



SAFETY DATA SHEET

Revision date 20-Oct-2022

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Methylprednisolone Acetate Injectable Suspension, Single-Dose Vial

Product Code(s) PZ01044

Synonyms PNU-8210

Trade Name: DEPO-MEDROL; DEPO-NISOLONE; DEPO-MEDRONE; DEPO-MODERIN; DEPO-MEDOL; DEPO-MEDRATE

Item Code H000400470, H000401047, H000401048, H000401071, H000401072, H000401073, H000401074, H000401105, H000420001, H000420005, H000011490, H000011491, H000011873, H000011874, H000401242, H000401243, H000020331, H000020536, H000402477, H000402479, H000402968, H000402474

Chemical Family: Glucocorticoid

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

Recommended Use Pharmaceutical product used as anti-inflammatory

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone CHEMTREC (24 hours): 1-800-424-9300

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Reproductive toxicity Category 1A - (H360D)
Specific target organ toxicity (repeated exposure) Category 2 - (H373)
Chronic aquatic toxicity Category 2 - (H411)

2.2. Label elements

Signal word Danger

Hazard statements
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood

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P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P273 - Avoid release to the environment
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Methylprednisolone Acetate (CAS #: 53-36-1)	4-8		200-171-3	Repr.1A (H360D) STOT RE.2 (H373) Aquatic Acute 3 (H402) Aquatic Chronic 1 (H410)	Not Listed	No data available	1
Myristyl-gamma-picolinium chloride (CAS #: 2748-88-1)	<1.0		220-387-1	Acute Tox.3 (H301)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A	No data available	No data available

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					:: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%		
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Polyethylene glycol (CAS #: 25322-68-3)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, monobasic (CAS #: 7558-80-7)	*		231-449-2	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Methylprednisolone Acetate 53-36-1	10000	No data available	No data available	No data available	No data available
Polyethylene glycol 25322-68-3	22000	20000	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
Sodium phosphate, monobasic 7558-80-7	8290	7940	0.83	No data available	No data available
Sodium phosphate, dibasic 7558-79-4	17000	No data available	No data available	No data available	No data available
Myristyl-gamma-picolinium	250	No data available	No data available	No data available	No data available

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
chloride 2748-88-1					
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

Additional information

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

5.3. Advice for firefighters

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Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Methylprednisolone Acetate

Pfizer OEL TWA-8 Hr: 40 µg/m³

Polyethylene glycol

Austria

1000 mg/m³

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Denmark	STEL 4000 mg/m ³
Germany	1000 mg/m ³ 250 mg/m ³ average molecular weight 200-600; because formation of a mist is possible, exposure should be minimized for reasons of occupational safety and hygiene Ceiling / Peak: 500 mg/m ³
Germany	200 mg/m ³
Russia	MAC: 10 mg/m ³
Slovakia	1000 mg/m ³
Switzerland	500 mg/m ³
SODIUM CHLORIDE	
Latvia	5 mg/m ³
Russia	MAC: 5 mg/m ³
Sodium phosphate, monobasic	
Russia	MAC: 10 mg/m ³
Sodium phosphate, dibasic	
Russia	MAC: 10 mg/m ³
Sodium hydroxide	
ACGIH OEL (Ceiling)	2 mg/m ³
ACGIH TLV	Ceiling: 2 mg/m ³
Austria	2 mg/m ³ STEL 4 mg/m ³
Bulgaria	2.0 mg/m ³
Czech Republic	1 mg/m ³ Ceiling: 2 mg/m ³
Denmark	Ceiling: 2 mg/m ³
Estonia	1 mg/m ³ STEL: 2 mg/m ³
Finland	Ceiling: 2 mg/m ³
France	2 mg/m ³
Hungary	1 mg/m ³ STEL: 2 mg/m ³
Ireland	STEL: 2 mg/m ³
Ceiling Limit Value	2 mg/m ³
Latvia	0.5 mg/m ³
Poland	STEL: 1 mg/m ³ 0.5 mg/m ³
Romania	1 mg/m ³ STEL: 3 mg/m ³
Slovakia	2 mg/m ³
Spain	STEL: 2 mg/m ³
Switzerland	2 mg/m ³ STEL: 2 mg/m ³
OSHA PEL	2 mg/m ³ (vacated) Ceiling: 2 mg/m ³
United Kingdom	STEL: 2 mg/m ³
+ Hydrochloric Acid	
ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm 8 mg/m ³ STEL 10 ppm
Bulgaria	STEL 15 mg/m ³ STEL: 10 ppm STEL: 15.0 mg/m ³
Czech Republic	5 ppm 8.0 mg/m ³ 8 mg/m ³ Ceiling: 15 mg/m ³

