



SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Methyprednisolone Acetate Suspension, USP, Sterile

Product Code(s) PZ01163

Synonyms PNU-8210; Depo-Medrol MDV

Trade Name: Depo-Medrol

Item Code H000005665, H000005666, H000020537, H000020538, H000020539, H000020540, H000020541, H000020572, H000020573, H000020574, H000020575, H000020576

Chemical Family: Mixture

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 1-800-424-9300 International Chemtrec (24 hours): +1-703-527-3887

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

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Signal word

Danger

Hazard statements

H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure: blood forming organs, adrenal gland
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
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical advice/attention
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

2 - 8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
2 - 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 (EC) No. | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---------------|----------|---------------------------|---------------------|---|------------------------------------|----------|----------------------|
| | | | | | | | |

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| | | | | | | | |
|---|------|--|-----------------------------|--|----------------|----------------------|----------------------|
| | | | | 1272/2008 [CLP] | | | |
| Methylprednisolone Acetate (CAS #: 53-36-1) | 2-8 | | 200-171-3 | Repr.1A (H360D) STOT RE.2 (H373) Aquatic Acute 3 (H402) Aquatic Chronic 1 (H410) | Not classified | No data available | 1 |
| BENZYL ALCOHOL (CAS #: 100-51-6) | <1.0 | | 202-859-9 (603-057-00-5) | Acute Tox. 4 (H302) Skin Sens. 1B (H317) Eye Irrit. 2 (H319) | Not classified | 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 phosphate, monobasic (CAS #: 7558-80-7) | * | | 231-449-2 | Not classified | Not classified | No data available | No data available |
| Polysorbate 80 (CAS #: 9005-65-6) | * | - | 500-019-9 | 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 |
| BENZYL ALCOHOL 100-51-6 | 1200 + 1230 | 2000 | 4.178 | No data available | No data available |
| Sodium phosphate, monobasic | 8290 | 7940 | 0.83 | No data available | No data available |

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| 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 |
|---|-----------------|-------------------|---|---|--------------------------------------|
| 7558-80-7 | | | | | |
| Polysorbate 80 9005-65-6 | 34.5 mL/kg | No data available | No data available | 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 |

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

Additional information

* Proprietary

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. Non-hazardous ingredients provided for completeness.

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 | |

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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

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Exposure Limits

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

Methylprednisolone Acetate

Pfizer OEL TWA-8 Hr: 40 µg/m³

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

Polyethylene glycol

Austria

TWA-TMW: 1000 mg/m³; inhalable fraction

Denmark

STEL-KZGW: 4000 mg/m³ (4 X 15 min); inhalable fraction

Germany DFG

TWA: 1000 mg/m³;

STEL: 2000 mg/m³;

TWA-MAK: 250 mg/m³; I(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;

BENZYL ALCOHOL

Bulgaria

TWA: 5.0 mg/m³;

Czech Republic

40 mg/m³

Finland

Ceiling: 80 mg/m³

TWA: 10 ppm;

Germany DFG

TWA: 45 mg/m³;

TWA-MAK: 22 mg/m³; I(2);

TWA-MAK: 5 ppm; I(2);

Peak: 44 mg/m³;

Peak: 10 ppm;

Sk

Germany TRGS

TWA-AGW; 5 ppm (exposure factor 2);

TWA-AGW; 22 mg/m³ (exposure factor 2);

Sk

Ceiling Limit Value

25 mg/m³

Latvia

TWA: 5 mg/m³;

Poland

TWA-NDS: 240 mg/m³;

Russia

MAC: 5 mg/m³

Switzerland

Skin

TWA-MAK: 5 ppm; aerosol, vapour

TWA-MAK: 22 mg/m³; aerosol, vapour

Sk

Sodium phosphate, monobasic

Russia

MAC: 10 mg/m³

Sodium phosphate, dibasic

Russia

MAC: 10 mg/m³

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 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)

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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/m ³ [4] [6] |

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/m ³ [4] [6] |

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 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 phosphate, monobasic 7558-80-7 | - | - | 50 mg/L | - | - |
| Sodium phosphate, dibasic 7558-79-4 | - | - | 50 mg/L | - | - |

8.2. Exposure controls

Engineering controls

Personal protective equipment

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. 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

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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 | No data available |
| 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)

Methylprednisolone

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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 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. Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. May produce allergic reactions following skin contact.

Long Term:

Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on 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.

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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

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg
Mouse Oral LD 50 1360 mg/kg
Rabbit Dermal LD 50 2 gm/kg

Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/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) | - |
| BENZYL ALCOHOL | = 1230 mg/kg (Rat) | = 2 g/kg (Rabbit) | > 4178 mg/m ³ (Rat) 4 h |
| Sodium phosphate, monobasic | = 8290 mg/kg (Rat) | > 7940 mg/kg (Rabbit) | > 0.83 mg/L (Rat) 4 h |
| Polysorbate 80 | = 34.5mL/kg (Rat) | - | - |
| Sodium phosphate, dibasic | = 17 g/kg (Rat) | - | - |

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

- 2 - 8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 2 - 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

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BENZYL ALCOHOL

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

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)

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

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.

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)

BENZYL ALCOHOL

Pimephales promelas (Fathead Minnow) EPA LC50 96 hours 460 - 770 mg/L

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Daphnia magna (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 500 mg/L

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

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

BENZYL ALCOHOL

OECD Activated sludge Ready 92 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation

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

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 |
| BENZYL ALCOHOL | Not PBT/vPvB |
| Sodium phosphate, monobasic | PBT assessment does not apply |
| Sodium phosphate, dibasic | 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

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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 |

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| | |
|---|--------------------------|
| Poisons (SUSMP) | Schedule 2 |
| BENZYL ALCOHOL | |
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 202-859-9 |
| 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 |
| Polysorbate 80 | |
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | Not Listed |
| 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 |

National regulations

France

Occupational Illnesses (R-463-3, France)

| Chemical name | French RG number |
|----------------------------|------------------|
| BENZYL ALCOHOL 100-51-6 | RG 84 |

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 |
|---------------|---|--|
|---------------|---|--|

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| | | |
|----------------------------|----|---|
| BENZYL ALCOHOL 100-51-6 | 75 | - |
|----------------------------|----|---|

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

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. H402 - Harmful to aquatic life. H410 - Very toxic to aquatic life with long lasting effects. H332 - Harmful if inhaled. H302 - Harmful if swallowed.

Classification procedure

Calculation method

Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information.

Reason for revision

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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Prepared By

Pfizer Global Environment, Health, and Safety

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