SAFETY DATA SHEET

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,H000011874H000401242, 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
66 Hudson Boulevard East
New York, New York 10001
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)
Hazardous to the aquatic environment - chronic	Category 2 - (H411)

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

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 - EU (§28, 1272/2008)
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
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 advice/attention
P314 - Get medical advice/attention if you feel unwell
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Unknown acute toxicity

4-8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
4-8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

2.3. Other hazards

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

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

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 (EU Index No)	Classification according to Regulation	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

				(EC) No. 1272/2008 [CLP]			
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 classified	No data available	1
Myristyl-gamma-picolinium chloride (CAS #: 2748-88-1)	<1.0		220-387-1	Acute Tox.3 (H301)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	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 (EU Index 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	Not classified	No data available	No data available
Polyethylene glycol (CAS #: 25322-68-3)	*		Not Listed	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
Sodium phosphate, monobasic (CAS #: 7558-80-7)	*		231-449-2	Not classified	Not classified	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	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	3550	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 chloride 2748-88-1	250	No data available	No data available	No data available	No data available
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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information
+ Substance with a Union workplace exposure limit
* 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 mists) may fuel fires/explosions.

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

Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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	TWA-TMW: 1000 mg/m³; inhalable fraction STEL-KZGW: 4000 mg/m³ (4 X 15 min); inhalable fraction
Denmark	TWA: 1000 mg/m³; STEL: 2000 mg/m³;
Germany DFG	TWA-MAK: 250 mg/m³; II(2);inhalable fraction Peak: 500 mg/m³; inhalable fraction
Germany TRGS	TWA-AGW; 200 mg/m³ (exposure factor 2); inhalable fraction
Russia	MAC: 10 mg/m³
Slovakia	TWA: 1000 mg/m³;
Switzerland	TWA-MAK: 500 mg/m³;

SODIUM CHLORIDE

Latvia	TWA: 5 mg/m³;
Russia	MAC: 5 mg/m³

Sodium phosphate, monobasic

Russia	MAC: 10 mg/m³

Sodium phosphate, dibasic

Russia	MAC: 10 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	TWA-TMW: 2 mg/m³; inhalable fraction STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m³; alkaline aerosols
Czech Republic	1 mg/m³ Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³;
Estonia	TWA: 1 mg/m³; STEL: 2 mg/m³;
Finland	Ceiling: 2 mg/m³;

France	2 mg/m³
Hungary	TWA-AK: 1 mg/m³; STEL-CK: 2 mg/m³;
Ireland	STEL: 2 mg/m³;
Ceiling Limit Value	2 mg/m³
Latvia	TWA: 0.5 mg/m³;
Poland	TWA-NDS: 0.5 mg/m³; STEL-NDSCh: 1 mg/m³;
Romania	TWA: 1 mg/m³; STEL: 3 mg/m³;
Slovakia	TWA: 2 mg/m³;
Spain	STEL (VLA-EC): 2 mg/m³;
Switzerland	TWA-MAK: 2 mg/m³; inhalable dust STEL-KZGW: 2 mg/m³; inhalable dust
OSHA PEL	TWA: 2 mg/m³ (vacated) Ceiling: 2 mg/m³
United Kingdom	STEL: 2 mg/m³;

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm; TWA-TMW: 8 mg/m³; STEL-KZGW: 10 ppm (8 X 5 min); STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm; TWA: 8.0 mg/m³; STEL: 10 ppm; STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³ Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm; STEL: 8 mg/m³;
Estonia	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
European Union	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Finland	STEL: 5 ppm; STEL: 7.6 mg/m³;
Germany DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m³; I(2); Peak: 4 ppm; Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m³; TWA-AK: 5 ppm; STEL-CK: 165 mg/m³; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm;

	TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm 3.0 mg/m³
Latvia	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³; STEL-NDSCh: 10 mg/m³;
Romania	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Russia	MAC: 5 mg/m³
Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m³; Ceiling: 15 mg/m³;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m³; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m³;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m³; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m³;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m³; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m³; gas and aerosol mist

