CAS-No.	Concentration Limits:	Safety Phrases
Methylprednisolone Acetate	53-36-1	No information	

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

Indication of danger:

Xn - Harmful.





16. OTHER INFORMATION

Preparation Date:6/27/2018Revision Date:6/27/2018Prepared 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

Product code: ME171 Product name:

METHYLPREDNISOLONE ACETATE,

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: ME171