

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Methylprednisolone Acetate Injectable Suspension
Other means of identification : 400 mg/10 mL (40 mg/mL) [Multi Dose Vial], Packaged Individually NDC 55150-313-01
400 mg/10 mL (40 mg/mL) [Multi Dose Vial], Carton of 25 NDC 55150-313-25
400 mg/5 mL (80 mg/mL) [Multi Dose Vial], Packaged Individually NDC 55150-314-01
400 mg/5 mL (80 mg/mL) [Multi Dose Vial], Carton of 25 NDC 55150-314-25

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC
279 Princeton Hightstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Irrit. 2 H315
Eye Irrit. 2 H319
Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



GHS07

GHS08

Signal word (GHS US) :

Warning

Hazard statements (GHS US) :

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Methylprednisolone Acetate	(CAS-No.) 53-36-1	4	Repr. 2, H361
Polyethylene glycol	(CAS-No.) 25322-68-3	2.91	Not classified
Sodium hydroxide	(CAS-No.) 1310-73-2	1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Sodium chloride	(CAS-No.) 7647-14-5	1	Not classified
Hydrochloric acid	(CAS-No.) 7647-01-0	1	Skin Corr. 1, H314 Eye Dam. 1, H318
Benzyl alcohol	(CAS-No.) 100-51-6	0.916	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332
Phosphoric acid, monosodium salt	(CAS-No.) 7558-80-7	0.68	Not classified
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives	(CAS-No.) 9005-65-6	0.194	Not classified
Sodium phosphate dibasic	(CAS-No.) 7558-79-4	0.142	Not classified

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water.
First-aid measures after ingestion : Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : None anticipated under normal product use conditions.
Symptoms/effects after skin contact : Causes skin irritation.
Symptoms/effects after eye contact : Causes serious eye irritation.
Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.
Methods for cleaning up : Place in a suitable container and dispose according to local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Polyethylene glycol (25322-68-3)		
AIHA	WEEL TWA	10 mg/m ³ (MW>200-aerosol)
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)		
Not applicable		
Phosphoric acid, monosodium salt (7558-80-7)		
Not applicable		
Sodium phosphate dibasic (7558-79-4)		
Not applicable		
Benzyl alcohol (100-51-6)		
AIHA	WEEL TWA [ppm]	10 ppm
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m ³
OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
IDLH	IDLH	10 mg/m ³
NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
Sodium chloride (7647-14-5)		
Not applicable		
Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
OSHA	OSHA PEL (Ceiling)	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
NIOSH	NIOSH REL C [ppm]	5 ppm
Methylprednisolone Acetate (53-36-1)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use neoprene or rubber gloves.
Eye protection : Wear protective goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : Wear NIOSH approved respirator when handling.

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: White to almost white
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: No data available
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Polyethylene glycol (25322-68-3)	
LD50 oral rat	22 g/kg
LD50 dermal rabbit	> 20 g/kg
ATE US (oral)	28000000 mg/kg
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)	
LD50 oral rat	34500 µl/kg

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

Phosphoric acid, monosodium salt (7558-80-7)	
LD50 oral rat	8290 mg/kg
LD50 dermal rabbit	> 7940 mg/kg
ATE US (oral)	8290 mg/kg
Sodium phosphate dibasic (7558-79-4)	
LD50 oral rat	17 g/kg
ATE US (oral)	17000000 mg/kg
Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg
LC50 Inhalation - Rat	8.8 mg/l/4h
ATE US (oral)	1230 mg/kg body weight
ATE US (dermal)	2000 mg/kg body weight
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	8.8 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg
Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation - Rat	> 42 g/m ³ (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

Benzyl alcohol (100-51-6)	
LC50 - Fish [1]	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 - Fish [2]	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log Pow)	1.1
Sodium chloride (7647-14-5)	
BCF - Fish [1]	(no bioaccumulation)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

International Air Transport Association (IATA)

In accordance with IATA

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

Phosphoric acid, monosodium salt (7558-80-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium phosphate dibasic (7558-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2. US State regulations

Polyethylene glycol (25322-68-3)	
U.S. - Minnesota - Hazardous Substance List	
Sodium phosphate dibasic (7558-79-4)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Benzyl alcohol (100-51-6)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2

Methylprednisolone Acetate Injectable Suspension

Safety Data Sheet

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H361	Suspected of damaging fertility or the unborn child

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.