Pfizer Occupational Exposure Band (OEB) Statement: The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

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

Band (OEB):

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Polyethylene glycol 25322-68-3	-	112 mg/kg bw/day [4] [6]	40.2 mg/m³ [4] [6]
SODIUM CHLORIDE 7647-14-5	-	295.52 mg/kg bw/day [4] [6] 295.52 mg/kg bw/day [4] [7]	2068.62 mg/m³ [4] [6] 2068.62 mg/m³ [4] [7]
+ Hydrochloric Acid 7647-01-0	-	-	8 mg/m³ [5] [6] 15 mg/m³ [5] [7]

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Polyethylene glycol 25322-68-3	40 mg/kg bw/day [4] [6]	-	7.14 mg/m³ [4] [6]
SODIUM CHLORIDE 7647-14-5	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	443.28 mg/m³ [4] [6] 443.28 mg/m³ [4] [7]
+ Hydrochloric Acid 7647-01-0	-	-	8 mg/m³ [5] [6] 15 mg/m³ [5] [7]

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Polyethylene glycol 25322-68-3	0.273 g/L	1 mg/L	27.3 mg/L	0.1 mg/L	-
SODIUM CHLORIDE 7647-14-5	5 mg/L	-	-	-	-
Sodium phosphate, monobasic 7558-80-7	0.05 mg/L	0.5 mg/L	0.005 mg/L	-	-
Sodium phosphate, dibasic 7558-79-4	0.05 mg/L	0.5 mg/L	0.005 mg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Polyethylene glycol 25322-68-3	1030 mg/kg sediment dw	103 mg/kg sediment dw	-	46.4 mg/kg soil dw	-
SODIUM CHLORIDE 7647-14-5	-	-	500 mg/L	4.86 mg/kg soil dw	-
Sodium phosphate, monobasic 7558-80-7	-	-	50 mg/L	-	-
Sodium phosphate, dibasic 7558-79-4	-	-	50 mg/L	-	-

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.
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.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	suspension
Physical state	Liquid
Color	White
Odor	No information available.
Odor threshold	No information available

Property	**Values**
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	

SADT (°C)	No data available
pH	3.5 to 7.0
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	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

Molecular formula	Mixture
Molecular weight	Mixture

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 information available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information 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.
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	May cause damage to organs through prolonged or repeated exposure. Classification is based on mixture calculation methods based on component data.
Reproductive toxicity	May damage the unborn child. 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/m^3
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)	-	-
Polyethylene glycol	= 22 g/kg (Rat)	> 20 g/kg (Rabbit)	-
SODIUM CHLORIDE	= 3550 mg/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.

Unknown acute toxicity

4-8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
4-8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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

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. Toxic to aquatic life with long lasting effects. 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)
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 Based on available data, the classification criteria are not met.

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

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Other adverse effects No information available.
PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products
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:
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.

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	Schedule 3
Poisons (SUSMP)	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
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

National regulations

France

Occupational Illnesses (R-463-3, France)

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

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018	Not applicable
Storage of Hazardous Material	Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20	Not applicable
Major Accidents Ordinance SR 814.012	Not applicable

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	75	-

1310-73-2		
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants
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

Ozone-depleting substances (ODS) Regulation (EU) 2024/590
Not applicable.

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)
Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15
H360D - May damage the unborn child. H373 - May cause damage to organs through prolonged or repeated exposure if

swallowed. H301 - Toxic if swallowed. H335 - May cause respiratory irritation. H314 - Causes severe skin burns and eye damage. H331 - Toxic if inhaled. H410 - Very toxic to aquatic life with long lasting effects. H402 - Harmful to aquatic life.

Classification procedure
Calculation method

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 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.
Revision date	02-Apr-2025
Prepared By	Pfizer Global Environment, Health, and Safety

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