

SAFETY DATA SHEET



1. Identification

Product identifier	Depo-Medrol®
Other means of identification	
Synonyms	Depo-Medrol * Depo-Medrol® methylprednisolone acetate injectable suspension USP * Depo-Medrol® methylprednisolone acetate sterile aqueous suspension * DEPO MEDROL® Injectable Corticosteroid * Methylprednisolone Acetate Suspension, 20 and 40 mg/ml
Recommended use	Veterinary product used as anti-inflammatory agent
Recommended restrictions	Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child) Specific target organ toxicity following repeated exposure	Category 1A Category 2 (Adrenal gland, blood forming organs)
Environmental hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	May damage the unborn child. May cause damage to organs (Adrenal gland, blood forming organs) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapour. Wear protective gloves/protective clothing/eye protection/face protection.

Response	IF exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	May be harmful if absorbed through skin. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Methylprednisolone Acetate		53-36-1	2-4
Sodium chloride		7647-14-5	<1
Myristyl-gamma-picolinium chloride		2748-88-1	<0.1
Polyethylene glycol		25322-68-3	*
Water		7732-18-5	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments * Non-hazardous Ingredients

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	May be absorbed through the skin and cause systemic effects. Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Get medical advice/attention if you feel unwell.
Eye contact	Remove contact lenses, if present and easy to do. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use has resulted in hormonal alterations. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Prolonged exposure may cause chronic effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe the mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions

7. Handling and storage

Precautions for safe handling

Use this product with adequate ventilation. Wear appropriate personal protective equipment. Avoid accidental injection. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. @ 15 - 25°C (59 - 77°F). Protect from sunlight. Do not allow material to freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components

Type

Value

Methylprednisolone Acetate
(CAS 53-36-1)

TWA

4 µg/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

OEL Additional Information: Skin - May be absorbed through the skin and cause systemic effects.

Control banding approach

Not available.

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves. Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Other

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Thermal hazards

Not applicable.

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

solution.

Physical state	Liquid.
Form	Liquid.
Colour	Colourless.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerisation does not occur.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Protect from freezing.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not known or expected under normal use.
Skin contact	May be absorbed through the skin and cause systemic effects.
Polyethylene glycol	Species: Rabbit Severity: Mild
Sodium chloride	Species: Rabbit Severity: Mild

Skin contact

Methylprednisolone Acetate

Species: Rabbit
Severity: No effect**Eye contact**

Polyethylene glycol

Direct contact with eyes may cause temporary irritation.

Species: Rabbit
Severity: Mild

Sodium chloride

Species: Rabbit
Severity: Moderate

Methylprednisolone Acetate

Species: Rabbit
Severity: No effect**Ingestion**

Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhoea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Clinical use has resulted in hormonal alterations. Prolonged exposure may cause chronic effects.

Information on toxicological effects**Acute toxicity**

Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components**Species****Test results**

Methylprednisolone Acetate (CAS 53-36-1)

Acute**Oral**

LD50

Rat

> 10000 mg/kg

Other

LD50

Mouse

> 1409 mg/kg [Sub-tenon injection (eye)]

Subcutaneous

LD50

Rat

265 mg/kg

Chronic**Other**

NOAEL

Rat

0.004 mg/kg/day, 52 weeks
[Subcutaneous, Target organ(s): Blood forming organs, Adrenal gland] Data for methylprednisolone**Subacute****Oral**

LOAEL

Dog

0.167 mg/kg/day, 42 days [Target organ(s): Adrenal gland] Data for methylprednisolone

Other

LOAEL

Rat

0.5 mg/kg/day, 6 weeks [Subcutaneous, Target organ(s): None identified] Data for methylprednisolone

Subchronic**Other**

NOAEL

Rat

0.0004 mg/kg/day, 14 weeks
[Subcutaneous, Target organ(s): Blood forming organs, Adrenal gland] Data for methylprednisolone

Myristyl-gamma-picolinium chloride (CAS 2748-88-1)

Acute**Intraperitoneal**

LD50

Rat

7500 ug/kg

Components	Species	Test results
Oral		
LD50	Rat	250 mg/kg
Other		
LD50	Rat	30 mg/kg
Subcutaneous		
LD50	Rat	200 mg/kg
Chronic		
Oral		
	Rat	2400 mg/kg, 60 days
Sodium chloride (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Methylprednisolone Acetate	Species: Rabbit	Severity: No effect
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Polyethylene glycol	Species: Rabbit	Severity: Mild
Sodium chloride	Species: Rabbit	Severity: Moderate
Methylprednisolone Acetate	Species: Rabbit	Severity: No effect
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	This product is not expected to cause skin sensitisation. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.	
Skin sensitisation		
Methylprednisolone Acetate	GPMT, (data for methylprednisolone)	Result: No effect Species: Guinea pig
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Methylprednisolone Acetate	Direct DNA Interaction	Result: negative Species: Not applicable
	In Vitro Cytogenetics	Result: negative Species: Not applicable
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
Reproductive toxicity	May damage the unborn child.	

Developmental effects

Methylprednisolone Acetate

0.1 mg/kg/day Embryo / Fetal Development, LOAEL
 Result: Teratogenic (Methylprednisolone)
 Species: Rabbit
 Organ: Intramuscular

1 mg/kg/day Embryo / Fetal Development, LOAEL
 Result: Fetotoxicity, Teratogenic (Methylprednisolone)
 Species: Rat
 Organ: Subcutaneous

330 mg/kg/day Embryo / Fetal Development, LOAEL
 Result: Teratogenic (Methylprednisolone)
 Species: Mouse
 Organ: Intramuscular

Reproductivity

Methylprednisolone Acetate

0.004 mg/kg/day Reproductive & Fertility, NOAEL
 Result: Paternal toxicity (Methylprednisolone)
 Species: Rat
 Organ: Subcutaneous

0.02 mg/kg/day Reproductive & Fertility, LOAEL
 Result: Fetotoxicity (Methylprednisolone)
 Species: Rat
 Organ: Subcutaneous

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

May cause damage to organs (Adrenal gland, blood forming organs) through prolonged or repeated exposure.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

May cause damage to organs through prolonged or repeated exposure.

Further information

Caution - Pharmaceutical agent. May be harmful if absorbed through skin.

12. Ecological information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test results
Polyethylene glycol (CAS 25322-68-3)		
Aquatic		
Fish	LC50	Atlantic salmon (<i>Salmo salar</i>) > 1000 mg/l, 96 hours
Sodium chloride (CAS 7647-14-5)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) 6020 - 7070 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Partition coefficient n-octanol / water (log Kow)

Myristyl-gamma-picolinium chloride

1.3, pH 7.4

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

Canadian regulations	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.	
Controlled Drugs and Substances Act	Not regulated.	
Export Control List (CEPA 1999, Schedule 3)	Not listed.	
Greenhouse Gases	Not listed.	
Precursor Control Regulations	Not regulated.	
International regulations		
Stockholm Convention	Not applicable.	
Rotterdam Convention	Not applicable.	
Kyoto protocol	Not applicable.	
Montreal Protocol	Not applicable.	
Basel Convention	Not applicable.	

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 17-May-2017

Version No. 01

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Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
GHS: Qualifiers