

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 & Drug Safety	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
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	CHEMTREC (24 hours): 1-800-424-9300
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 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/vapours. 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.
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.
Other hazards	None known.

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. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.
Skin contact	Wash off immediately with soap and plenty of water. Get medical advice/attention if you feel unwell. If skin irritation or rash occurs: Get medical advice/attention. May be absorbed through the skin and cause systemic effects. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Get medical advice/attention if you feel unwell.
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. 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. For personal protection, see section 8 of the SDS.

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	Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS. Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.
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Methods and materials for containment and cleaning up

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

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. Clean surface thoroughly to remove residual contamination.

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

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use this product with adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Avoid accidental injection.

Conditions for safe storage, including any incompatibilities

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

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

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	
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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Heat, flames and sparks. Contact with incompatible materials. 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	Prolonged inhalation may be harmful.
Skin contact	May be absorbed through the skin and cause systemic effects.
Polyethylene glycol	Species: Rabbit Severity: Mild
Sodium chloride	Species: Rabbit Severity: Mild
Methylprednisolone Acetate	Species: Rabbit Severity: No effect
Eye contact	Direct contact with eyes may cause temporary irritation.
Polyethylene glycol	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)		
<u>Acute</u>		
Oral		
LD50	Rat	> 10000 mg/kg
Other		
LD50	Mouse	> 1409 mg/kg [Sub-tenon injection (eye)]
Subcutaneous		
LD50	Rat	265 mg/kg
<u>Chronic</u>		
Other		
NOAEL	Rat	0.004 mg/kg/day, 52 weeks [Subcutaneous, Target organ(s): Blood forming organs, Adrenal gland] Data for methylprednisolone
<u>Subacute</u>		
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
<u>Subchronic</u>		
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)		
<u>Acute</u>		
Intraperitoneal		
LD50	Rat	7500 ug/kg
Oral		
LD50	Rat	250 mg/kg
Other		
LD50	Rat	30 mg/kg
Subcutaneous		
LD50	Rat	200 mg/kg
<u>Chronic</u>		
Oral		
	Rat	2400 mg/kg, 60 days

Components	Species	Test Results
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 sensitiser.	
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	Not available.	
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 Prolonged inhalation may be harmful. 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 Avoid release to the environment. 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.

Components	Species	Test Results
Polyethylene glycol (CAS 25322-68-3)		
Aquatic		
<i>Acute</i>		
Fish	LC50	Atlantic salmon (<i>Salmo salar</i>)
		> 1000 mg/l, 96 hours
Sodium chloride (CAS 7647-14-5)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)
		340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Rainbow trout, donaldson trout (<i>Oncorhynchus mykiss</i>)
		4747 - 7824 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available for this product. The following information is available for the individual ingredients.

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 The waste code should be assigned in discussion between the user, the producer and the waste disposal company. 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.

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 Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Revision date	13-September-2023
Version No.	02
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.