



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.2

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

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

Trade Name: Atgam Sterile Solution
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as immunosuppressive agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Lymphocyte immune globulin, anti-thymocyte globulin (equine)	Not assigned	Not listed	5
Hydrochloric Acid	7647-01-0	231-595-7	**
Sodium hydroxide	1310-73-2	215-185-5	**

Ingredient	CAS Number	EU EINECS List	%
Glycine	56-40-6	200-272-2	*
Water for Injection	7732-18-5	231-791-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Pink or brown sterile solution
Signal Word: DANGER

Statement of Hazard: Suspected of damaging the unborn child.
Causes damage to immune system.

Additional Hazard Information:
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.

EU Indication of danger: Toxic to Reproduction; Category 3

EU Hazard Symbols:

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EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

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:** Not applicable
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Not applicable

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

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General Handling: Prevent inhalation, contact with eye, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Use adequate ventilation. Wash thoroughly after handling.

Storage Conditions: Store in a cool, dry place away from light. **Keep refrigerated.**

Storage Temperature: 2 - 8 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m³ Peak

Sodium hydroxide

OSHA - Final PELs - TWAs: 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak

Analytical Method: No method available .

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

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
Molecular Formula: Mixture
Color: Pink to brown
Molecular Weight: Mixture

Solubility: Soluble: Water

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

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

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

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Glycine

Rat Oral LD 50 7930 mg/kg
Mouse Oral LD 50 4920 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

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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 Symbol: Xn
EU Indication of danger: Toxic to Reproduction; Category 3

EU Risk Phrases:
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Suspected of damaging the unborn child.
Causes damage to immune system.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 500 lb TPQ gas only
Inventory - United States TSCA - Sect. 8(b)	= 5000 lb EPCRA RQ gas only
Australia (AICS):	T
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS List	Schedule 5
	Schedule 6
	231-595-7

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Sodium hydroxide

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

Glycine

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-272-2

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: Corrected Section 1.

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

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End of Safety Data Sheet