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Denmark	Ceiling: 5 ppm
Estonia	Ceiling: 8 mg/m ³ 5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
European Union	TWA: 5 ppm TWA: 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Finland	STEL: 5 ppm STEL: 7.6 mg/m ³
Germany	2 ppm 3.0 mg/m ³ Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m ³
Germany	2 ppm 3 mg/m ³
Hungary	8 mg/m ³ STEL: 16 mg/m ³
Ireland	8 mg/m ³ 5 ppm STEL: 10 ppm STEL: 15 mg/m ³
Italy	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Ceiling Limit Value	2 ppm 3.0 mg/m ³
Latvia	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Netherlands	8 mg/m ³ STEL: 15 mg/m ³
Poland	STEL: 10 mg/m ³ 5 mg/m ³
Romania	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Russia	MAC: 5 mg/m ³
Slovakia	5 ppm 8.0 mg/m ³
Spain	5 ppm 7.6 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Switzerland	2 ppm 3 mg/m ³ STEL: 4 ppm STEL: 6 mg/m ³
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m ³
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³ Ceiling: 5 ppm Ceiling: 7 mg/m ³

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United Kingdom

TWA: 1 ppm
TWA: 2 mg/m³
STEL: 5 ppm
STEL: 8 mg/m³

SODIUM CHLORIDE

Pfizer Occupational Exposure
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium phosphate, monobasic

Pfizer Occupational Exposure
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium phosphate, dibasic

Pfizer Occupational Exposure
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Suspension

Color

White

Odor

No information available.

Odor threshold

No information available

Molecular formula

Mixture

Molecular weight

Mixture

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<u>Property</u>	<u>Values</u>
pH	3.5 to 7.0
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30
Methylprednisolone
Predicted 7.4 Log D 1.99

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

Hazardous polymerization Will not occur.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

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10.5. Incompatible materials

Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:

The information included in this section describes the potential hazards of the individual ingredients The information included in this section describes the potential hazards of various forms of the active ingredient.

Short term

May be harmful if absorbed through the skin.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus and blood and blood forming organs

Known Clinical Effects:

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.

Acute toxicity

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

STOT - single exposure

Based on available data, the classification criteria are not met.

STOT - repeated exposure

Classification is based on mixture calculation methods based on component data.

Reproductive toxicity

Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Methylprednisolone Acetate

Rat Oral LD50 >10,000 mg/kg

Mouse Sub-tenon injection (eye) LD50 >1,409 mg/kg

Rat Subcutaneous LD50 265 mg/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

Myristyl-gamma-picolinium chloride

Rat Oral LD 50 250 mg/kg

Rat Para-periosteal LD50 30 mg/kg

Rat Intraperitoneal LD50 7500 ug/kg

Rat Subcutaneous LD50 200 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Methylprednisolone

Rat Oral LD 50 > 2000 mg/kg

Mouse Oral LD 50 450 mg/kg

Rat Intraperitoneal LD 50 1000 mg/kg

Mouse Intraperitoneal LD 50 1409 mg/kg

Rat Subcutaneous LD 50 >3000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Methylprednisolone Acetate	> 10 g/kg (Rat)	-	-

