SAFETY DATA SHEET

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

Product Identifier

Material Name: RETACRIT (epoetin-alfa-epbx)

Trade Name: RETACRIT
Synonyms: Epoetin-alfa-epbx
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product

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

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
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Calcium chloride USP</td>
<td>10035-04-8</td>
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<td>Glutamic acid</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Polysorbate 20</td>
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<td>Not Listed</td>
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</tr>
</tbody>
</table>

Additional Information:  
* Proprietary  
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:**  
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: Fine particles (such as dust and mists) may fuel fires/explosions.

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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. 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
Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Sodium chloride
- Latvia OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 5 mg/m³

Glutamic acid
- Latvia OEL - TWA: 10 mg/m³

Leucine
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Exposure Controls

- **Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

- **Personal Protective Equipment:** 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:** Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

- **Eyes:** Wear safety goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

- **Skin:** Wear impervious protective clothing to prevent skin contact. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

---

<table>
<thead>
<tr>
<th>Substance</th>
<th>Pfizer Occupational Exposure Band (OEB):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium chloride</td>
<td>OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m³ to &lt; 1000ug/m³, provide additional precautions to protect from skin contact)</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)</td>
</tr>
<tr>
<td>Epoetin alfa</td>
<td>B-OEB 5 (control exposure to &lt;10 µg/day)</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Glycine</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>L-Isoleucine</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>L-Threonine</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Calcium chloride</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>L-Isoleucine</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>L-Threonine</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
<th>Clear, colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value)

Sodium chloride
No data available
Epoetin alfa
No data available
Sodium Phosphate Monobasic, Monohydrate
No data available
L-Threonine
No data available
Polysorbate 20
No data available
Water for Injection
No data available
Calcium chloride USP
No data available
Glycine
No data available
Glutamic acid
No data available
Phenylalanine
No data available
L-Isoleucine
No data available
Leucine
No data available
Sodium phosphate, dibasic
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
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: As with any protein, the possibility of allergic reactions exists.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, cardiovascular system.
Known Clinical Effects: Adverse effects associated with therapeutic use include increase in blood pressure (hypertension), joint pain muscle cramps, dizziness, respiratory infection, cough, effects on cardiovascular system.

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

Sodium chloride
  Rat Oral LD50 3000 mg/kg
  Mouse Oral LD50 4000 mg/kg

Calcium chloride USP
  Rat Oral LD50 1000 mg/kg
  Mouse Oral LD50 1940 mg/kg

Glycine
  Rat Oral LD50 7930 mg/kg
  Mouse Oral LD50 4920 mg/kg

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

Sodium chloride
  Eye Irritation Rabbit Moderate
  Skin Irritation Rabbit Mild

Calcium chloride USP
  Eye Irritation Rabbit Moderate
11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Epoetin alfa
Embryo / Fetal Development  Rat  Intravenous 500 mg/kg/day  NOAEL  Not teratogenic, Maternal toxicity
Embryo / Fetal Development  Rabbit  Intravenous 500 mg/kg/day  NOAEL  Not Teratogenic, Maternal Toxicity

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

Epoetin alfa
In Vitro Bacterial Mutagenicity (Ames)  Not specified  Negative
In Vitro HGPRT Forward Gene Mutation Assay  Not specified  Negative
In Vitro Chromosome Aberration  Not specified  Negative
In Vivo Micronucleus  Mouse  Negative

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been 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

### Calcium chloride USP

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
<td>California Proposition 65</td>
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<tr>
<td>Australia (AICS):</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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### Sodium chloride

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### Polysorbate 20

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### Glutamic acid

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### Leucine

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<tbody>
<tr>
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<tr>
<td>California Proposition 65</td>
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<td>Australia (AICS):</td>
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<td>EU EINECS/ELINCS List</td>
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### L-Threonine

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<th>Regulation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
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<tr>
<td>California Proposition 65</td>
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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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### L-Isoleucine

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<tr>
<td>California Proposition 65</td>
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15. REGULATORY INFORMATION

<table>
<thead>
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<th>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</th>
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<td>Present</td>
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<td>Water for Injection</td>
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<td></td>
<td>Present</td>
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<td>231-448-7</td>
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<tr>
<td>Epoetin alfa</td>
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<td>200-272-2</td>
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<tr>
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<td></td>
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<td>Present</td>
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<tr>
<td>Phenylalanine</td>
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<td></td>
<td></td>
<td>Present</td>
<td>Present</td>
<td>200-568-1</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 15-May-2018

Prepared by: Product Stewardship Hazard Communication

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