MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
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1-212-573-2222

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: PF-03512676 Sterile Solution

Trade Name: Promune
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of lung cancer.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
PF-03512676	207623-20-9	Not listed	58
Hydrochloric Acid	7647-01-0	231-595-7	###
Sodium hydroxide	1310-73-2	215-185-5	###

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	*
Water for Injection	7732-18-5	231-791-2	###

Additional Information:
* Proprietary
as required
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear sterile solution
Signal Word: WARNING

Statement of Hazard: May cause damage to: immune system, kidneys, liver through prolonged or repeated exposure.

Additional Hazard Information:
Long Term: Animal studies indicate that this material may cause adverse effects on the immune system, kidneys, blood, cardiovascular system and liver.
Known Clinical Effects: Adverse effects most commonly reported in clinical use include flu-like syndrome, diarrhea, local irritation, thirst, nausea, vomiting.
EU Indication of danger: Harmful

EU Hazard Symbols:

EU Risk Phrases:

R48 - Danger of serious damage to health by prolonged exposure.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not available

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid open handling. Minimize generation of mists. Use local exhaust or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store at 2 - 8 °C in properly labeled containers. Protect from light. Do not freeze.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PF-03512676

Pfizer OEL TWA-8 Hr: 20ug/m^3

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m^3 Peak

Sodium hydroxide

OSHA - Final PELS - TWAs: 2 mg/m^3
ACGIH Ceiling Threshold Limit: = 2 mg/m^3 Ceiling
Australia PEAK = 2 mg/m^3 Peak

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Sterile solution	**Color:**	Clear
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Light
Incompatible Materials: No data available

11. TOXICOLOGICAL INFORMATION

General Information: The information in this section describes the potential hazards of the individual ingredients and the formulation.

Active Drug Substance Toxicity Data:

Acute toxicity

Species	Route	End Point	Dose (mg/kg)
Mouse	Intramuscular	Maximally Tolerated Dose	1.5

Repeated Dose Toxicity

Duration	Species	Route	Dose (mg/kg/day)	End Point	Target Organ(s)
4 Week(s)	Rat	Intravenous	2	NOAEL	Kidneys, Liver, Immune system
4 Week(s)	Rat	Subcutaneous	0.01	LOAEL	Blood, Immune system, Kidneys
26 Week(s)	Rat	Intravenous Subcutaneous	*0.5	LOAEL	Blood, Kidneys, Liver, Immune system
26 Week(s)	Non-human Primate	Subcutaneous Intravenous	*0.5	LOAEL	Kidneys, Blood, Immune system, Cardiovascular system, Liver

Repeated Dose Toxicity Comments: *dosing twice/week

Reproduction & Developmental Toxicity

Study Type	Species	Route	Dosage (mg/kg/day)	End Point	Effect(s)
Embryo/Fetal Development	Rabbit	Subcutaneous	0.3	NOAEL	Maternal toxicity, Fetoxicity
Embryo/Fetal Development	Rabbit	Subcutaneous	5	NOAEL	No effects at maximum dose
Embryo/Fetal Development	Rat	Subcutaneous	1	NOAEL	Maternal toxicity, Fetoxicity
Embryo/Fetal Development	Rat	Subcutaneous	10	NOAEL	No effects at maximum dose

Genetic Toxicity

Study Type	Cell Type / Organism	Result
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
In Vivo Micronucleus	Mouse	Negative
Bacterial Mutagenicity (Ames)	*Salmonella* , *E. coli*	Negative

Ingredients:

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

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 4000 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

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

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Sodium phosphate, dibasic
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Sodium chloride
10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below .

Hydrochloric Acid
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Harmful

EU Risk Phrases:
R48 - Danger of serious damage to health by prolonged exposure.

EU Safety Phrases:
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

OSHA Label:
WARNING

May cause damage to: immune system, kidneys, liver through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, and Subdivision B.

Ingredients:

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	231-595-7

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-598-3

Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-448-7

Sodium phosphate, monobasic

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-449-2

Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present

Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet