SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Methylprednisolone Acetate Suspension, USP, Sterile

Product Code(s) PZ01163
Synonyms PNU-8210
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)
Chronic aquatic toxicity Category 2 - (H411)

2.2. Label elements

Signal word Danger

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

Precautionary Statements
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
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 attention/advice
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

2.3. Other hazards

Other hazards

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

Note:

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Methylprednisolone Acetate (CAS #: 53-36-1)	2-8		200-171-3	Repr.1A (H360D) STOT RE.2 (H373) Aquatic Acute 3 (H402) Aquatic Chronic 1 (H410)	Not Listed	No data available	1
BENZYL ALCOHOL (CAS #: 100-51-6)	<1.0		202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Polyethylene glycol (CAS #: 25322-68-3)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, monobasic (CAS #: 7558-80-7)	*		231-449-2	Not classified as hazardous	Not Listed	No data available	No data available
Polysorbate 80 (CAS #: 9005-65-6)	*	-	500-019-9	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Methylprednisolone Acetate 53-36-1	10000	No data available	No data available	No data available	No data available
Polyethylene glycol 25322-68-3	22000	20000	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1230	2000	4.178	No data available	No data available
Sodium phosphate, monobasic 7558-80-7	8290	7940	0.83	No data available	No data available
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

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 dust and mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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

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

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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

Methylprednisolone Acetate
Pfizer OEL TWA-8 Hr: 40 µg/m³

BENZYL ALCOHOL
Pfizer OEL TWA-8 Hr: 10 ppm

Polyethylene glycol

Austria	1000 mg/m³
	STEL 4000 mg/m³
Denmark	1000 mg/m³
Germany	250 mg/m³ average molecular weight 200-600;because formation of a mist is possible, exposure should be minimized for reasons of occupational safety and hygiene
	Ceiling / Peak: 500 mg/m³
Germany	200 mg/m³
Russia	MAC: 10 mg/m³
Slovakia	1000 mg/m³
Switzerland	500 mg/m³

BENZYL ALCOHOL

Bulgaria	5.0 mg/m³
Czech Republic	40 mg/m³
	Ceiling: 80 mg/m³
Finland	10 ppm
	45 mg/m³
Germany	22 mg/m³ can occur as vapor and aerosol at the same time
	5 ppm can occur as vapor and aerosol at the same time
	Ceiling / Peak: 44 mg/m³
	Ceiling / Peak: 10 ppm
	Skin
Germany	5 ppm
	22 mg/m³
	H*
Ceiling Limit Value	25 mg/m³
Latvia	5 mg/m³
Poland	240 mg/m³
Russia	MAC: 5 mg/m³
	Skin
Switzerland	5 ppm
	22 mg/m³

	H*
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.

8.2. Exposure controls

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

Environmental exposure controls No information available.

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

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

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

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

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Suspension
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	No data available

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

Partition Coefficient: (Method, pH, Endpoint, Value)
Methylprednisolone
Predicted 7.4 Log D 1.99

9.2. Other information
No information available

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity
Reactivity No data available.

10.2. Chemical stability
Stability Stable under normal conditions.

Explosion data
Sensitivity to Mechanical Impact No data available.
Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No information available.
Hazardous polymerization Will not occur.

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

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.
STOT - repeated exposure	Classification is based on mixture calculation methods based on component data.
Reproductive toxicity	Classification is based on mixture calculation methods based on component data.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Methylprednisolone Acetate

Rat Oral LD50 >10,000 mg/kg
Mouse Sub-tenon injection (eye) LD50 >1,409 mg/kg
Rat Subcutaneous LD50 265 mg/kg

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/m³ (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.

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

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 No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

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

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
Polyethylene glycol	The substance is not PBT / vPvB
BENZYL ALCOHOL	The substance is 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 No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

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

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

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

5 kg/5L Exception:
UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

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

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

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

Water

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

Methylprednisolone Acetate

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

Polyethylene glycol

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

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

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

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)

Persistent Organic Pollutants

Not applicable

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

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment
Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Full text of H-Statements referred to under section 3
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child. Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure. Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life. Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects. Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled. Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed.

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 12 - Ecological Information. Updated Section 14 - Transport Information.
Revision date	20-Oct-2022
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.