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

Material Name: R-Gene 10

| Trade Name: | R-Gene          |
| Synonyms:   | 10% Arginine Hydrochloride Injection, USP |
| Chemical Family: | Mixture       |
| Intended Use: | Pharmaceutical product used as HGH/Immune system stimulator |

2. HAZARDS IDENTIFICATION

Appearance: Solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

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.

EU Indication of danger: Not classified


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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
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<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C;R35 T;R23</td>
<td>**</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Arginine Hydrochloride</td>
<td>1119-34-2</td>
<td>214-275-1</td>
<td>Not Listed</td>
<td>10</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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.

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 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

General 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.

Storage Conditions:
Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
Austria OEL - MAKs 5 ppm
Belgium OEL - TWA 5 ppm
Bulgaria OEL - TWA 5 ppm
Cyprus OEL - TWA 5 ppm
Czech Republic OEL - TWA 5 ppm
Estonia OEL - TWA 5 ppm
Germany - TRGS 900 - TWAs 2 ppm
Germany (DFG) - MAK 2 ppm
Greece OEL - TWA 5 ppm
Hungary OEL - TWA 5 ppm
Ireland OEL - TWAs 5 ppm
Italy OEL - TWA 5 ppm
Japan - OELs - Ceilings 5 ppm
Latvia OEL - TWA 5 ppm
Lithuania OEL - TWA 5 ppm
Luxembourg OEL - TWA 5 ppm
Malta OEL - TWA 5 ppm
Netherlands OEL - TWA 5 ppm

Revision date: 21-Feb-2013
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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
- Molecular Formula: Mixture
- Color: No data available.
- Molecular Weight: Mixture
- pH: 5.0-6.5

10. STABILITY AND REACTIVITY

- Chemical Stability: Stable under normal conditions of use.
- Conditions to Avoid: None known
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

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

Product Level Toxicity Data

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dosage (mg/kg/day)</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo/Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt;10 grams</td>
<td>NOAEL</td>
<td>Not teratogenic</td>
</tr>
<tr>
<td>Embryo/Fetal Development</td>
<td>Mouse</td>
<td>Oral</td>
<td>&gt;10 grams</td>
<td>NOAEL</td>
<td>Not teratogenic</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

<table>
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<tr>
<th>Ingredients</th>
<th>Rat</th>
<th>Oral</th>
<th>&gt;10 grams</th>
<th>NOAEL</th>
<th>Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive &amp; Fertility</td>
<td></td>
<td></td>
<td></td>
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<td>Fertility</td>
</tr>
</tbody>
</table>

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

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

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

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)

12. ECOLOGICAL INFORMATION

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

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

EU Indication of danger: Not classified
15. REGULATORY INFORMATION

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

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
- 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 5000 lb and their Reportable Quantities: 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs 5000 lb
- 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

Arginine Hydrochloride
- 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 mentioned in Section 3

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 8 - Exposure Controls / Personal Protection. Updated Section 4 - First Aid Measures.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet