
	Sagent Pharmaceuticals, Inc.		
	Document Type Safety Data Sheet (SDS)	Document Title Methylprednisolone Acetate Injectable Suspension, USP	
	Document No. MSDS-0127	Version 1.0	Effective Date 10 Oct 2021

Section 1 - Identification

- (a) **Product Identifier:** Methylprednisolone Acetate Injectable Suspension, USP
- (b) **NDC:** 25021-820-05, 25021-821-05, 25021-820-10
- Common/Trade Name:** Depo-Medrol
- Chemical Name:** pregna-1,4-diene-3,20-dione, 21(acetyloxy)-11,17-dihydroxy-6-methyl-,(6 α ,11 β)-
- Chemical Family:** Anti-inflammatory glucocorticoid
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Pre-filled vial
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618


Section 2 - Hazards Identification

- (a) **Classification:** N/A
- (b) **Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**
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P202: Do not handle until all safety precautions have been read and understood

P281: Use personal protective equipment as required.

P308+P313: If exposed or concerned: get medical advice/attention.
- (c) **Description of Hazards:** H361: Suspected of damaging fertility or the unborn child
- (d) **Unknown Acute Toxicity** N/A

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Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Methylprednisolone acetate	Methylprednisolone acetate	40 mg/80 mg	53-36-1	N/A
Polyethylene glycol 3350	Polyethylene glycol 3350	29.1 mg/28.2 mg	25322-68-3	N/A
Polysorbate 80	Polysorbate 80	1.94 mg/1.88 mg	9005-65-6	N/A
Monobasic sodium phosphate	Monobasic sodium phosphate	6.8 mg/6.59 mg	10049-21-5	N/A
Dibasic sodium phosphate, USP	Dibasic sodium phosphate, USP	1.42 mg/1.37 mg	7558-79-4	N/A
Benzyl alcohol	Benzyl alcohol	9.16 mg/8.88 mg	100-51-6	N/A

Section 4 - First Aid Measures

- Eye Exposure:** Flush eyes with large volumes of water for 15 minutes or more. Get medical attention if irritation or signs of exposure are noted.
- Skin Exposure:** Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted.
- Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.
- Inhalation:** If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) Extinguishing Media** Water spray, carbon dioxide, dry chemical powder or appropriate foam.

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- (b) **Hazardous Combustion Products:** N/A
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

Section 6 - Accidental Release Measures

- Spill:** Prevent further leakage or spillage. Do not let product enter drains.
- Release to Air:** If aerosolized, reduce exposures by ventilating area.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

- General Handling:** When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors associated with the product.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Section 8 - Exposure Controls / Personal Protection


(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Methylprednisolone Acetate	OSHA	N/A	N/A

(b) Engineering Controls

Ventilation: Use in a chemical fume hood. Safety shower and eye bath.


(c) Individual Protection Measures

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Respiratory Protection:	Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
Eye Protection:	Safety glasses
Skin Protection:	Work uniform or laboratory coat.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	3.5 – 7.0
(e)	Melting Point:	Approx. 215 °C
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Soluble in dioxane, sparingly soluble in acetone, alcohol, chloroform, and methanol, and slightly soluble in ether. It is practically insoluble in water.
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available

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(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not available
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	Not available
(d)	Conditions to Avoid	Not available
(e)	Incompatible Materials	Strong oxidizing agents
(f)	Hazardous Decomposition Products	Under fire conditions: carbon oxides.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	N/A

(d) Acute Toxicity


Component	Type	Route	Species	Dosage
Methylprednisolone Acetate	LD ₅₀	Oral	Rat	10g/Kg
Methylprednisolone Acetate	LD ₅₀	IP	Mouse	1409 mg/kg

(e) Hazardous Chemical Listings

NTP: No IARC: No OSHA: No NIOSH: No

(f) Carcinogenesis, Mutagenesis, Impairment of Fertility

No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis or mutagenesis. Steroids may increase or decrease motility and number of spermatozoa in some patients. Corticosteroids have been shown to impair fertility in male rats.

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(g) Pregnancy: Teratogenic Effects

Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Section 12 - Ecological Information

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	N/A
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	N/A
(e)	Other Adverse Effects	N/A


Section 13 - Disposal Considerations

Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

DOT: Not dangerous goods.
IATA: Not dangerous goods.
IMDG: Not dangerous goods.

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: No

CERCLA: Not on this list

SARA 302: Not on this list

SARA 313: Not on this list

California Proposition 65: This product does NOT contain chemicals known to the State of California to cause cancer or reproductive effects.

Section 16 - Other Information


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)

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IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)