SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Injectafer® (Ferric Carboxymaltose Injection)

Product Code: NDC-0517-0650-01

1.2. Intended Use of the Product

Use of the substance/mixture: Treatment of iron deficiency anemia.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor
American Regent, Inc.
One Luitpold Drive
PO Box 9001
Shirley, NY 11967
1-800-645-1706

Manufacturer
PharmaForce Inc.
Subsidiary of Luitpold Pharmaceuticals, Inc.
6610 New Albany Road East
New Albany, OH 43054
1-614-436-2222

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

May cause an allergic reaction in sensitive individuals. The most common adverse reactions are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, chest pain, and peripheral edema. Hemosiderosis has been observed following overdosage. Refer to prescribing information for more information.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water for injection	(CAS No) 7732-18-5	83	Not classified
Ferric Carboxymaltose	(CAS No) 9007-72-1	17	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Hydrochloric acid	(CAS No) 7647-01-0	Used to adjust pH	Met. Corr. 1, H290 Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: Go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Seek medical attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention.
First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: May cause an allergic reaction in sensitive individuals.
Symptoms/Injuries After Inhalation: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact: May cause skin irritation and sensitization.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.
Chronic Symptoms: Excessive and/or chronic dosages of Injectafer may lead to accumulation of iron in storage sites potentially leading to hemosiderosis (iron overload disorder). May cause adverse cardiovascular effects and hepatic effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.
Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Do not breathe vapor or mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).
Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".
Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Vacuum must be fitted with HEPA filter to prevent release of particulates during clean-up. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Finish cleaning the area with small amounts of soap and water on the spill area.

6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.
Storage Conditions: Store in original container. Store in a dry, well-ventilated place.
Incompatible Products: Strong acids. Strong bases. Strong oxidizers.
Storage Temperature: 20 - 25 °C (68 - 77 °F)

7.3. Specific End Use(s)

Pharmaceutical.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	2 mg/m³
USA IDLH	US IDLH (mg/m³)	10 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³

Hydrogen chloride (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	7 mg/m³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m³)	7 mg/m³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Safety glasses.

Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection : In case of inadequate ventilation wear respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Dark brown

Odor : Mild

Odor Threshold : No data available

pH : 5.0 - 7.0

Evaporation Rate : No data available

Melting Point : No data available

Freezing Point : No data available

Boiling Point : 100 °C (212 °F)

Flash Point : Approx. to water

Auto-ignition Temperature : No data available

Decomposition Temperature : No data available

Flammability (solid, gas) : No data available

Vapor Pressure : No data available

Relative Vapor Density at 20 °C : No data available

Specific Gravity : 1.2

Solubility : Soluble in hot water

Partition Coefficient: N-Octanol/Water : No data available

Viscosity : No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.
10.5. Incompatible Materials: Strong oxidizers. Strong acids.
10.6. Hazardous Decomposition Products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Water for injection (7732-18-5)	
LD50 Oral Rat	> 90000 mg/kg

Hydrogen chloride (7647-01-0)	
LD50 Oral Rat	238 - 277 mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	781 ppm/4h (reported as 3124 ppm/1 h)

Skin Corrosion/Irritation: Not classified (**pH:** 5.0 - 7.0)
Serious Eye Damage/Irritation: Not classified (**pH:** 5.0 - 7.0)
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Carcinogenicity: Not classified

Hydrogen chloride (7647-01-0)	
IARC group	3

Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Aspiration Hazard: Not classified
Symptoms/Injuries After Inhalation: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact: May cause skin irritation and sensitization.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.
Chronic Symptoms: Excessive and/or chronic dosages of Injectafer may lead to accumulation of iron in storage sites potentially leading to hemosiderosis (iron overload disorder). May cause adverse cardiovascular effects and hepatic effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

12.2. Persistence and Degradability Not established
12.3. Bioaccumulative Potential Not established
12.4. Mobility in Soil No additional information available
12.5. Other Adverse Effects
Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport
14.2. In Accordance with IMDG Not regulated for transport
14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Water for injection (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Hydrogen chloride (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Listed on United States SARA Section 313	
SARA Section 302 Threshold Planning Quantity (TPQ)	500 (gas only)
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

Sodium hydroxide (1310-73-2)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations

Hydrogen chloride (7647-01-0)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 03/16/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Refer to Luitpold/American Regent prescribing information for further inforation at: http://americanregent.com/AllProducts.aspx

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

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