



SAFETY DATA SHEET

Revision date 13-Sep-2025

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

1.1. Product identifier

Product Name Methyprednisolone Sodium Succinate for Injection, USP

Product Code(s) METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION

Trade Name: Solu-Medrol; Solu-Medrone; Solu-Moderin

Item Code H000481110,F338901000,F338901003,F338901005,F338901010,F338901082,H000013878,H000013879,H000013880,H000013881,H000401106,H000401107,H000401108,H000401109,H000401111,H000401112,H000401113,H000401114,H000401115,H000401116,H000401117,H000478304,H000478305,H000481096,H000481096,H000481098,H000481110,H000481150,H000481160

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)
Endocrine disruption for human health	Category 1 - (EUH380)
Hazardous to the aquatic environment - acute	Category 3 - (H402)
Hazardous to the aquatic environment - chronic	Category 1 - (H410)
Endocrine disruption for the environment	Category 1 - (EUH430)

OSHA Classification

Physical Hazard Combustible Dust

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

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Not applicable

2.2. Label elements



Signal word

Hazard statements

Danger

H360D - May damage the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure: blood forming organs.

H402 - Harmful to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

OSHA - May form combustible dust concentrations in air

EUH380 - May cause endocrine disruption in humans

EUH430 - May cause endocrine disruption in the environment

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

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 to an approved waste disposal plant

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

Contains a known or suspected endocrine disruptor.

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Methylprednisolone Sodium Succinate	Substance has endocrine disrupting properties

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

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3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Methylprednisolone Sodium Succinate (CAS #: 2375-03-3)	67-87		219-156-8	Repr. 1A (H360D) STOT RE.2 (H373) ED HH (EUH380) Aquatic Acute 3 (H402) Aquatic Chronic 1 (H410) ED ENV (EUH430)	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. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified	Not classified	No data available	No data available
Lactose (CAS #: 63-42-3)	*	-	200-559-2	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

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
Methylprednisolone Sodium Succinate 2375-03-3	5000	No data available	No data available	No data available	No data available
Sodium phosphate, dibasic	17000	No data available	No data available	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
7558-79-4					
Lactose 63-42-3	10000	No data available	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
BENZYL ALCOHOL 100-51-6	1200+ 1230	2000	4.178	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

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

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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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.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
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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 the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface 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 Minimize dust generation and accumulation. Avoid breathing dust. 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.

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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 Sodium Succinate

Pfizer OEL TWA-8 Hr: 40 µg/m³

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

Sodium phosphate, dibasic

Russia

MAC: 10 mg/m³

Sodium phosphate, monobasic

Russia

MAC: 10 mg/m³

BENZYL ALCOHOL

Bulgaria

TWA: 5.0 mg/m³;

Czech Republic

40 mg/m³

Ceiling: 80 mg/m³

Finland

TWA: 10 ppm;

TWA: 45 mg/m³;

Germany DFG

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

Skin

Switzerland

TWA-MAK: 5 ppm; aerosol, vapour

TWA-MAK: 22 mg/m³; aerosol, vapour

Sk

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, dibasic

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)

8.2. Exposure controls

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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

Physical state	Powder
Color	White
Odor	No information available.
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
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	Soluble Water Alcohols
Vapor pressure	No data available

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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

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.

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 various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.
Short term	May cause eye irritation (based on components) May be harmful if absorbed through the skin.
Long Term:	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.

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Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

Acute toxicity

Serious eye damage/eye irritation

Skin corrosion/irritation

Respiratory or skin sensitization

STOT - single exposure

STOT - repeated exposure

Reproductive toxicity

Germ cell mutagenicity

Carcinogenicity

Aspiration hazard

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

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

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

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

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

Classification is based on mixture calculation methods based on component data. May cause damage to organs through prolonged or repeated exposure.

May damage the unborn child. Classification is based on mixture calculation methods based on component data.

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

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

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

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

Methylprednisolone Sodium Succinate

Rat Oral LD 50 > 5000 mg/kg

Rat Para-periosteal LD 50 718 mg/kg

Mouse Intravenous LD 50 953 mg/kg

Rat Intraperitoneal LD 50 512 mg/kg

Mouse Intraperitoneal LD 50 902 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

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
Methylprednisolone Sodium Succinate	> 5 g/kg (Rat)	-	-
Sodium phosphate, dibasic	= 17 g/kg (Rat)	-	-
Lactose	> 10 g/kg (Rat)	-	-
Sodium phosphate, monobasic	= 8290 mg/kg (Rat)	> 7940 mg/kg (Rabbit)	> 0.83 mg/L (Rat) 4 h
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m ³ (Rat) 4 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)

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

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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 Sodium Succinate

Reproductive & Fertility Rat Subcutaneous 40 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Subcutaneous 40 mg/kg/day LOAEL Teratogenic

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 Sodium Succinate

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 This mixture contains a substance that has endocrine disrupting properties with respect to humans.

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Methylprednisolone Sodium Succinate	health effects

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

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

BENZYL ALCOHOL

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

Chemical name	PBT and vPvB assessment
Sodium phosphate, dibasic	PBT assessment does not apply
Sodium phosphate, monobasic	PBT assessment does not apply
BENZYL ALCOHOL	Not PBT/vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties This mixture contains a substance that has endocrine disrupting properties with respect to non-target organisms.

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Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Methylprednisolone Sodium Succinate	Environmental effects

12.7. Other adverse effects

Other adverse effects
PMT or vPvM properties

No information available.
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 Sodium Succinate)
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

Methylprednisolone Sodium Succinate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed

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EINECS	219-156-8
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
Lactose	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-559-2
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
BENZYL ALCOHOL	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-859-9
AICS	Present

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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH	Substance subject to authorization per
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	Annex XVII	REACH Annex XIV
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/NDL - 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

H302 - Harmful if swallowed. H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation H373 - May cause damage to organs through prolonged or repeated exposure. H360D - May damage the unborn child. H402 - Harmful to aquatic life H410 - Very toxic to aquatic life with long lasting effects EUH380 - May cause endocrine disruption in humans EUH430 - May cause endocrine disruption in the environment

Data Sources:

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

Reason for revision

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

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Prepared By

Pfizer Global Environment, Health, and Safety

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