# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: R-Gene 10**

**Trade Name:** R-Gene
**Synonyms:** 10% Arginine Hydrochloride Injection, USP
**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as HGH/Immune system stimulator

**Details of the Supplier of the Safety Data Sheet**

**Pfizer Inc**
**Pfizer Pharmaceuticals Group**
**235 East 42nd Street**
**New York, New York 10017**
**1-800-879-3477**

**Emergency telephone number:**
**CHEMTREC (24 hours): 1-800-424-9300**
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Pfizer Ltd**
**Ramsgate Road**
**Sandwich, Kent**
**CT13 9NJ**
**United Kingdom**
**+00 44 (0)1304 616161**

**Emergency telephone number:**
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**EU Classification:**

EU Indication of danger: Not classified

**Label Elements**

**Other Hazards** No data available
**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**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 | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

| | | | | | |
|---|---|---|---|---|---|
| Hydrochloric Acid | 7647-01-0 | 231-595-7 | T; R23<br>C; R35 | Press. Gas<br>Skin Corr. 1A; H314<br>Acute Tox. 3; H331 | ** |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Water for Injection | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | * |
| Arginine Hydrochloride | 1119-34-2 | 214-275-1 | Not Listed | Not Listed | 10 |

**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 R phrases and 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:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**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:** Not applicable

**Advice for Fire-Fighters**

During all fire fighting 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. Clean up operations should only be undertaken by trained personnel. |

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation. 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<br>7.5 mg/m$^3$ |
| **Austria OEL - MAKs** | 5 ppm<br>8 mg/m$^3$ |
| **Belgium OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 5 ppm<br>8.0 mg/m$^3$ |
| **Cyprus OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 8 mg/m$^3$ |
| **Estonia OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Germany - TRGS 900 - TWAs** | 2 ppm<br>3 mg/m$^3$ |
| **Germany (DFG) - MAK** | 2 ppm<br>3.0 mg/m$^3$ |
| **Greece OEL - TWA** | 5 ppm<br>7 mg/m$^3$ |
| **Hungary OEL - TWA** | 8 mg/m$^3$ |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Ireland OEL - TWAs** | 5 ppm<br>8 mg/m$^3$ |
| **Italy OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Japan - OELs - Ceilings** | 5 ppm<br>7.5 mg/m$^3$ |
| **Latvia OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Lithuania OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Luxembourg OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Malta OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Netherlands OEL - TWA** | 8 mg/m$^3$ |
| **Poland OEL - TWA** | 5 mg/m$^3$ |
| **Portugal OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Romania OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Slovakia OEL - TWA** | 5 ppm<br>8.0 mg/m$^3$ |
| **Slovenia OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Spain OEL - TWA** | 5 ppm<br>7.6 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 2 ppm<br>3.0 mg/m$^3$ |
| **Vietnam OEL - TWAs** | 5 mg/m$^3$ |

**Exposure Controls**

| | |
|---|---|
| **Engineering Controls:** | Engineering controls should be used as the primary means to control exposures. For laboratory use, handle in a lab fume hood. General room ventilation is adequate unless the process generates dust, mist or fumes. |
| **Personal Protective Equipment:** | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |
| **Hands:** | Wear impervious gloves if skin contact is possible. |
| **Eyes:** | Wear safety glasses or goggles if eye contact is possible. |
| **Skin:** | Not required for the normal use of this product. Wear protective clothing when working with large quantities. |
| **Respiratory protection:** | Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---|---|---|
| **Physical State:** | Solution | **Color:** | No data available. |
| **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 |
| **pH:** | 5.0-6.5 |
| **Melting/Freezing Point (°C):** | No data available |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Boiling Point (°C):** No data available.
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Arginine Hydrochloride**
No data available
**Water for Injection**
No data available
**Hydrochloric Acid**
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

**Flammablity:**
- **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:** None known
- **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 in this section describes the potential hazards of the individual ingredients and the formulation.
**Short Term:** May cause eye and skin irritation (based on components) . Not acutely toxic (based on animal data) .
**Known Clinical Effects:** The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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

**Arginine Hydrochloride**
Rat Oral LD50 12 g/kg
Rat Sub-tenon injection (eye) LD50 3793mg/kg

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

## 11. TOXICOLOGICAL INFORMATION

**Hydrochloric Acid**
Skin Irritation Severe
Eye Irritation Severe

**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)

**Product Level Toxicity Data**

**Reproduction & Developmental Toxicity**

| Study Type | Species | Route | Dosage (mg/kg/day) | End Point | Effect(s) |
|---|---|---|---|---|---|
| Embryo/Fetal Development | Rat | Oral | >10 grams | NOAEL | Not teratogenic |
| Embryo/Fetal Development | Mouse | Oral | >10 grams | NOAEL | Not teratogenic |
| Reproductive & Fertility | Rat | Oral | >10 grams | NOAEL | Fertility |
| Reproductive & Fertility | Mouse | Oral | >10 grams | NOAEL | Fertility |

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties 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

## 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**

**Canada - WHMIS: Classifications**
**WHMIS hazard class:**
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**Ingredients:**

**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 |

**Hydrochloric Acid**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | 1.0 % |
| **CERCLA/SARA Hazardous Substances and their Reportable Quantities:** | 5000 lb<br>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<br>Schedule 6 |
| **EU EINECS/ELINCS List** | 231-595-7 |

**Arginine Hydrochloride**

| | |
|---|---|
| **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** | 214-275-1 |

## 16. OTHER INFORMATION

**Text of R phrases and 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

T - Toxic
C - Corrosive

R23 - Toxic by inhalation.
R35 - Causes severe burns.

| | |
|---|---|
| **Data Sources:** | Pfizer proprietary drug development information. Publicly available toxicity information. |
| **Reasons for Revision:** | Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. |
| **Revision date:** | 01-Apr-2015 |
| | 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**