



SAFETY DATA SHEET

Revision date: 18-May-2018

Version: 3.1

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

Product Identifier

Material Name: Lymphocyte immune globulin, anti-thymocyte globulin (equine) sterile solution

Trade Name: ATGAM

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as immunosuppressive agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required

Hazard Statements: Not classified in accordance with international standards for workplace safety.

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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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3. COMPOSITION / INFORMATION ON INGREDIENTS

Lymphocyte immune globulin, anti-thymocyte globulin (equine)	Not assigned	Not Listed	Not Listed	5
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Glycine	56-40-6	200-272-2	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

Prevent inhalation, contact with eye, 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm
	8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium hydroxide	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs 2 mg/m³

Glycine

Latvia OEL - TWA 5 mg/m³

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

Lymphocyte immune globulin, anti-thymocyte globulin (equine)

Pfizer Occupational Exposure Band (OEB): B-OEB 1 (control exposure to the range of ≥ 10000 $\mu\text{g}/\text{day}$)

Exposure Controls

Engineering Controls: Personal Protective Equipment:

Engineering controls should be used as the primary means to control exposures. 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.

Hands:

Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

If airborne exposures are within or exceed the Biotherapeutic Occupational Exposure Band (B-OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the B-OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Sterile solution

Color:

Pink to brown

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

Solubility:

Soluble: Water

pH:

No data available.

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

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

Glycine

No data available

Water for Injection

No data available

Sodium hydroxide

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Hydrochloric Acid

No data available

Lymphocyte immune globulin, anti-thymocyte globulin (equine)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Short Term: May cause irritation : skin, eye (based on components) May produce allergic reactions after systemic administration.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include fever, chills, skin reaction, blood cell changes, systemic toxicity. Serious allergic reactions, including anaphylaxis, have been reported.

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

Glycine

Rat Oral LD 50 7930 mg/kg

Mouse Oral LD 50 4920mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

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11. TOXICOLOGICAL INFORMATION

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Hydrochloric Acid

Skin Irritation Severe
Eye Irritation Severe

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

Lymphocyte immune globulin, anti-thymocyte globulin (equine)

14 Day(s) Monkey Intravenous 40 mg/kg/day NOAEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Lymphocyte immune globulin, anti-thymocyte globulin (equine)

Embryo / Fetal Development Monkey Intravenous 10 mg/kg/day NOAEL Fetotoxicity, Not Teratogenic
Reproductive & Fertility Monkey Intravenous 40 mg/kg/day NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Lymphocyte immune globulin, anti-thymocyte globulin (equine)

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative

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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

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 waste water 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.

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Lymphocyte immune globulin, anti-thymocyte globulin (equine)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
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/ELINCS List	231-595-7

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg

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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
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/ELINCS List	215-185-5

Glycine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-272-2

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 18-May-2018

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

End of Safety Data Sheet