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Polyethylene glycol	= 22 g/kg (Rat)	> 20 g/kg (Rabbit)	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Sodium phosphate, monobasic	= 8290 mg/kg (Rat)	> 7940 mg/kg (Rabbit)	> 0.83 mg/L (Rat) 4 h
Sodium phosphate, dibasic	= 17 g/kg (Rat)	-	-
Myristyl-gamma-picolinium chloride	= 250 mg/kg (Rat)	-	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Methylprednisolone Acetate

Eye Irritation Rabbit No effect
Skin Irritation Rabbit No effect

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

SODIUM CHLORIDE

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Methylprednisolone

Skin irritation Rabbit No effect
Eye irritation Rabbit No effect
Skin Sensitization - GPMT Guinea Pig No effect

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Myristyl-gamma-picolinium chloride

60 Day(s) Rat Oral 2400 mg/kg Death

Methylprednisolone

42 Day(s) Dog Oral 167 µg/kg/day LOAEL Adrenal gland
6 Week(s) Rat Subcutaneous 500 µg/kg/day LOAEL None identified
14 Week(s) Rat Subcutaneous 0.4 µg/kg/day NOAEL Blood forming organs, Adrenal gland
52 Week(s) Rat Subcutaneous 4 µg/kg/day NOAEL Blood forming organs, Adrenal gland

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methylprednisolone

Reproductive & Fertility Rat Subcutaneous 0.004 mg/kg/day NOAEL Paternal toxicity
Reproductive & Fertility Rat Subcutaneous 0.02 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Subcutaneous 1.0 mg/kg/day LOAEL Fetotoxicity, Teratogenic
Embryo / Fetal Development Mouse Intramuscular 330 mg/kg/day LOAEL Teratogenic
Embryo / Fetal Development Rabbit Intramuscular 0.1 mg/kg/day LOAEL Teratogenic

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Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Methylprednisolone Acetate

Direct DNA Interaction Not applicable Negative
In Vitro Cytogenetics Not applicable Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Methylprednisolone

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis Rat Hepatocyte Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
Direct DNA Interaction Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

+ Hydrochloric Acid

IARC Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided. Classification is based on mixture calculation methods based on component data

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Methylprednisolone

Daphnia magna (Water Flea) N/A EC50 48 hours > 85 mg/L
Daphnia magna (Water Flea) N/A NOEC 48 hours 85 mg/L
Ceriodaphnia dubia (Daphnids) N/A EC50 48 hours 19 mg/L
Ceriodaphnia dubia (Daphnids) N/A EC10 48 hours 6.1 mg/L
Pseudokirchneriella subcapitata (Green Alga) N/A NOEC 96 hours 160 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Methylprednisolone

Ceriodaphnia dubia (Daphnids) N/A 7 Day(s) EC50 0.23 mg/L
Ceriodaphnia dubia (Daphnids) N/A 32 Day(s) EC10 0.031 mg/L Reproduction
Ceriodaphnia dubia (Daphnids) N/A 32 Day(s) EC50 0.094 mg/L Reproduction

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

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Myristyl-gamma-picolinium chloride

Predicted 7.4 Log D 1.30

Methylprednisolone

Predicted 7.4 Log D 1.99

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Polyethylene glycol	The substance is not PBT / vPvB
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Sodium phosphate, monobasic	PBT assessment does not apply
Sodium phosphate, dibasic	PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater 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.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transport as a hazardous material/dangerous good under IMDG, ADR, IATA but not under DOT.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Methylprednisolone Acetate)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

5 kg/5L Exception:

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UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Methylprednisolone Acetate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	200-171-3

Polyethylene glycol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	Not Listed
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 3 Schedule 2

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

Sodium phosphate, monobasic

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-449-2
AICS	Present

Sodium phosphate, dibasic

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-448-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

Myristyl-gamma-picolinium chloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	220-387-1

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AICS	Present
Sodium hydroxide	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6
+ Hydrochloric Acid	
CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

EU - Biocides

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

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Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child. Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure if swallowed. Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed. Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation. Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage. Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled. Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects. Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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